HTA for Health Systems Sustainability

www.htai.org

Pre-Conference: June 25th – 26th, 2011

Conference: June 27th, 28th & 29th, 2011

Book of Abstracts

8th annual meeting
Rio de Janeiro 2011
HTAi

www.htai2011.org

Contents

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SCIENTIFIC REPORTS

OVERVIEW OF THE PARALLEL PANEL SESSIONS

The secretariat received 86 proposals for Parallel Panel Sessions! The proposals were evaluated by three different ISPC members, according to: scientific quality, relevance of the topic to HTAi goals and appropriateness of speakers' qualifications to present the topic.
Each proposal was evaluated by the average score given. The co-chairs gave their final indication, taking into account the topics, panelists and country balance, thus 30 panels were approved as Parallel Panel Sessions, four as Special Sessions and one as a Networking Session.

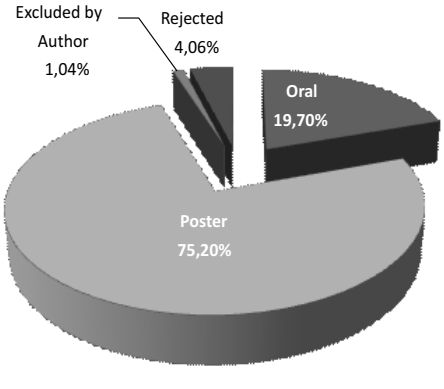
OVERVIEW OF THE SCIENTIFIC ABSTRACTS

Health Technology Assessment (HTA) plays an essential role in modern health care, supporting evidence-based decisions in health policy and practice. The 8th Annual Meeting of HTAi will be an unparalleled opportunity to reach the entire community that produces and uses HTA in Brazil and Latin America as a whole, providing a global forum for the exchange of information, methods, and knowledge. The annual meeting will also include the participation of countries that are on the cutting edge of HTA as well as professional societies, health researchers, decision-makers, administrators, and industry representatives. The HTAi Annual Meeting will focus on the sustainability of health care systems and the role of HTA in supporting these systems.
The organization has received 863 scientific abstract submissions from 45 different countries. In order to accommodate the best presentations within the limited time of the meeting, an abstract reviewing committee evaluated all scientific abstracts submitted to the conference and this process is briefly described below.

Selection Process

An abstract review committee, composed of 78 international experts from 21 countries, was responsible for reviewing the abstracts submitted for the annual meeting. Each abstract underwent three reviews by three separate reviewers, with the authors' identities remaining anonymous. The average number of scientific abstracts reviewed per expert were 11.06.

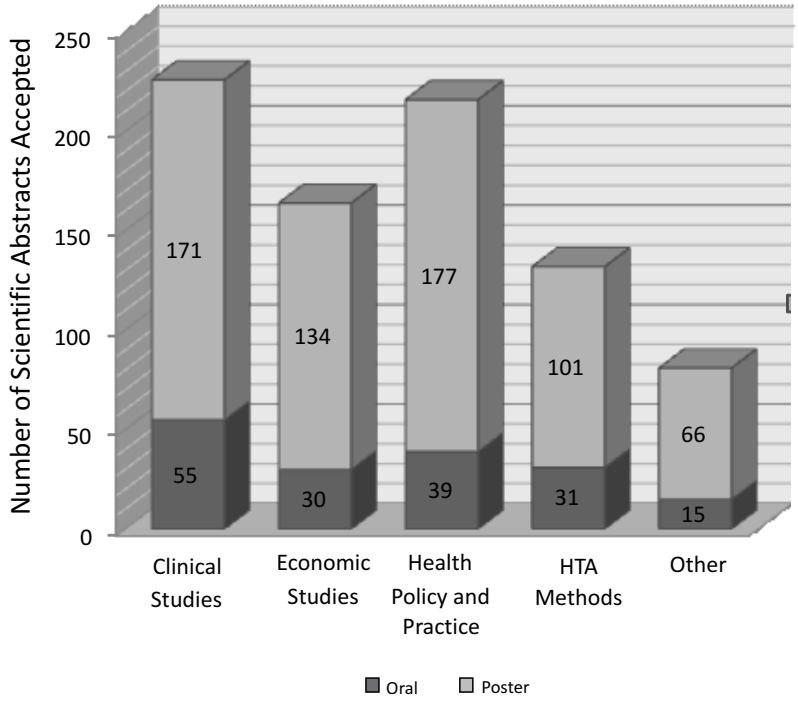
Abstracts were graded on a scale between one and five with five representing "definitely an oral presentation", four representing "perhaps oral", three representing "definitely poster", two representing "perhaps poster" and one representing "rejected". Grading was based on the criteria of relevance to the topic, methodological adequacy and applicability. The scores were combined into a single composite score per evaluator and then the average value of the reviewers' scores was used to determine the abstract's acceptability and, where applicable, the type of presentation for which it was accepted. There was no limit to the number of abstracts an author or group of authors could submit. However, only one oral presentation and two poster presentations were allowed per presenting author, thereby maximizing the number of registrants able to present their



Source: LOC and ISPC, 2011

The distribution of the scientific abstracts approved for oral presentation and poster exhibition are 27% in the clinical studies area, 20% in economic studies, 26% in health policy and practice, 16% in HTA methods and 10% were classified by authors as "other".

Graph 1. Scientific Abstracts Approved by Area and Type HTAi 2011 – Rio de Janeiro

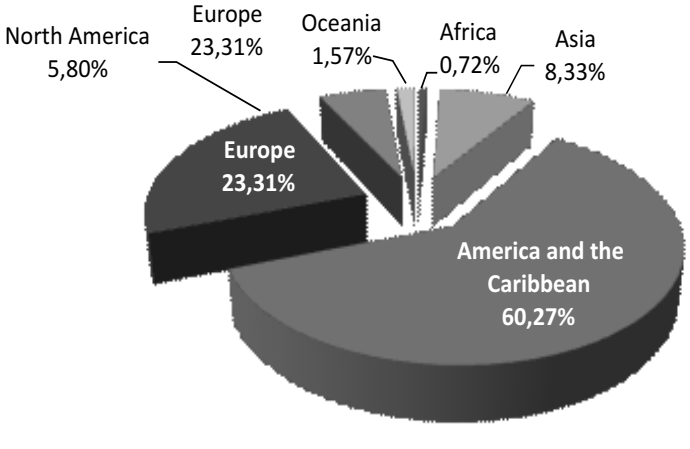


Source: LOC and ISPC, 2011

Origin of approved scientific abstracts

Accepted scientific abstracts represent 44 different countries. Latin America and the Caribbean region had 499 scientific abstracts; followed by Europe with 193; Asia with 69; North America with 48; Oceania with 13 and Africa with 6. Due to the numerous origins of the abstracts, a diversity of experience is assured. Below, Chart 2 shows the distribution by country and region and Table 1 shows the frequency.

Chart 2. Accepted Abstracts by Region HTAi 2011 – Rio de Janeiro



Source: LOC and ISPC, 2011

Table 1. Country of origin of accepted abstracts

Country	Reagion	Frequency	%
Brazil	South America	454	54.8%
United Kingdom	Europe	52	6.3%
Spain	Europe	34	4.1%
Italy	Europe	30	3.6%
Canada	North America	25	3.0%
United States	North America	23	2.8%
Korea (Republic of Korea)	Asia	18	2.2%
Argentina	South America	16	1.9%
Malaysia	Asia	13	1.6%
Uruguay	South America	14	1.7%
Australia	Oceania	13	1.6%
Poland	Europe	12	1.4%
Singapore	Asia	12	1.4%
Mongolia	Asia	9	1.1%
Sweden	Europe	11	1.3%
Austria	Europe	8	1.0%
Mexico	Central America	7	0.8%
Netherlands	Europe	7	0.8%
Denmark	Europe	6	0.7%
Germany	Europe	6	0.7%
Colombia	South America	5	0.6%
Kazakhstan	Asia	5	0.6%
Switzerland	Europe	5	0.6%
Philippines	Asia	3	0.4%
Portugal	Europe	3	0.4%
Belgium	Europe	3	0.4%
China	Asia	3	0.4%
Czech Republic	Europe	3	0.4%
Finland	Europe	3	0.4%
Norway	Europe	2	0.2%
South Africa	Africa	3	0.4%
Croatia	Europe	2	0.2%
France	Europe	2	0.2%
Ghana	Africa	2	0.2%
Japan	Asia	2	0.2%
Lithuania	Europe	2	0.2%
Paraguay	South America	2	0.2%
Taiwan, Province of China	Asia	2	0.2%
Cuba	Caribbean	1	0.1%
Georgia	Asia	1	0.1%
Iran, Islamic Republic of	Asia	1	0.1%
Nigeria	Africa	1	0.1%
Russian Federation	Europe	1	0.1%
Slovenia	Europe	1	0.1%
Total		**828**	**100.00%**

Parallel Panel Sessions

Panel 13 – EVIDENCE-INFORMED POLICY MAKING IN HEALTH: INSTITUTIONS MATTER

Kalipso Chalkidou, NICE; Alexandre Lemgruber, ANVISA; Yot Teerawattananon, HITAP; Sean Tunis, CMTP; Ruth Lopert, TGA

Evidence-based clinical guidelines, health technology assessments (HTA) and pharmaceutical formulary listing decisions can contribute to reducing unwarranted variation and improving quality and efficiency within healthcare systems. However, the role of locally owned and led institutions to drive the adaptation of existing comparative technology evaluations or the development of new ones has not been systematically studied.

In this session we propose to discuss the national experiences of 5 different countries in institutionalizing evidence-informed policy-making through the establishment of dedicated agencies or programs for carrying out and applying HTAs to decision making.

Each of the five countries represented is at a different stage in this process, with some like the UK and Australia having long-standing entities responsible for turning evidence into implementable policies, and others, such as Thailand and Brazil, having only recently established such functions or being in the process of doing so. The US example will also be discussed, where, despite high levels of health spending, problematic access and large variation, institutionalizing evidence-based policy-making, especially when value-for-money is included, has been met with significant resistance.

Using individual entities as case studies, we will explore their establishment and historical evolution, and the various political, technical, governance and other challenges as well as opportunities, emerging at different points in their development processes. We will draw both generalisable and context-specific lessons for policy -makers from different countries in the process of building new or strengthening existing frameworks to drive evidence-informed policy-making in healthcare, including how a system's characteristics, such as its structure, funding sources and levels, and cultural underpinnings, can support or inhibit institution-building.

Panel 53 – MULTINATIONAL ECONOMIC EVALUATIONS: THEIR ROLE IN A "GLOBALLY LOCAL" DECISION MAKING ENVIRONMENT

Andres Pichon-Riviere, Institute For Clinical Effectiveness and Health Policy - IECS; Federico Augustovski Provac Initiative PAHO/WHO, IECS; Lou Garrison, University of Washington, USA; Andrew Briggs, Centre for Population & Health Sciences, University of Glasgow; Charalabos-Markos Dintsios, Institute for Quality and Efficiency in Health Care – IQWIG, Germany

Health technology assessment is now a truly international activity. Therefore, given the limitations on the resources for HTA and Health Economic Evaluations (HEE) there are likely benefits from more international collaboration.

Conducting multi-country HEE is a strategy that was used but for which there is still relatively little experience. The objective of the session will be to discuss the role of multinational HEE in the current global but also local decision making environment.

Speakers in this session will address issues such as:

- Present some specific experiences about multinational HEE already completed or in progress. Challenges and difficulties encountered and the solutions that were implemented;
- Discuss what the potential advantages (if any) are and applications of the multinational HEE from different perspectives: decision-makers, industry, researchers and academics;
- What do multinational HEE really mean? What are their characteristics? Could they be a valuable tool? How this strategy compares to a simpler adaptation of a HEE from other jurisdiction? What features do countries need to have in order to be grouped or included in a multinational HEE? Do they have to share some or any characteristic? Could they be completely dissimilar?
- What specific role can they have in Lower and Middle Income Countries? What was the experience in developed countries? What role can they have in the future? Should they be advocated for? If so, which things should be done to promote them (harmonization of guidelines and requirements for regulatory bodies, homogeneous cost bases, and analytical tools).

Chair

Andres Pinchon-Riviére, Institute for Clinical Effectiveness and Health Policy- IECS, Argentina

Speakers

What Role Can Have Multinational Hee from the Perspective of the Industry? Transferability of Regulatory Benefit-Risk Assessment VS Cea

Lou Garrison, University of Washington, USA

Methodological Issues in Multi-Country HEE

Andrew Briggs, Centre for Population & Health Sciences, University of Glasgow

The PAHO/WHO Initiative for Multi-Country HEE for Vaccines

Federico Augustovski, PROVAC Initiative PAHO/WHO, IECS

Multi-Country HEE in Europe

Charalabos-Markos Dintsios, Institute for Quality and Efficiency in Health Care, Germany

Panel 77 – METHODOLOGICAL GUIDANCE FOR THE LIFE SCIENCES INDUSTRY

Sean Tunis, President, Center for Medical Technology Policy; Carole Longson, Director, Centre for Health Tech Evaluation, National Institute for Health and Clinical Excellence; Francois Meyer, Director, HTA Division, Haute Authorite de Sante; Finn Børlum Kristensen, Director, EUnetHTA Secretariat at National Board of Health; Chris Henshall, Chair, HTAi Policy Forum; Ansgar Hebborn, Global Head of Economic Value Strategy, Roche Pharma

This panel presentation will provide a progress report on an international, multi-stakeholder collaboration that is developing a process for producing methodological guidance for clinical research performed by the life sciences industry, intended to better address the information needs of health technology assessment organizations and payers. The panel participants are all members of the collaborative working group and will provide the key perspectives of HTA organizations from several countries, payers, and the life sciences industry.

Over the past decade, there has been increasing recognition of the impact of payers and health technology assessment (HTA) bodies on the adoption and use of drugs, devices and diagnostics. Historically, the clinical development process in the life sciences industry focused mainly on fulfilling regulatory requirements, believing correctly that favorable reimbursement decisions would generally follow from studies done for regulatory review. Therefore, clinical studies were designed to address the information needs of regulators and paid less attention to generating evidence targeted to payers and the HTA bodies that support them.

Recently, several payers and HTA bodies have recognized the need to provide "scientific advice" to product developers on trial design to ensure that studies are more consistently designed to provide the evidence needed for their review. It is unrealistic and inefficient to expect product developers to solicit input on trial design from multiple payers and HTA bodies around the world, potentially resulting in conflicting suggestions on key aspects of their proposed study protocols. It is similarly burdensome and inefficient for payers and HTA bodies to meet with each manufacturer individually to provide input on their clinical development plans.

Having explicit and harmonized methodological guidance reflecting the input of multiple payers and HTA bodies will likely reduce the number of poorly designed studies, while increasing the likelihood that appropriate and consistent comparators and outcomes are included in industry funded research. In addition, having clear and consistent guidance from payers and HTA bodies will reduce the uncertainty currently faced by the life sciences industry in the early stages of product development, as the evidentiary requirements for achieving favorable reimbursement will be defined well in advance.

To explore the feasibility of international collaboration on the development of methodological guidance clinical research done by life sciences companies, the Center for Medical Technology Policy (CMTP) has convened a working group representing payers and HTA bodies from countries with established HTA capacity, as well as regulators, life science industry, and methodologists.

This panel session will allow selected members of the working group to provide an interim summary of their perspective on a number of key issues associated with this work, including:

- Topic selection – What approach should be used to prioritize the clinical conditions and technologies for which guidance would be developed?
- Guidance development process – specific steps involved in drafting, revising and finalizing guidance.
- Organizational and governance issues – which institutions could provide a "home" for the guidance development process, and what mechanism would be necessary to ensure neutral and effective oversight?
- Funding – what potential sources of funds could support the ongoing development and updating of this methods guidance?

Panel 84 – HTA AND REGULATION – CAN WE IMPROVE COORDINATION AND COHERENCE FOR A BETTER PATIENT CARE AND HEALTH SYSTEM SUSTAINABILITY?

Chris Henshall, Chair HTAi Policy Forum; Katrine Frønsdal, NOKC, HTAi Scientific Secretariat; Brian O'Rourke, CADTH; Wim Goettsch, CVZ, EUnetHTA; David Grainger, Lilly; Adriana Velasquez , WHO

There is increasing interest in the relationship between HTA and regulation and in how regulators and payers can work together. Discussions are being held in a number of fora, and various forms of collaboration are being developed. A number of factors appear to underpin these developments, including: a desire to coordinate and/or streamline systems and processes to speed up decisions and patient access and if possible reduce the burden for industry and a desire to define the roles of the different bodies in assessing comparative effectiveness.

The HTAi Policy Forum exists to promote dialogue between those developing and using HTA in industry and health systems for decisions about the development and use of drugs, diagnostics and devices.

The Forum has discussed this topic with a view to considering how payers, HTA bodies, regulators and industry might work together to allow better and faster decisions about the use and reimbursement of safe, effective and affordable technologies in health care systems.

The panel session will be chaired by the HTAi Policy Forum Chair and introduced by the HTAi Policy Forum Scientific Secretariat outlining issues discussed at the HTAi Policy Forum meeting 2011, with a focus on the sustainability of health care systems.

Four speakers representing views from the public sector in Canada, Europe and the EU Joint Action on HTA, industry in Australia, and WHO (medical devices) and Mexico (for Latin America) will then discuss examples and implications of initiatives of coordination between HTA and regulatory bodies and offer their perspectives on the issues and preferred ways forward to promote a more sustainable health care system.

Panel 135 – HTA AND ECONOMIC ANALYSIS: COST-EFFECTIVENESS THRESHOLD AND OTHER FACTORS IN THE DECISION MAKING PROCESS

Uwe Siebert, University of Health Sciences, Medical Informatics and Technology in Austria; Andres Pichón–Riviere, IECS: Instituto de Efectividad Clínica y Sanitaria, Argentina; Carisi Anne Polanczyk, IATS, Federal University of Rio Grande do Sul

The aim of this panel session is to discuss the role of cost-effectiveness analysis in priority setting, in particular the use of so-called 'thresholds' in deciding what can and can't be reimbursed. In addition to a discussion of standard cost-effectiveness rules used to judge whether any given technology represents good value for money, there will be an examination of the theoretical basis of the threshold associated with such judgments.

To begin with we will critically examine approaches to estimating the threshold including establishing a societal willingness-to-pay and empirical analyses that consider actual spending decisions. We will explore how the threshold has been applied in actual decision making with reference to a variety of countries engaged in health technology assessment and priority setting. We will show how other factors influence judgments of cost-effectiveness that may appear to lead to adjustments upwards (or downwards) of any stated thresholds.

Important issues in the application of cost-effectiveness thresholds relating to budget impact and the availability of a common unit of benefit (for example the Quality Adjusted Life Year, or QALY) will be discussed and any controversies explored.

In this context, we will also explore the role of the efficiency frontier method, in particular, and how judgments are made using indication-specific cost-effectiveness data. Advantages and disadvantages of this approach will be discussed.

We hope to close this panel session with some proposals on how new HTA-adopting countries could establish a cost-effectiveness threshold (or thresholds). In addition, the panel will set out are other important factors (for example non utilitarian criteria) that should be considered by policy makers when making coverage decisions.

36 – HTA CAPACITY BUILDING IN DEVELOPING COUNTRIES – EXPLORATION OF DIFFERENT MODELS

Joseph I. Mathew, Advanced Pediatrics Centre, Chandigarh; Paulo Picon, Faculty of Internal Medicine at Federal University of Rio Grande do Sul; Rabia Kahveci, Turkish Evidence-Based Medicine Association

Background: As HTA is becoming increasingly important in health-care systems in developing countries, it is important to explore different ways to build local capacity and capability. This panel session will explore different models to achieve this.

Objectives: To outline four models of capacity building and their relative advantages/disadvantages) viz (i) Traditional workshop-based knowledge transfer (both top-down and bottom-up), (ii) Learning-by-doing approach at multiple levels and (iii) Online teaching/learning for/by different stakeholders. Each presenter will highlight a specific model and elucidate the local experience using the particular model.

Why this session is important: HTAi 2011 will be attended by academics, researchers, and health-care policy planners from various developing countries; with a shared interest in building local capacity/capability. These stakeholders will benefit from discussion on the various models to achieve this.

Presentations

Introduction

Traditional Top-Down Workshop Approach

Dr. Rabia Kahveci

Bottom-Up Knowledge Transfer

Prof. Paulo Picon

Online Teaching/Learning and Learning-By-Doing Approach

Dr. Joseph Mathew

Discussion

All Facilitators and participants

Summary and Conclusions

Joseph L. Mathew Comments

Dr. Joseph Mathew is Chair of HTAi ISG on Developing Countries, Programme Manager of HTA Capacity Building in India and Lead of the “Peoples-Uni” Online Teaching Course

Dr. Rabia Kahveci is Chair of the Turkish Evidence-Based Medicine Association

Dr. Paulo Picon is Associate Professor of Internal Medicine at Federal University of Rio Grande do Sul

All are well-known leaders in HTA and related disciplines

Panel 37 – THE USE OF HTA BY PUBLIC AND PRIVATE PAYERS AS PART OF THE SYSTEM TO ESTABLISH PRICES FOR NEW INTERVENTIONS: INTERNATIONAL EXAMPLES AND LESSONS LEARNED

Steven Pearson, Institute for Clinical and Economic Review – ICER; Andrew Mitchell, PhD, Pharmaceutical Benefits Advisory Council – PBAC; Lise Rochaix, PhD, Haute Autorite de Sante – HAS; Tanisha Carino, PhD, Avalere, LLC; Jens Grueger, PhD, Pfizer, LTD

HTA is used commonly by payers to help determine whether new tests and treatments are to be funded (covered) by the insurance system. But as payers continue to look for new ways to improve value without reducing access to effective interventions, greater attention is being paid to the potential for HTA to be used as part of the system to establish the prices that will be paid for funded items and services.

In some health care systems, HTA that includes economic analysis is used to judge whether a price already determined through other mechanisms represents good value for money. In theory, economic analysis could be used to suggest the price at which a new intervention would be considered "cost-effective."

Alternatively, in some countries HTA findings on clinical effectiveness are linked through a categorical framework to a prospective process used to determine pricing levels. What are the varying ways that HTA has been produced and integrated into approaches to establishing prices? How do approaches taken across countries and across types of payers differ? What is on the horizon?

The objective of this panel will be to address these questions and share the lessons learned by public and private payers in countries with different underlying health care systems. Topics to be addressed:

- What are the different ways that HTA can be used to help establish prices? How has this varied across the globe, and what are the reasons for this variation?
- From the perspectives of different stakeholders, what has worked well, and not so well, in efforts to use HTA to establish prices? What roles do HTA agencies, public and private payers, and manufacturers play in these different approaches?
- What general policy and procedural lessons can HTA agencies, payers, and manufacturers learn from the experience to date with using HTA to establish prices?

Panel 47 – USING HEALTH TECHNOLOGY ASSESSMENT (HTA) TO INFORM PUBLIC SAFETY DECISIONS: THE CASE OF SEXUAL OFFENSES

Paula Corabian, Institute of Health Economics; Sophie Werkö, PhD, Swedish Council for Technology Assessment in Health Care – SBU; Brynjar Landmark, MD, PhD, Norwegian Knowledge Centre for the Health Services

Public safety issues have emerged as a relatively new field in which HTA is being used to inform decision–making. Sexual offenses constitute a public health problem requiring complex management approaches that involve public sectors beyond the health care system such as child care and criminal justice systems.

This panel session presents challenges of using HTA to enhance adoption of evidence-informed decision-making on topics of public health interest such as sexual offences. It focuses on HTA studies recently conducted to identify evidence-based therapeutic interventions for individuals who have committed or are at risk of committing sexual offences and their victims.

The Institute of Health Economics in Alberta conducted an HTA study that used a scientifically rigorous approach to overview the systematic reviews reporting on the effectiveness of psychotherapy and pharmacotherapy interventions delivered within programs to reduce recidivism rates among convicted adult male sex offenders.

HTA analysis on other aspects of the evaluated interventions was not conducted. Involvement of important stakeholders at various points in the HTA process improved relevance and trust in the evidence produced and enhanced its impact.

The Swedish Council for Technology Assessment in Health Care has undertaken an evaluation of the effects of treatment methods of persons who have committed or are at risk of committing sexual offences against children. The report includes a systematic review of the literature and sections on health economy and ethical and societal aspects on the topic. Whereas the systematic review focuses on offenders, the purpose of the interventions assessed is to protect society. Both the economical and ethical aspects center on future and present victims and their families. Also unique to this project were stakeholders outside the health care system.

As part of a comprehensive systematic review on treatment options for sexual health issues, the Norwegian Knowledge Centre for the Health Services has synthesized the evidence on the effectiveness of interventions offered for offensive behavior and sexual offenders as well as for victims of sexual abuse.

The selected studies have been summarized for populations of children, adolescents and adults separately. No HTA analysis on organization, health economic and legal issues was conducted. Descriptions of the different HTA approaches used to exercise evidence-informed decision-making on a topic like sexual offenses will facilitate discussions on the following topics:

- What HTA methods can be used to address questions related to public safety issues?
- What are the practical implications and challenges of using HTA to enhance the adoption of evidence-informed public health decision-making?
- How can the HTA process improve to overcome the challenges of evidence-informed public health decision-making and maximize its efficiency as an analytic tool in this field?
- What challenges do stakeholders outside the health care system pose?

Panel 67 – HEALTH TECHNOLOGY ASSESSMENT: ISSUES IN THE SELECTION OF DRUGS FOR AN ESSENTIAL MEDICINE LIST?

Luciane Cruz Lopes, Ministry of Health Brazil, University of Sorocaba, SP; Gordon Guyatt Mcmaster University; Adriana Berumen Velasquez, Ministry of Health Brazil; José Miguel do Nascimento Júnior, Ministry of Health Brazil

In this panel session we shall explore issues in the choice of drugs from standard essential medicine lists. This panel session will address methodological challenges and pressing issues in criteria for essential medicines selection and will be of interest to both doers and users of HTAs. It will highlight for the attendees approaches currently being used and discuss the advantages and disadvantages of each approach.

The policy from WHO to essential medicines and the challenges in developing countries - Suzanne Hill. Essential medicines, as defined by the World Health Organization are “those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford”.

The WHO has published a model list of essential medicines. Each country is encouraged to prepare their own lists taking into consideration local priorities. The core list presents a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment.

We will share information from many countries about methodologies and strategies to select medicines in these countries.

Using Grade in the Selection of Essential Medicines

Gordon Guyatt

GRADE provides a systematic approach to rating the quality of evidence and summarizing relative and absolute effects. This transparent approach provides a level playing field for evaluating candidate drugs for an essential medicines list.

Ten Years of Essential Drugs List in Brazil Using Methodologies Considering Scientific Evidence

Dra. Luciane Cruz Lopes

Since 1999, the National List of Essential Medicines is updated with reasonable intervals and its process of elaboration is guided by medicine based on evidence which ensures accuracy selection methodology that incorporates set or keep drug effectiveness and safety, or deletes for not complying over time these criteria. We want to show the strategies and methodologies adopted by 2010 as well as highlight the challenges that we still have to win.

Finally, an interactive participants-panelists discussion will be encouraged, to discuss the individual contributions and appraise the advantages and disadvantages of the methodologies approaches presented.

Panel 83 – WHAT PRINCIPLES SHOULD GOVERN THE USE OF MANAGED ENTRY AGREEMENTS IN A SUSTAINABLE HEALTH CARE SYSTEM? – PERSPECTIVES FROM THE HTAI POLICY FORUM

Jed Weissberg, Chair Kaiser; Carole Longson, NICE; Jens Grueger, Pfizer; Andrew Mitchell, PBAC; Marianne Klemp, NOKC, HTAi Scientific Secretariat

To ensure rapid access to new potentially beneficial health technologies, obtain best value for money and ensure affordability, health care payers are adopting a range of innovative reimbursement approaches that may be called Managed Entry Agreements (MEAs).

In 2010, the HTAi Policy Forum sought to identify why MEAs might be used, issues associated with implementation and develop principles for their use. MEAs may be aimed at managing budget impact, managing uncertainty relating to clinical and/or cost-effectiveness and/or managing utilization to optimize performance.

The rationale for using these approaches and their advantages and disadvantages differ. However, all forms of MEA should take the form of a formal written agreement amongst stakeholders, clearly identifying the rationale for the agreement, aspects to be assessed, methods of data collection and review, and the criteria for ending the agreement.

Main conclusions from the Forum meeting 2010 were that MEAs should only be used when HTA identifies issues or concerns about key outcomes and/or costs and/or organizational/budget impacts that are material to a reimbursement decision.

They provide patient access and can be useful to manage technology diffusion and optimize use. However, they are administratively complex and may be difficult to negotiate and their effectiveness has yet to be evaluated. The panel session will be chaired by the person who was final discussant at the Forum meeting.

Three speakers representing views from different stakeholders will then present examples of agreements and experience with implementation of MEAs from different jurisdictions (NICE, CANADA and AUSTRALIA) regarding both drugs and devices. The panel session will then be roundup by the HTAi Scientific Secretariat bringing together perspectives on what principles that should govern the use of MEAs in a sustainable health care system.

Panel 96 – DRIVING HEALTHCARE SYSTEM EFFICIENCY THROUGH HTA: HOW CAN WE BOOST PATIENT PERFORMANCE?

Alexandre Lemgruber, Brazilian Health Surveillance Agency - ANVISA; Chris Henshall, Discussant, HTAi Policy Forum; Andrea Rappagliosi, Chair, Co-Chair EFPIA HTA Task Force; GSK; Finn Børlum Kristensen, Director, EUnetHTA Coordinating Secretariat, National Board of Health, Denmark; Alastair Kent, Chair of EPPOSSI, UK

The global financial crisis is a wake-up call - it is an extraordinary moment for our economies and we need to recognize that business as usual would consign healthcare systems to a gradual decline. The goal of healthcare policies should be to maximize population health within the limits of available resources. The aim of this session is to explore the role of HTA in optimizing healthcare system efficiency and patient performance when affordability and long-term sustainability of both healthcare systems and industrial innovation capacity are under pressure.

Economic realities are moving faster than political realities, as we have seen with the global impact of the financial crisis. Global austerity measures introduced as a consequence of the financial crisis are beating hard on the healthcare sector and its capacity to deliver on unmet medical needs and on equitable provision of healthcare.

To achieve a sustainable future, we must look beyond the short term. This should go hand in hand with reforms to get more value for money and tackle fragmentation. HTA bodies and policy decision-makers should collaborate to ensure that efficiency of healthcare systems are improved as well as their performance in delivering positive outcomes for patients.

In recent years, payer emphasis has shifted away from striving to adopt the latest medicines at the best possible price towards getting the maximum value from more efficient use of existing therapies, in particular generics. In this session we will address the potential role of HTA in increasing quality of healthcare, improving equity of access to new technologies for those patients who need them, and improving the management of the available financial resources.

The panel sessions will be organized as follows:

Session Introduction Chair to set the scene: Andrea Rappagliosi, Co-Chair EFPIA HTA Task Force; GSK

Joint Actions In HTA: What are the European Commission and the EU Member States Doing to Improve Equity in Patient Care?

Finn Børlum Kristensen, Director, EUnetHTA Coordinating Secretariat, National Board of Health, Denmark

This presentation will address the challenges of pan-European collaboration to foster equity in access throughout the European Union.

Improving Healthcare Outcomes in Latin America: is HTA the Right Tool?

Alexandre Lemgruber, Brazilian Health Surveillance Agency – ANVISA

This presentation will introduce the challenges of HTA in ensuring long-term sustainability in Latin America.

Can patients play a role in setting a policy agenda to improve efficiency of healthcare systems?

Alastair Kent, Chair of EPPOSSI, UK

Panel 106 – INFORMING THE IMPLEMENTATION OF HEALTH TECHNOLOGIES FROM RESEARCH

Andy Haines, London School of Hygiene and Tropical Medicine, Great Britain, John-Arne Røttingen, Norwegian Knowledge Centre for the Health Services, Norway; Ulysses Panisset, WHO, Geneva; Jeremy Grimshaw, Department of Medicine, University of Ottawa, Canada; Anne Karin Lindahl, Norwegian Knowledge Centre for the Health Services, Norway

Studies have demonstrated that most HTA reports are strong on assessing the effectiveness of the technology and its cost-effectiveness, and that fewer reports include broader assessment topics on implementation challenges related to policy decisions, management, organization of care and delivery arrangements. In addition, when reports include these issues, they are often informed by deliberative processes among selected experts and stakeholders without systematic use of research evidence on these domains, which are both general and contextual. This session will discuss these issues and utilize experiences from different approaches that have been engaged in utilizing research evidence on implementation issues with a main focus on low- and middle income country settings. In scarce resource contexts, is it possible to develop policies that integrate high quality research evidence on effectiveness and cost-effectiveness with contextual, deliberative processes among stakeholders?

Chair: Professor Andy Haines, London School of Hygiene and Tropical Medicine, Great Britaintain.

How Can HTA Reports Utilize Research Evidence When Informing the Uptake And Delivery of New Health Technologies?

Professor John-Arne Røttingen, Norwegian Knowledge Centre for the Health Services, Norway

Policymaking Mechanisms to Integrate the Systematic Use of Research Evidence With Contextual, Deliberative Processes Among Stakeholders: Experiences of Evipnet in Low-And Middle Income Countries

Dr. Ulysses Panisset, WHO

Informing Implementation and Delivery Considerations from Systematic Reviews. What Kind of Reviews May be Useful? Experiences from the Epoc Review Group within the Cochrane Collaboration.

Professor Jeremy Grimshaw, Department of Medicine, University of Ottawa, Canada

Increasing Capacity to Produce Systematic Reviews with Relevance to Implementation in Low- and Middle Income Countries. Experiences from the Oslo Epoc Lmic-Satellite

Dr. Anne Karin Lindahl, Norwegian Knowledge Centre for the Health Services, Norway

General Discussion

Panel 109 – USING RESEARCH TO INFORM HEALTH SYSTEMS STRENGTHENING

Jeremy Grimshaw, Department of Medicine, University of Ottawa; John-Arne Røttingen, Norwegian Knowledge Centre for The Health Services; Sebastian Garcia Marti, Institute for Clinical Effectiveness and Health Policy, Buenos Aires; Andy Haines, London School of Hygiene and Tropical Medicine; Ulysses Panisset, WHO

HTA has been successful in informing clinical policy making, reimbursement decisions and guidelines development in many countries when it comes to drugs, vaccines, devices, clinical interventions and some public health programs like screening and vaccination. However, studies have demonstrated that a rather low proportion of HTA reports are evaluating the "higher level" health management and health system interventions which are essential to ensure equitable uptake of safe, effective and cost effective technologies, even if the broad definition of "health technologies" also include such interventions. Lessons from using HTA as an approach to informing policy making based on the best available research evidence should also be utilized for improving the health system on meso and macro levels. This session will discuss the challenges of doing so, and present experiences from different initiatives and approaches that have been established which aim to strengthen the health of populations and the robustness of national health systems through evidence informed health policy making in low- and middle income countries.

Chair: Dr. Ulysses Panisset, WHO

Cochrane Collaboration's Work on Producing Systematic Reviews on Health Systems Issues. Experiences from the EPOC Review Group

Professor Jeremy Grimshaw, Department of Medicine, University of Ottawa, Canada

The Need for Systematic and Collaborative Approaches In Synthesizing Health Systems Research. Experiences from the Alliance for Health Policy and Systems Research

Professor John-Arne Røttingen, Norwegian Knowledge Centre for the Health Services, Norway

Bridging the gap between systematic reviews and policy making processes. Experiences from the SUPPORT Collaboration

Dr Sebastian Garcia Marti, Institute for Clinical Effectiveness and Health Policy, Buenos Aires, Argentina

Approaches to Making Guidance for Health Systems Strengthening. Presentation of Recommendations from a WHO Task Force

Professor Andy Haines, London School of Hygiene and Tropical Medicine, Great Britain

General discussion

Panel 122 – HOSPITAL BASED HTA: WHAT ABOUT METHODS, IMPACT AND FUTURE PERSPECTIVE?

Marco Marchetti, HTA Unit University Hospital Agostino Gemelli; Lennart Jivegård, Sahlgrenska University Hospital, Göteborg, Sweden; Laura Sampietro-Colom, Hospital Clinic Barcelona, Spain; Americo Cicchetti, School of Economics, Università Cattolica del Sacro Cuore, Italy; Gro Jamtvedt, Norwegian Knowledge Centrefor the Health Services – NOKC

Health care managers are more and more interested in identifying some decision making tool and technical methodologies to support decisions regarding relevant matter such as the acquisition and the allocation of technological resources. Health technology assessment (HTA) can help on this. As reported in a world-wide survey performed within the HTAi ISG "hospital based health technology assessment", HTA approach in hospitals is now considered an emerging phenomenon in many countries and it is mainly used both to inform clinical practice and managerial decision making.

HTA seems to be applicable in different fashions with many different organizational solutions, depending on institutional and other socio-economic factors characterizing each health care system and type of hospital.

HTA activities could be carried out in different manners in terms of:

- Type of technology assessed (medical devices, diagnostic tests, pharmaceuticals, equipments);
- Dimensions analyzed (efficacy, safety, economic and organizational aspects);
- Competences and professional profiles involved - tools and methods implemented;
- Kind of output produced;
- Stakeholders involved.

At international level there is an attempt to standardize the methods and dimensions to be assessed within a process of HTA, but the relevance given to different dimensions can vary at macro, meso and micro level.

Nowadays efficacy/effectiveness, organizational and economic impact are the dimensions more frequently assessed in HTA report at hospital level. Systematic literature review should always be the first step to find evidences and information about new technologies, but the analysis of the dimensions can be conducted with different levels of detail in health care organizations. It is obvious that more methods are clear, rigorous and shared, more the impact of HTA on decision making will increase. The rigor of methods, however, should strike a balance with other needs such as limited timeframe and the paucity of both human and financial resources, so that the whole process maintains a profile of cost-effectiveness. Additionally, since HTA is context dependent, processes and models can vary at hospital level depending on the characteristics of the health care system and the type of hospital where HTA is being performed.

In recent years the Health Technology Assessment is being spread widely in health care organizations, but certain variability is observable in the existing approaches on the application of HTA process and tools among hospitals in different health care systems. The purpose of this parallel panel section is to provide a comparison between different HTA organizational models (HTA Unit, Mini-HTA, Internal Committee), process and methods in different countries.

Furthermore, the attention will be focused on the impact, and limitations, of hospital HTA on patients and professionals, as well as possible future developments and its future role and impact in decision-making at hospital level.

Panel 76 – STAKEHOLDER ENGAGEMENT IN DIFFERENT CULTURAL CONTEXTS: LESSONS FROM THE FIELD

Bethany Kupferschmidt, MA, Candidate for MSPH 2011, Center for Medical Technology Policy; Johns Hopkins University Bloomberg School of Public Health; Peter Littlejohns, Clinical and Public Health Director, NICE; Federico Augustovski, Instituto de Efectividad Clinica e Sanitaria – IECS

Stakeholder engagement is widely agreed to be critical to the success of HTA and healthcare research in general. Engaging stakeholders helps ensure that priorities reflect social values, patient needs and payor concerns; that study protocols account for usual patterns of care; and that findings are both applicable to real-world settings and useful for end users.

Obtaining different stakeholder perspectives is also essential to identifying and mitigating any unintended consequences of HTA, including macro-economic effects.

In this session, panelists from Argentina, the United Kingdom and the United States will discuss their experiences engaging stakeholders in different political and cultural environments and in different research contexts. Examples will include a national citizen advisory board tasked with considering difficult social and ethical issues; a government funding agency's systematic initiative to increase their capacity for and activities in stakeholder engagement; the creation of disease-specific guidance for future comparative effectiveness research; and multi-country model-based economic evaluations.

In each country and region, the philosophical underpinnings of and rationale for stakeholder engagement can be very different, and cultural challenges make each case unique. However, common tools do exist, and best practices are rapidly developing.

This panel session will discuss the value of engaging stakeholders as research partners. It will focus on how political and cultural pressures can affect stakeholder engagement, even the very definition of "stakeholder," and the methods used to engage them. Globally, stakeholders can function as a continuing source of knowledge, feedback, advice and support for research and policy, and effective engagement will enable the implementation of HTA outputs.

Panel 27 – BEYOND ASSESSMENTS: AN INTERNATIONAL PERSPECTIVE ON THE ETHICAL DIMENSIONS OF HTA SYSTEMS

Debora Diniz, Anis, University off Brasilia; Kalipso Chalkidou, NICE; Reiner Banken, INESSS; Joseph Mathew, Postgraduate Institute of Medical Education and Research; Andre Medici, World Bank

Health Technology Assessment is predominantly considered a technical exercise providing objective scientific evidence to inform health policy decisions, including high level prioritization decisions, formulation of health benefits packages or deployment of high cost technology in health systems. Hence, those driving HTA initiatives often tend to neglect the important role played by ethical, procedural and socio-political factors such as good governance, transparency and stakeholders' participation in HTA-based decision-making systems.

In this session, we will discuss the ethical dimensions of HTA systems, drawing on the experience of various jurisdictions such as Brazil, the UK, India and Québec, all at different stages of institutionalizing HTA-informed policy-making in healthcare. We will examine how different aspects of Daniels & Sabin Accountability for Reasonableness (A4R) have been applied by NICE in the UK. We will also explore the Latin American experience of developing health benefits packages and the role of the Courts in strengthening procedural fairness and enforcing entitlements. In the case study from Québec, we will explore the links between the governance of a tax based public health system; the transparent production of scientifically sound, context-relevant HTA knowledge; and its utilization by different stakeholders.

Finally we will explore the role of HTA in prioritization decisions in India, with examples from state and the federal levels. These experiences will show that the ethical issues of HTA systems are being dealt with through different approaches, including the institutional responsibilities of HTA agencies (e.g. the assessment vs. appraisal dichotomy); downstream legal adjudication; and other context-specific initiatives. Despite the variation, we will aim to demonstrate the importance of ensuring good governance of the production and uptake of HTA-based decisions, and highlight the most critical elements of such governance.

Panel 66 – SUSTAINABLE HEALTHCARE SYSTEM APPROACHES FOR RARE DISEASES

Chair: Virginia Alejandra Llera, MD, Founder Geiser Foundation, Rare Disease, NGO, LA&C, President Elected ICORD; Adrian Pollitt, Former Director of National Specialist Commissioning in the UK; Professor Jack Goldblatt, Royal Perth Hospital, Chair of the Australian Gaucher Disease Advisory Committee; Prof. Gerald Evans, MD, Chair of the Committee to Evaluate Drugs of Ontario Ministry of Health and Long Term Care; Dr. Joseph I. Mathew, Assistant Professor at the Advanced Pediatrics Centre, Chair, HTAi Interest Sub-Group Developing Countries

Many healthcare systems around the globe have faced the challenge of providing equitable access to treatment for people with very rare disease. Different systems have and are developing different responses to the challenge. Rare Diseases are those that appear with a low frequency in the population (around 5/ 10.000 EU) and the majority of them are chronic and with risk of life. The characteristics of this low frequency include geographical dispersion, huge diversity and isolation of professionals and patients. All this generate a very specific social situation that includes: lack of information about the disease, lack of knowledge about the epidemiological profile rare diseases population, lack information about the natural history of the disease and also about the best practices.

The vulnerable community of citizens living with rare disorders, professionals and government authorities daily need to make decisions within a very uncertainly context. For all these reasons rare diseases are unique and unlike other broad based conditions.

Given the complexity and unique nature of these diseases they should be reviewed outside of traditional HTA methodologies. Certain countries have developed ways outside of the traditional HTA to review these diseases and treatments that honor the distinct and complex nature of rare diseases.

The objective of this session is explain the value of different HTA models and processes for rare diseases, providing examples from experienced healthcare systems that evolved policy and HTA practice to provide sustainable solutions for these conditions, and also the experience of the patient advocacy contribution within the health systems playing an active role as a partner in this process.

Panel 72 – CHALLENGES OF HTA TRANSLATION INTO NATIONAL CLINICAL PRACTICE GUIDELINES IN DEVELOPING COUNTRIES: EXPERIENCE OF ARGENTINA AND CHILE

Victoria Wurcel, HTA Coordination Unit, UCEETS – Department of Quality in Health, Ministry of Health of Argentina; Graciela Demirdjian, HTA Coordination Unit , UCEETS, National Pediatric Hospital J. P. Garrahan; Luis Vera Benavides, HTA Unit, ETESA, Department of Quality and Patient Safety-Ministry of Health of Chile; Patricia Kraemer, HTA Unit, ETESA, Department of Quality and Patient Safety, Ministry of Health of Chile

Clinical practice guidelines are considered valuable instruments for quality improvement and health equity in Argentina and Chile; their development has advanced in both countries in the past few years. Until recently, many of them were not evidence-based and their erratic implementation methodology led to waste of our scarce resources and low effectiveness. Development of HTA-based guidelines suitable for use in resource-poor settings is a challenge because high quality evidence usually originated from developed countries may not be applicable to the needs of low income regions, may not be easily retrieved or there may be a shortage of necessary expertise to collect and analyze the information.

Successful implementation of clinical guidelines is dependent on strategic planning and the support of key stakeholders, not easily achieved in the complex, rapidly changing developing world. Considering this situation, both Ministries of Health of Chile and Argentina develop and implement National Clinical Practice Guidelines using HTA methodology and work actively in the promotion of knowledge transfer among local health stakeholders and community leaders. They also coordinate activities within National HTA Units and are joining efforts and sharing experiences between both countries in a variety of HTA related areas.

The aim of this panel will be to present the experience of two South American countries in developing and implementing clinical practice guidelines at national and local levels using HTA methodology and tools adapted to their needs, share their progress, setbacks and challenges. The panelists will address the topics listed below, from the perspective of each country at national and local levels:

- PAST and present of hta-based clinical practice guideline development in Argentina and Chile: who, what and how? National and hospital level development. What has changed? Progress and setbacks.
- HTA input to select implementation strategies. What really works? Sustainable strategies. Knowledge translation and sensitization for key Stakeholders.
- Joint Projects and Future Challenges.

Panel 94 – INCLUDING THE PATIENT PERSPECTIVE IN HEALTH TECHNOLOGY ASSESSMENT – NEEDS, PRIORITIES AND FEASIBILITY: EXPERIENCE FROM EUROPE, NORTH & SOUTH AMERICA, AND ASIA-PACIFIC

Chair: Jean Mossman, Policy Lead for European Federation of Neurological Associations

Peter Littlejohns, NICE; Janet Wale, Cochrane Consumer Network; Durhane Wong Reiger, Institute for Optimizing Health Outcomes; Joao Paulo Altenfelder, SEI Consultoria.

'Nothing about me without me' is a concept which patients have grasped with enthusiasm. However, many HTA agencies do not seem convinced of the value of this approach and how to achieve patient input continues to be the subject of numerous patient group deliberations.

How can patients improve their understanding of the HTA process and decisions?

Is simplifying the language of HTA enough to help patients engage in the process?

At what stage should they be involved and to what extent?

Can representativeness and independence be assured – and should patients be singled out from other contributors in these questions?

The purpose of this panel is to explore how the HTA systems in different parts of the world engage the patient perspective.

Does it differ based on healthcare systems and priorities?

On government expectations of patient involvement?

In the process used by an agency?

On how skilled patients and their representatives are?

The aim is to initiate a lively debate on best practice and experience from past errors leading to a robust way forward to achieve patient involvement.

Panel 101 – HTA BASED ON HEALTH CARE SYSTEM EFFICIENCY: USING REAL – LIFE DATA TO IMPROVE HEALTH CARE MANAGEMENT

Gabriela Tannus Branco de Araújo, ISPOR Brazil, AXIA BIO; Federico Augustovski, IECS – Instituto de Efectividad Clínica y Sanitaria, Argentina; Uwe Siebert , Harvard University, UMIT – University for Health Sciences, Medical Informatics and Technology, Austria

HTA based on health care system efficiency: Using real-life data to improve health care management despite the evaluation of new health technologies, technologies already adopted by health care systems need to be periodically re-assessed.

Considering the large numbers of patients using health technologies, evaluations that focus not only on clinical efficacy and effectiveness, but that also examine health system efficiency must be designed.

In this scenario, patient follow-up and observational studies not only represents an important clinical and epidemiological milestone, but also a way to measure the causal impact of technology use in the real word through a careful consideration of resource utilization. This in turn provides important information to decision makers about benefits derived from use of health technology and whether alternatives should be considered. Through the strategic utilization of medical and other appropriate sources of data, these types of analyses can represent a powerful tool for decision makers.

The objective of this section is to discuss how this can best be accomplished, and what data sources are required to examine health system efficiency and how this can be used as a resource for decisions and decision makers in health authorities. In addition, the key problems and principles of causal epidemiologic methods for analyzing routine observational data will be critically addressed.

The panelists will discuss concepts, methods, real-life examples and perspectives from decision makers in several important international contexts including Europe, North America and Latin America.

Panel 89 – THE EVIDENCE-BASED MEDICINE AND THE RIGHT TO HEALTH: ECONOMIC AND LEGAL SUSTAINABILITY

Douglas Henrique Marin dos Santos, Brazilian Cochrane Center – Attorney General's Office; Rachel Riera, Brazilian Cochrane Center – Federal University of Sao Paulo; Edina M. Koga da Silva, Brazilian Cochrane Center – Federal University of Sao Paulo; Alvaro Nagib Atallah, Brazilian Cochrane Center - Federal University of Sao Paulo

It is known that the great majority of nations worldwide, including Brazil, provide the right to health to its population. It is generally a fundamental right. Thus, the right to health proposes a doubled guarantee: first of all, disease prevention with the encouragement of prophylactic measures; second, effective and safe treatment to diseases, so it may lead to cure or, at least, ensuring the dignity of patients. In fact, such broader health protection has been expanding all over the globe.

The United States, recently, approved the Affordable Care Act, which promoted changes in the public and supplemental health of the country, expanding coverage and assistance. Such benefits, in Brazil or elsewhere in the world, are remarkable by its high budgetary costs. In fact, resources are scarce and social demands are immense.

The debate is even more imperative when considered countries like Brazil, with strong judicial activism and health policy judicialization. It means that, in many cases, the judicial branch may have a decisive influence on health policies and, worse, disregarding any evidence or scientific basis. Indeed, few individuals will access high-cost treatments, which, in most cases, do not reach the expected outcome.

That way, judicial decisions may violate the collective right to health, due to excessive and scientifically ungrounded spending. Also, those decisions may undermine the individual's right to health, as plaintiffs may get treatments with lack of scientific guarantees about its effectiveness and, above all, safety. So, it is relevant to encourage changes on law's decision-making model, especially considering the great and fast evolution of science. It is a matter of questioning whether the law's conventional methods are adequate in an era of increasing scientific complexity.

This discussion is essential when we consider highly judicialized countries, in which policies are severely influenced by judges. Indeed, the aim of the proposed panel is highlighting the relevant relationship between Evidence-Based Medicine and law, with a particular focus at the right to health, which may be modulated by medical science as an instrument of the system's sustainability.

The Brazilian Cochrane Center has been focusing the issue. It seems clear that the right to health may be qualified as a right to evidence based health. It is an essential first step towards an universal and sustainable health system. So, the panelists may address the following items:

- Concept and limits of the right to health;
- Evidence-based policy and the Brazilian experience: scientific evidence and the ministry of health;
- Evidence-based law: legal decision-making can be purely scientific?
- Evidence-based medicine and law: safety parameters and management of scarce resources;
- Judicialization and judicial activism: science as a parameter for legitimacy.

Panel 31 – TRANSCONTINENTAL HTA. WHAT CAN WE LEARN FROM HTA COLLABORATION ON DIFFERENT LEVELS?

Alric Ruether, IQWIG; Maya Zuellig, Swiss Federal Office of Public Health; Wim Goettsch, Health Care Insurance Board, CVZ; Flavia Elias, Ministry of Health; Clifford Goodman, the Lewin Institute

Collaboration on HTAs is emerging. On different levels, such as within countries, between countries and even between continents attempts are being made to work more closely in the production of HTAs. Main goals of this collaboration are to increase the methodological quality of the HTAs, to decrease duplification of the HTA efforts and to increase the actual production of HTAs. In order to increase the effectiveness of these collaborations it is essential to share the experience with actual cooperation worldwide.

Actual cooperation is often delayed because of several reasons such as incompatibilities in health care systems; different political and hierarchical structures and different frameworks for methodological basis of the HTAs.

In this panel session we want address these differences by discussing a number of collaborations on different levels. Based on the identification of these differences subsequently solutions to handle these differences will be proposed.

Panel 56 – STRENGTHENING PATIENT AND PUBLIC VOICES IN HEALTH TECHNOLOGY ASSESSMENTS: NEW FINDINGS FROM SEVERAL RESEARCH AND CONSULTATION PROJECTS

Josie Messina, University of Sheffield, UK & Eli Lilly & Co; Alastair Kent, EPPOSSI; Dr. Sophie Staniszewska, University of Warwick, Coventry, UK; Dr. Marie-Pierre Gagnon, Université Laval, Quebec, Canada

This session would include 4 panelists, each reporting on an original research or consultation project that has elicited new and additional information on what patients and the public want in engagement with HTA and how systems might be improved to deliver this.

Panelist 1: Reports Qualitative Research With a Range of Stakeholders in Australian, Canada and the UK and Recommends a Series of Process Improvements to HTA Systems. Includes Considerations for Manufacturers, HTA Agencies and Patient Advocates and an Overall "Roadmap" for improvement.

Panelist 2: Reports on 2 Workshops Held With a Range of Stakeholders in Europe and Makes Recommendations on Patient Engagement.

Panelist 3: Reports on Work on Patient Reported Outcome Measures. These Are Direct Reports from Patients About How They Function or Feel In Relation to a Health Condition or Its Treatment – Without Interpretation by Others. They Are Increasingly Recognised as Important Outcome Measures But Could Be Made More Patient Focused. This Presentation Will Initiate This Discussion, Review Current Limitations, Consider The Involvement of Patients and Discuss the Development of Methodology to Support the Future Collaborative Development of Proms.

Panelist 4: Reports the Results of Qualitative Research with a Range of Stakeholders on Strategies for Improving Local Level Engagement in various HTA Activities

Panel 63 – CONTESTABILITY IN HTA: INTERNAL APPEALS MECHANISMS AND THE ROLE OF THE JUDICIARY

Antonio Sarria-Santamera, AETS-ISCIII; Debora Diniz, ANIS; Dilian Francisca Toro, Senate of Colombia; Alric Rüther, IQWIG; Kalipso Chalkidou, NICE

Health Technology Assessment (HTA) is one explicit way of combining scientific and social value judgements to inform decisions on healthcare policy and practice. With explicitness comes, however, greater public scrutiny and the potential for legal challenge. When managed, contestability of the process and even possibly the content of resource allocation decisions can strengthen their legitimacy and enhance the likelihood they make an impact. On the other hand, constant judicial challenge and interventions by the Courts may delay decision-making and distort priorities at both national and local levels.

In this session we will discuss means for introducing managed contestability into the process of decision-making as part of the HTA process and explore the role of the Judiciary drawing on experiences from Europe and Latin America from the perspective of policy-makers, legal experts and service users. In some countries, such as Colombia and Costa Rica, Human Rights legislation, combined with an explicit Health Benefits Package and weak home-grown prioritisation processes, have led to repeated interventions by the High Courts with significant financial implications. As these countries are considering formalizing HTA-informed decision-making through institution-building, the role of extra-judiciary contestability mechanisms both to strengthen process legitimacy and to improve the usefulness of the actual decisions, becomes increasingly important.

In the UK, Human Rights legislation is usually interpreted as a negative right and, as such, individual decisions are rarely challenged at court. When they are, it is the process that is usually challenged rather than the content of the decisions or the methods of HTA followed to reach those.

Drawing on several countries experiences (Brazil, Colombia, UK, Germany, and Spain), and incorporating different perspectives (HTA professionals, elected officials, bioethics) we will review how internal contestability mechanisms affect decisions and what the role of that courts are playing in shaping priority-setting in the health care systems.

Panel 39 – PILOTS OF MULTI-STAKEHOLDER CONSULTATIONS IN EARLY-STAGE DRUG DEVELOPMENT

Paolo Siviero, Agenzia Italiana del Farmaco; Fredrik Nilsson, Dental & Pharmaceutical Benefits Agency; Carole Longson, Health Technology Evaluation Centre Director, NICE; Bruno Flamion, Faculties Universitaires Notre-Dame de La Paix; Adrian Griffin, Johnson & Johnson; Nicholas Gertler, Tapestry Networks

The purpose of this panel would be to communicate learning from innovative pilots of multi-stakeholder consultations in early-stage drug development. This European initiative aims to improve clarity and alignment among healthcare constituencies regarding what constitutes a medicine's value and what evidence is required to demonstrate that value most effectively. Constituencies include HTAs, regulatory agencies, clinicians, patients, payers and industry from France, Germany, the Netherlands, Sweden, the UK and the European Medicines Agency. The agreed consultation process is engaging all participants on questions of therapeutic value and questions of economic value that are derived from therapeutic benefits.

Participating companies are seeking early advice regarding a pipeline medicine for the treatment of either breast cancer or type 2 diabetes, with consultations occurring in 2010 – 2011. Participants anticipate that this experimental initiative will shape subsequent multi-stakeholder consultations and broader initiatives supporting early consultation.

This proposed panel will discuss the potential for this initiative to advance the influence of the HTA process on drug company evidence development and investment decisions. Ensuring awareness of the HTA perspective in earlier phases of drug development could both encourage methodology and data better suited to HTA reviews and better accommodate societal demand for responsible innovation directed to unmet medical needs. Additionally, the pilots provide an opportunity to identify areas where the HTA perspective may align or diverge from the views of other decision-makers using a real medicine in development.

The panel will also address how drug development stakeholders can support the complementary goals of improving health outcomes and enhancing the climate for innovation while acknowledging pressures to control healthcare costs. One opportunity, demonstrated by this initiative, is to increase collaboration amongst stakeholders, emphasizing transparency, openness and equal standing among institutions. Accordingly, the panel will explore the principles appropriate to guide public-private interactions toward improved outcomes for all healthcare stakeholders.

Panel 75 – HTA TO INFORM SHARED DECISION MAKING

Britta Bjerrum Mortensen, Master of Antropology, Danish Center for Health Technology Assessment, Dacehta; Sophie Werkö, Phd, the Swedish Council for Technology Assessment in Health Care, SBU; Javier Gracia San Roman, MD, MSc, Health Technology Assessment Unit, UETS, Lain Entralgo Agency, Madrid, Spain; Denis Bélanger, B.SC.PHM., ACPR, Director, Impact, Partnerships and Outreach, Canadian Agency for Drugs and Technologies in Health, CADTH; Chair: Professor Marjukka Mäkelä, Director of the Finnish Office for HTA, Finohta

Chronic disease is a growing problem that challenges the sustainability of health services. One strategy is to promote better self-management by offering patient education and by providing well-targeted information to support decision making by clinicians in partnership with patients. However, in these difficult economic times it is important to ensure that such initiatives are assessed in a similar way to any other health technology to understand impacts of different approaches, the most beneficial delivery mechanisms and develop approaches following implementation to gain optimal value.

Topics to be addressed

This panel session will address the following questions:

- What do patients gain from patient education and decisions aids?
- Does education affect the patients' ability to manage their own chronic disease better?
- Can patient education contribute to reducing social inequality?
- How to develop patient decision aids to promote shared decision making?
- How can results from Rx for Change database improve consumers' drug use?

The Swedish Council for Technology Assessment in Health Care, SBU has assessed how educational interventions and motivational interviewing have an impact on patient education for persons with type 2 diabetes. The presentation will assess the impact and the implications of assessing an intervention as patient education, as well as reactions to the report from stakeholders.

Canadian Agency for Drug and Technologies in Health, CADTH will focus on its Rx for Change database, the research gaps that exist in the areas of patient education and broader strategies to target patients with the intent of improving drug use. The Rx for Change database summarizes current research evidence on the impact of strategies to improve prescribing practice and drug use. CADTH will discuss how the database can produce solid knowledge for improving consumers' drug use.

Danish Center for Health Technology Assessment, DACEHTA will present the results of a broad HTA of patient education. The discussion will focus on what patient's gain from patient education and how patient education can be improved to meet patient's needs even more.

Health Technology Assessment Unit in Madrid, Spain, UETS will present their work on developing Patient Decision Aids (PDA) tools in breast and colorectal cancer. This is both based on previous systematic reviews as well as on conducting new qualitative research with patients, professionals and other stakeholders. The impact of using these tools will also be covered.

Panel 111 – HTA CAPACITY BUILDING – EXPLORATION OF DIFFERENT MODELS OF NATIONAL GUIDELINES DEVELOPMENT AND IMPLEMENTATION

Paulo D. Picon, Advisor of Brazilian Ministry of Health; Itajaí Oliveira Albuquerque, Secretariat of Health Care Attention, Ministry of Health, Brazil; Sivalal Sadasivan, Malaysia Ministry of Health; Cindy Farquhar, University of Auckland, New Zealand; Victoria Wurcel, Argentinian Ministry of Health

As part of HTA process of introduction of Evidence-Based Medicine into Practice, the creation and implementation of National Guidelines for Rational Use of Medicines is becoming increasingly important in health-care systems especially in countries where resources are scarce. Doctor tends not to follow new recommendation and it is important to explore different ways to build local capacity for implementation and dissemination of evidence-based recommendation.

This panel session will explore different models to achieve those goals. The main objectives are: to explore different models adopted by different countries (and their relative advantages/disadvantages) for:

- Strategies of creation of national guidelines for rational use of medicines;
- Strategies of implementation;
- Strategies of dissemination;
- Multiple level of involvement (different stakeholders);

Each presenter will highlight a specific strategy and giving examples will elucidate the local experience (pros and cons).

Panel 112 – VARIOUS APPROACHES FOR THE DEVELOPMENT OF AMBULATORY INTERVENTIONAL AND SURGICAL PROCEDURES

Gerard Parmentier, UNHPC; Constantino Gallo, Padova's Hospital; Guy Maddern, Queen Elizabeth Hospital; Jean Michel Dubernard, HAS; Michele Morin-Surroca, HAS

Medical innovation and progress, as well as rising health costs, have led to the transfer of interventional and surgical practices from hospitals to ambulatory settings. This move has required the health care system to rethink/re-evaluate the organization of these activities and consequently, to define the most appropriate settings for performing those procedures. This reorganization is based on the development of ambulatory health care settings that is the creation of e.g. free standing units and the transfer of part of those activities from traditional hospitals to these new health care settings. This implies an evolution from an organization that is hospital centered towards one that is patient centered and also contributes to the sustainability of healthcare.

OBJECTIVE: To illustrate how different heath care systems define appropriate technical environment to safely perform interventional and surgical procedures when developing ambulatory health care settings and to address the issue of the required systems of control and regulation Including: nature of evolution, rationale for the evolution, difficulties of implementation and key factors of success and whenever data are available the quality of care and economic impact.

This session will be of interest to conference attendees from countries which:

- Have already implemented and assessed the reorganization of interventional and surgical activities – but need to refine it further;
- Are in the process of implementing such a reorganization or aspire to do so in the future.

The session will present the experiences of four countries that have established or are in the process of implementing such reorganization.

Experiences to be presented

- Australia: University of Adelaide, South Australia – Pr Guy Maddern, Australia
- France: Haute Autorite Sante – HAS- Mr. Gérard Parmentier, France
- Italy: Padova's Hospital – Dr Constantino Gallo, Italy
- Professor Dubernard (HAS) is the moderator

The speakers will explore the following:

- The current, ongoing or already implemented reorganization process in their respective countries;
- Any lessons learned that could benefit countries that are in the initial stages of this type of reorganization;
- The potential for benchmarking (e.g. to avoid shortcomings or to optimize the use of resources).

This Parallel Session proposal arises from the recent completion of a health technology assessment aimed at defining the most appropriate environment for ambulatory interventional and surgical procedures in France, as well as the criteria to guide the choice of the most appropriate setting to perform a specific intervention.

Panel 113 – MEDICINES FOR DISEASES THAT AFFECT THE WORLD'S POOR – RESEARCH AND DEVELOPMENT IN THE PERSPECTIVE OF SUSTAINABILITY OF HEALTH SYSTEMS AND HUMAN RIGHTS

Panel Session Organizers: Claudia Garcia Serpa Osorio de Castro, Vera Lúcia Luiza, Ângela Esher
Center for Pharmaceutical Policies, Núcleo de Assistência Farmacêutica – NAF, Sérgio Arouca National School of Public Health – ENSP, Oswaldo Cruz Foundation – Fiocruz

The panel intends to bring together key actors in the field of neglected diseases to discuss the need for sustainable strategies for innovation and access and the role played by Health Technology Assessment in the perspective of guaranteeing human rights.

At present, there is controversy on which diseases may be called neglected and which are being prioritized by funding where research and development for innovative medicines is concerned. Notwithstanding, diseases such as malaria, tuberculosis and aids and many neglected diseases such as bacterial pneumonia, meningitis, diarrhoeal diseases, Chagas´, leishmaniasis, dengue, leprosy and trachoma are still rampant in many low and middle-income countries. While these diseases persist, costly new technologies for other ailments may be perceived as a better investment opportunity in R&D.

More profit is expected from technologies that afflict population segments that are better off and can actually buy medicines or that are attended to by healthcare systems in high-income countries. In addition to this, R&D funding has not been homogeneous among diseases or among targets – new medicines, vaccines, diagnostics, vector control products and basic research.

We propose to discuss targets and funding for R&D in relation to diseases that affect the world´s poor and burden low and middle income country-health systems, while pointing to possible strategies to enhance innovation and access that may be sustainable for health systems as a whole, including the to-be-enhanced role of Health Technology Assessment.

The topics to be presented by panel invitees are the new and challenging targets for research and development in neglected diseases, followed by a discussion on possible alternative sources and mechanisms for the funding of innovation research and health technology assessment for medicines that affect low and middle-income countries, many in which the costs of treatment are entirely fielded by the public sector. Strategies for enhancing access will also be addressed.

Since it was introduced, the Patent Pool has been referred to as an important strategy for innovation and access to medicines.

Finally, a presentation on aspects that surround R&D, innovation and HTA is intended. Discussion is to center on interests that permeate R&D for medicines for diseases that affect the world's poor, the possibilities for sustainable innovation and the role to be played by health technology assessment in sustainability of healthcare systems, in the perspective of human rights.

Challenging Targets in R&D for Neglected Diseases

Isabela Ribeiro PhD, Head of Chagas Clinical Program, DNDi

Exploring Alternative Mechanisms to Fund Innovation for Medicines for Diseases that Affect the World's Poor

Michelle Childs – Director of Policy Advocacy, MSF Campaign for Access to Essential Medicines

The Patent Pool as a Strategy for Innovation and Access to Medicines

Jorge Bermudez MD, PhD, Executive Secretary, UNITAID

What Interests Permeate R&D for Medicines for Diseases That Affect the World's Poor? Is Sustainable Innovation Possible?

Lia Hasenclever PhD, Associate Professor, Economics Institute, Federal University of Rio de Janeiro, Brazil

Carlos Médicis Morel MD PhD, Coordinator for Innovation, Oswaldo Cruz Foundation, Rio de Janeiro, Brazil

Panel 28 – HEALTH TECHNOLOGY ASSESSMENT AND INTRODUCTION OF NEW VACCINES IN NATIONAL IMMUNIZATION PROGRAMS: WHAT ARE THE CHALLENGES?

Hillegonda Maria Dutilh Novaes, Associate Professor, Department of Preventive Medicine, Faculdade de Medicina/USP, Brazil; Damian G. Walker, Bill and Melinda Gates Foundation; Jon k. Andrus, Provac Initiative, Pan American Health Organization - PAHO; Cláudio Maierovitch Pessanha Henriques, Secretariat of Health Surveillance, Ministry of Health, Brazil

In the last decade many new vaccines have been marketed and considered for introduction in national immunization programs, and the demand and use of economic evaluations in decision making processes has increased. Vaccines have features that demand specific economic evaluation and impact analysis methods and decision making processes and they have been the object of important discussions in academic and health and science and technology policy environments. The panel proposes to present and discuss the major challenges in this area.

Cooordinator: Hillegonda Maria Dutilh Novaes, Associate Professor, Department of Preventive Medicine, Faculdade de Medicina – USP, Brazil

Special Session – Critical Perspectives on HTA (Panel 104 and 95)

Panel 104 – CRITICAL PERSPECTIVES ON HTA

Emeritus Prof. Dr. Sebastião Loureiro, University of Texas, Federal Univ. Bahia; Full Prof. Dr. Beatriz González López-Valcárcel, Univ. las Palmas de GC, Spain, Mit Cambridge; Dr. Jose-Ramon Repullo-Labrador, Federal University of Bahia

Traditional HTA has emphasized traditional studies about safety, efficacy and cost-effectiveness of health technologies. While such studies are really important, from the viewpoint of universal healthcare systems – such as Brazilian, Norwegian and Spanish systems – we must consider the social relevance of health technologies, their impact on welfare policies and ethical issues involved. Thus, this panel proposes to bring to discussion social and ethical perspectives that should complement the contribution of HTA managing healthcare systems. Economic constraints, social and political factors determine the direction taken by the process of scientific and technological development.

Depending on policy-makers' decisions on which technological model a country should adopt, governmental costs and a equity access of health care services would be affected. The dependence on the use of certain machine-based technology, would not demonstrate necessarily the best allocation of resource. Fortunately, recent advances in measuring social performance include health as a welfare goal – with short-term and long-term implications and with intergenerational redistributions of resources. Reasons why a particular model of HTA is adopted by a Country is "not available in a formal and analytical sense"; however, it is important to highlight the role and responsibility of decision-makers if an inappropriate use of technology is adopted providing inefficient allocation of resources and consequently an increase of inequalities, interfering in people's quality of life. Thus, ethical concerns surrounding the development and diffusion of health technologies should be considered by HTA and policy makers when drawing explicit eligibility criteria in scaling up health programs.

Based in what was mentioned above, we understand that when new technologies in health are introduced, the responsibility to increase people's quality of life lies in responsible health policies that should be based on a multidisciplinary activity that should consider not only the technical performance and cost-effectiveness, but also the social and ethical issues.

Panel 95 – EFFICIENCY IN HEALTHCARE DECISION MAKING: HOW COMPLEX DOES HTA NEED TO BE?

Prof Finn Børlum Kristensen, Coordinating Secretariat, EUNETHTA; Dr. Krzysztof Landa, Central & Eastern European Society of Technology Assessment in Health Care; Dr. Americo Cicchetti, Catholic University of Sacred Heart; Dr. Mel Walker, Chair, Centre for Socioeconomic Research, University of Wales, GSK R&D; Jean Mossman, European Patients' Forum

The global uptake of HTA to support healthcare decision making has continued at a rapid rate. Meanwhile, the methodologies used for HTA have also evolved with an increasing tendency towards greater complexity, resulting in a situation where many decision makers may not have the technical capability to implement some of the state of the art approaches currently recommended. With HTA now an integral part of most rational healthcare decision making, the aim of this session is to explore whether HTA methodologies are fit for purpose?

Decisions about adopting new healthcare interventions should be based on fit for purpose methodologies.

Questions for consideration include:

- Should the cost of HTA be considered when selecting ways to evaluate healthcare interventions? How should this cost relate to the cost of the intervention itself?
- What is the degree of methodological complexity required to support rational healthcare decisions? What simpler approaches might be considered fit for purpose?
- How does technical capability in the healthcare system influence choice of method? Do approaches need to be fully understood by healthcare decision maker?

The global prominence of leading HTA agencies such as NICE may result in attempts by emerging HTAs to adopt comprehensive cost effectiveness methodologies without first evaluating their decision making requirements. Adoption of fit for purpose approaches may be encouraged by ensuring good understanding of local decision making context and a broader knowledge of available HTA methods.

Session Introduction
Chair to set the scene
Mel Walker, Centre for Socioeconomic Research, University of Wales and GSK R&D, UK

The EUNETHTA "Core HTA Dossier" – Simple Enough?
Prof. Finn Borlum Kristensen, Director, Coordinating Secretariat, EUnetHTA
This presentation will explore how successful EUnetHTA has been in terms of simplifying multiple HTA agency requirements into a core HTA structure? What resources are required for core information preparation and evaluation compared to a multiple HTA approach? Could requirements be simplified further?

Reducing HTA Complexity – What "Light" Models Have Been Developed for Use By Decision Makers?
Krzysztof Landa, Vice-president, CEESTAHC
What alternatives to complex and resource intensive NICE-like appraisals could be considered by middle income countries? Can decision makers blindly adopt guidance published by other HTA agencies? What "light" HTA models are available that may require less resources?

The Use of Mini HTA for Formulary Decision Making
Dr. Americo Cicchetti, Catholic University of Sacred Heart
This presentation will share methods used by healthcare providers to make formulary decisions for new medicines. The level of resources required for mini HTA approaches will be discussed along with the tradeoffs made when compared to full HTA.

How Patients Evaluate Benefit Risk – Lessons for Simpler HTA?
Jean Mossman, European Patients Forum

This presentation will explore how patients evaluate benefit risk and how such evaluations are currently integrated into HTA appraisals. What simpler approaches to decision making are considered useful by patients and what HTA models would they like to see adopted?

Panel Discussion

Chair to moderate an interactive participants-panelists discussion with an emphasis on understanding the factors influencing selection of HTA methodology, the complexity of approach required, when simpler alternatives are needed, and how to ensure methods are fit for purpose and relevant to local decision making.

Special Session – Starting Up HTA (Panel 16 and 50)

Panel 16 – BEGINNERS GUIDE TO HEALTH TECHNOLOGY ASSESSMENT

Joseph L. Mathew, Postgraduate Institute of Medical Education and Research, PGIMER, Chandigarh, India; Kalipso Chalkidou, National Institute of Health and Clinical Excellence, NICE, UK; Brendon Kearney, HPACT, Australia's HTA Committee and Site Clinical Director, Royal Adelaide Hospital, SA Pathology; Srabani Banerjee, Canadian Agency for Drugs and Technologies in Health, CADTH

Background: Significant participation of newcomers to HTA, is expected during the HTAi 2011 Annual Meeting. A user-friendly, participatory panel session will be a welcome innovation to facilitate understanding of the principles and process of HTA, and applicability in individual health-care systems.

Objectives: To outline (i) What HTA is and how it supports informed decision-making for stakeholders, (ii) Why HTA is relevant and important across different health-care systems/settings, (iii) How HTA is undertaken and applied, (iv) Useful resources to learn more and/or collaborate.

Why this session is important HTAi 2011 will witness several newcomer participants, owing to the conference being held (for the first time) in South America; as well as participants' expectation of interacting with international HTA leaders, and greater financial support for people from developing countries. Experience from previous Annual Meetings suggests that newcomers would greatly appreciate a basic-level introduction to HTA.

Presentations

What?

This Presentation Will Highlight (I) The Basic Concept of HTA, (II) How It Differs from Evidence-Based Medicine, (III) Glossary of Common Principles and Concepts, (IV) Role in Informed Decision-Making By Different Stakeholders, Across Different Health-Care Systems/Settings.

Kalipso Chalkidou

WHY?

This Presentation Will Highlight (I) The Need for Using HTA in Decision-Making, (II) Added Value of Considering Economic and Social Implications, (III) Role of HTA in Enhancing Performance and Quality of Health-Care Systems, (IV) Role of HTA in Reimbursement/Payment Decisions, and (V) Problems With Alternate Methods Of Decision-Making.

Brendon Kearney

HOW?

This Presentation Will Highlight (I) How HTA Is Undertaken, (II) How HTA Reports are Produced and Used, (III) What to Look For in HTA Reports, and (IV) Adaptability in Contexts/Settings Other Than Where HTA Reports Are Produced. (4D) WHO and Where? Joseph L. Mathew. This Presentation Will Highlight Useful Collaborating Opportunities For Newcomers, By Presenting (I) Function/Structure of HTAI and INAHTA, (II) HTAI ISG on Developing Countries, (III) HTA Agencies in Various Countries, (IV) HTAI-WHO Collaboration, (V) Online Resources.

Srabani Banerjee

Panel 50 – UNDERSTANDING HTA METHODOLOGY IN SMALL DOSES

Joseph L Mathew, Postgraduate Institute of Medical Education and Research; Srabani Banerjee Canadian Agency for Drugs and Technologies in Health, CADTH; Kalipso Chalkidou, NICE, UK; Brendon Kearney, HPACT, Australia's HTA Committee and Site Clinical Director, Royal Adelaide Hospital, SA Pathology; Luiz Odorico Monteiro de Andrade, Secretary of Strategic and Participatory Management

Background: New participants at HTAi 2011 may be unfamiliar with HTA methodology, but lack the time/interest/resources to participate in a full workshop on this. An easy-to-understand session will benefit these diverse health-care decision-making stakeholders. This session will also complement the panel session 'Beginners' Guide to Health Technology Assessment'.

Objectives: To outline HTA methodology and the process of making informed decisions viz (i)Types of research evidence including synthesis through systematic reviews, (ii) Appraisal of health technologies to determine effectiveness in the local context, (iii) Assessment of economic value of health technologies, and (iv) Informed decision-making taking all these into consideration.

Presentations

Introduction

Does It Work?

This Presentation Will Cover Methodologies to Assess Efficacy of Health Technologies Through Research (Designs), Superiority of Randomized Trials in Certain Situations, and Systematic Reviews.

Srabani Banerjee

Can It Work Here?

This Presentation Will Highlight Issues Relevant to the Health-Care System and Local Context, Which Should Be Considered When Applying Results from Research.

Brendon Kearney

Is It Worth It?

This Presentation Will Outline the Basic Concepts of Health Economics to Determine the Value of Health Technologies in Economic Terms.

Joseph L. Mathew.

Should We Use It?

This Presentation Will Outline How the Preceding Concepts Are Factored Into Locally Appropriate, Informed Decision-Making, And the Associated Challenges.

Kalipso Chalkidou

Discussion

All facilitators and participants

Summary and Conclusions

Joseph L Mathew

Special Session – Pharmaceutical Pricing: on cost and value

Panel 54 – PHARMACEUTICAL PRICING: ON COST AND VALUE

Andres Pinchón-Riviere, Institute for Clinical Effectiveness and Health Policy, IECS; Carole Longson, NICE; Alexandre Lemgruber, ANVISA; Adrian Towse, Office for Health Economics; Oscar Ivan Cañon, Fundacion Salud y Equidad – Colombia

Cross-national differences in pharmaceutical prices are of great interest around the world as the price of medicine could be one of the most important obstacles to access in many countries. Pharmaceutical market structures differ greatly around the world. Variations in systems of drug price regulation, procurement and distribution channels, taxation policies, reimbursement, and competition could greatly influence the price of medicines. Measuring and understanding the reasons for such price variations could help inform more effective pricing policies in order to ensure access to cost-effective medicines at affordable prices, whilst appropriately rewarding innovation.

The objective of the session will be to discuss the prices differences in medicines around the world and the way health care system characteristics and price regulation policies can influence them. Speakers in this session will address specific case studies from countries:

Chair: Prof. Andres Pichon-Riviere MD MSc PhD

Executive Director & Director of the HTA and Economic Evaluation Department , Institute for Clinical Effectiveness and Health Policy, IECS Argentina. Professor of Public Health, University of Buenos Aires. Vice-President of INAHTA

Value Based Pricing and the Pricing Reforms in UK

Speakers: Prof. Carole M Longson, Director, Centre for Health Technology Evaluation – NICE, UK

The prices of medicines in the UK are currently managed by a voluntary agreement between the government and the pharmaceutical industry known as the Pharmaceutical Price Regulation Scheme (PPRS). Building on a report by the Office of Fair Trading in 2007, in late 2010, the new UK coalition Government issued a public consultation document proposing that the PPRS profit-control approach is replaced by a 'value-based pricing' approach. It is envisaged that the new system will come into effect when the PPRS expires in 2014 and that NICE will continue to have a central role in the proposed arrangements.

The value based pricing consultation paper sets out the following key aims:

- improve outcomes for patients through better access to effective medicines;
- stimulate innovation and the development of high value treatments;
- improve the process for assessing new medicines, ensuring transparent, predictable and timely decision-making;
- include a wide assessment, alongside clinical effectiveness, of the range of factors through which medicines deliver benefits for patients and society;
- ensure value for money and best use of National Health System (NHS) resources.

For a value based pricing system to work effectively, the value of a technology to the health system needs to be described. For example, if the primary purpose of the NHS is to improve health then a technology is of value if the health gain expected from its use exceeds the health forgone as other NHS activities are displaced.

In the Government proposals, it is envisaged that higher threshold prices will be allowed for medicines indicated for diseases with a higher burden of illness (a combination of the severity of the condition and the level of unmet need), that can demonstrate greater therapeutic innovation and improvement and have a wider societal impact.

An overview and key aspects of the proposed new UK value based pricing process will be presented and implications for NICE will be explored.

Comparative Efficacy and International Reference Pricing as Part of the Pricing and Marketing Authorization Policy: the Brazilian Experience

Alexandre Lemgruber MSc, HTA Manager, Brazilian Health Agency ANVISA, Brazil

The fast increase of pharmaceutical prices in the end of the 90s led the Brazilian Government to create in 2000 the so-called Chamber of Pharmaceuticals, which is responsible for the price regulation of medicines. At the beginning, the major concern was to control the prices of the medicines that were already in the market, but the great budget impact caused by the new technologies motivated a change in the rules, and new criteria based on HTA were established on May 2004. The objective of this presentation is to describe the role of HTA in the price regulation of new medicines in Brazil and to give some results of the new policy. The price of a new drug is decided based on a comparison between the new drug and the gold standard for the therapy. The evaluation is made by the Brazilian Health Agency (ANVISA), and includes an appraisal of the literature on clinical evidence and an economic evaluation. If the study indicates that the new chemical entity brings additional benefit for the treatment, then the new drug is classified in Category I, and a premium price is allowed, limited to the lowest price in developed countries. If there is no improvement, the new medicine is classified in Category II, and its price is limited to the price of the comparator. According to the ANVISA database, of the 33 new drugs that were evaluated under the new criteria, 4 (12%) were considered as Category I and 29 (88%) as Category II.

Industry Perspective (and Strategy) on Pharmaceutical Pricing, Value Based Pricing and the Pricing Reforms

Adrian Towse, Office for Health Economics – UK

Pharmaceutical Pricing; Variation, Misinformation, Inefficiency and Inequity. An Analysis of the Latin-American Market

Prof. Oscar Ivan Cañon, President, Fundación Salud y Equidad, Colombia, Professor of Health Economics, Universidad Santo Tomás, Universidad Jorge Tadeo Lozano

The statistical variability of drug prices shows the lack of efficiency of drug markets. Ensuring access to price information is a prerequisite for improving the efficiency of drug markets. Only in this way, it is possible to achieve an ethical duty (and legal in some states), to use the best possible way (in terms of QoL, morbidity, mortality and equity) money from health systems.

Several works reports a considerable variability in the price of drug. For the same brand and commercial presentation, between branded and generic products (even the same company), among products within a proprietary name, and in one drug paid by a single entity, either between institutions or between countries.

At present are serious problems of access to information on drug prices that prevent maximize social welfare through open competition. It has been proved theoretically and empirical evidence that symmetry of information is required to make markets efficient.

Networking Session

Panel 73 – HTA E6 PROJECT: IMPROVING HTA IN 6 EMERGING COUNTRIES

Rabia Kahveci, Turkish Evidence Based Medicine Association; Flávia Tavares Silva Elias, Brazilian Ministry of Health, Brazil; Joseph Mathew, HTAi DC ISG; Krzystof Landa, CEESTAHC; Rosa Maria Ceballos, Mexican Ministry of Health; JIE CHEN, Fudan University

Emerging countries promise huge potential for growth but also pose significant political, monetary, and social risks. Such economies now play an increasing role in the world economy and on political platforms. These are also markets that there is huge pressure on policymakers regarding decisions related to technological developments. It is now more prominent that the improvement of HTA in emerging economies is an urgent need.

HTA E6 Project was started to seek for common challenges for HTA in 6 emerging countries and look for any opportunity to define common strategies.

This panel session will discuss the achievements of the Phase 1 of the HTA E6 Project.

Objectives: To describe the project objectives and planning, discuss current status of HTA in emerging countries and common challenges, what has been achieved in phase 1 of the project and what is expected to be gained in the process?

Introduction
Dr. Rabia Kahveci

What Is Special About Emerging Countries?
Dr. Joseph Mathew

HTA and Decision-Making in Emerging Countries
Flávia Tavares Silva Elias

HTA Challenges in Emerging Economies
Krzystof Landa

HTA E6 Project
Dr. Rabia Kahveci

The Achievements of Phase 1
Rosa Maria Ceballos

What to Do Next in the Project
Jie Chen

Discussion
All Facilitators and participants

Summary and Conclusions
Dr. Rabia Kahveci

Oral Sessions

185 – ROUTINE HEALTH SERVICE INFORMATION CAN BE A USEFUL SOURCE OF DATA TO VALIDATE AND IMPROVE THE COVERAGE OF OBSERVATIONAL DATA

Hannah Patrick, National Institute for Health and Care Excellence, United Kingdom; Stephen Goode, Sheffield University and Northern General Hospital, British Society of Interventional Radiology, United Kingdom; Victoria Axe, National Institute for Health and Care Excellence, United Kingdom; Trevor Cleveland, Sheffield University and Northern General Hospital, British Society of Interventional Radiology, United Kingdom; Peter Gaines, Sheffield University and Northern General Hospital, British Society of Interventional Radiology, United Kingdom; Bruce Campbell, National Institute for Health and Care Excellence, United Kingdom

There is increasing international interest in the use of observational data for health technology assessment. Progress has been impeded by concerns about their quality. Poor coverage may be an important source of bias leading to justifiable concerns about validity. It is rare for publications using observational data to assess their coverage. The aim of this work was to assess and improve the coverage and validity of the National Carotid Artery Stent (CAS) Register by cross validation against a national routine dataset. Methods The UK CAS Register was established by the British Society of Interventional Radiology (BSIR) and contains data from 1998 to 2009. Data submission was voluntary. In 2010 the National Institute for Health and Care Excellence (NICE) requested data from the register to inform their review of guidance on CAS for the UK. These data were compared with routinely collected data held by the Hospital Episode Statistics (HES) system for 04/2006- 04/2008 using OPCS procedure code L31.4 which defines CAS. Inconsistencies between the two sources were investigated by personal communication with interventional radiologists. Results In the 2 year period, radiologists in 15 hospitals submitted data on 245 patients to the CAS Register. HES identified another 108 CAS procedures from an additional 38 hospitals which had not been reported to the Register. To date, 12 clinicians confirmed that the total number of procedures undertaken across all their hospitals was within 23 of the total number identified on HES for that 2 year period. Conclusion: Collecting accurate data about interventional procedures is difficult, and use of more than one data source is advantageous. Routine hospital statistics can identify both hospitals and clinicians who have not submitted relevant patients to registers. This allows active case finding in order to increase coverage of registry data and so boost their credibility and usefulness.

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339 – REGISTRIES FOR EVIDENCE GENERATION FOR ORPHAN DISEASES

Judy Kempf, Genzyme, United States

In making the right treatments available to the right patients while developing and maintaining a sustainable healthcare delivery system, decision-makers look to make evaluations based on good evidence. Yet the quality of evidence can vary depending on the data available and the methodologies used. Orphan diseases, with very small patient populations, often globally distributed, can present a challenge to obtaining sufficient data to generate good evidence. Within a single orphan disease cohort, large variations in disease severity and progression, age at diagnosis, and national and regional treatment and support service access make generating sufficient evidence difficult. Registries, focusing on a disease, a treatment or a regional population, are viewed as crucial for increasing our knowledge of orphan diseases and their treatments. This review will look at the strengths and weaknesses of evidence generated from registry data and provide real world examples. Are these data resources appropriate and sufficient for analyzing treatment outcomes, comparative effectiveness, cost-effectiveness? What biases, inherent in this type of observational data, should decision-makers be alerted to when assessing the quality of studies based on registry data for orphan diseases? If single data sources, such a national registry, are too limited, what is the feasibility and what issues arise in attempting to combine data sources? Can registry data expand our knowledge of personalized medicine for patients with orphan diseases – that is, needs of specific sub-population patient groups or patients in specific locations? Good quality evidence is essential to supporting a fair and sustainable healthcare system. The pros and cons, strengths and weaknesses of registry data and methodologies to analyze that data will be described to give decision-makers a framework for assessing the quality of registry data and analyses for orphan diseases.

554 – EVALUATION OF ELECTRONIC HEALTH RECORDS SYSTEMS BASED ON CERTIFICATION PROCESS OF BRAZILIAN SOCIETY OF HEALTH INFORMATICS

Eduardo Alvarez Ribeiro, University of São Paulo, Brazil; Juliana Pereira Souza, University of São Paulo, Brazil; Paulo Mazzoncini de Azevedo-Marques, University of São Paulo, Brazil

Goal: This paper presents an initial proposal of evaluation of electronic health records (EHR) systems at a University Hospital based on the process of software certification of the Brazilian Society for Health Informatics (BSHI). This study aims to contribute improvements to the quality of systems. Methods: The certification process of BSHI is composed of a set of requirements based on the concepts, and national and international standards in health informatics, as ISO standards, and HL7 and TISS standards, resolutions of the CFM, and concepts defined by the Special Committee of Health Informatics of ABNT. All requirements are outlined in the Certification Manual SBIS version 3.3 used in this work. This manual contains mandatory, recommended and optional requirements for building and evaluating the architecture of an EHR. The Operational Manual of Tests and Analysis version 1.2 is used as a guideline for the implementation of routines. The manual contains the details to verify compliance to the requirements. Security Requirements Level 1 and Structure, Content and Feature Requirements were verified. The study was conducted in EHR at Clinical Hospital of Medicine School of Ribeirão Preto at University of São Paulo. Results: In total, 84 routines were tested concerning to 106 requirements. The evaluation resulted in 37 routines that are in compliance with the manual, 6 non-compliant, 37 not applicable and 4 partially consistent. The compliance routines refer to 36 requirements resulting in 33.96% of the requirements in accordance; not applicable were 35.84% and 5.66% were non-compliant. Conclusions: It was demonstrated the effectiveness of this method to detect deficiencies in the system evaluated. These results can contribute to development and improvement of solutions. The methods used here will be expanded to other systems of others hospitals.

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641 – FACTORS THAT INFLUENCE THE CITATION OF HTA DOCUMENTS. A MULTIVARIATE ANALYSIS

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Objective: To analyze the factors that influence the citations of documents produced by the Spanish agencies of Health Technology Assessment (AUnETS group). Methods: we analyzed the production of AUnETS, both documents and articles published between 2000 and 2006 and studied the characteristics of them: language of publication, year of publication, journal type, position of the first author of the agency, impact factor, source of funds, indexing (INAHTA, Medline, DARE, Iberoamerican Cochrane, IME, IBECS,) and the number of citations in reference databases (Scopus, Google Scholar and ISI WoK). Subsequently we performed a bivariate analysis of the factors that have relation with citation. Finally we built a model based on a multivariate logistic regression, that explained the reasons why a document was cited or not. We also calculated the area under the COR curve. Results: A total of 570 documents were produced by Spanish agencies in the studied period, the documents produced a total of 1,790 cites. The analysis of the documents found that agencies publish reports or monographs (52.1%), in Spanish and not indexed in traditional databases. The factors that were finally related to citations ($p<0.05$) were document type, year of publication, type of intervention, funding source, indexed in CRD, Scopus, ISI-Wok, Cinahl and language of publication. Discussion: the policies of diffusion of HTA documents are extremely important for the impact of those products, especially in the case of meso (managers) and micro (clinicians) level. In those levels professionals are accustomed to journal articles publication type. These results showed that policies that took into account the correct indexing of the products have better success in final citation of them. Other complementary researches should be performed to analyze how to improve the policies of diffusion at the macro (policy-makers) and public levels.

847 – ANALYSIS OF HTAS ON SPINAL CORD STIMULATION (SCS) AND SACRAL NEUROMODULATION (SNM) THERAPIES, AND IDENTIFICATION OF PATIENT REPORTED OUTCOME (PRO) USE AND ASSESSMENT FOR SUSTAINABLE AND EVIDENCE-BASED DECISION-MAKING

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Objective: Sustainable decision-making necessitates the inclusion of patient-reported outcomes (PROs) and a strong evidence base. We examined published HTAs for Spinal Cord Stimulation (SCS) and Sacral Neuromodulation (SNM) in order to assess the degree Evidence-Based Medicine (EBM) principles and PRO use and evaluation have become embedded in HTA methodology. Methods: Databases and websites were searched to identify HTAs evaluating SCS and SNM therapies, for all approved indications, globally. Only published HTAs were included for analysis. Filters for date and language restrictions were not applied. A data framework (tracker) was utilized to extract the necessary information. Findings: We identified 14 published HTAs, 10 for SNM and 4 for SCS, from 6 different agencies in 5 countries (2000-2009). All four SCS HTAs used various evidence grading systems, compared to 50% of the SNM HTAs. Only the most recent one explicitly referred to a grading system and made use of the PICO approach to define distinct populations and select appropriate comparators and population-matched clinical endpoints. This PICO categorization allowed for a transition from an initially unfavorable funding decision to a favorable one for expanded indications. Although most HTAs evaluated PRO research, there was a limited usage of disease-specific questionnaires. The systematic inclusion of relevant PROs by means of disease-specific tools was confirmed in only two HTAs. Finally, only the 3 most recent HTAs tackled uncertainty through sensitivity analysis, two for SCS and one for SNM, allowing for more relevant and sustainable decision-making. Conclusions: There is evidence that EBM principles are starting to be adopted, albeit without methodological uniformity. The incorporation of EBM principles alone is not sufficient to ensure sustainable and relevant decision-making. Appropriate use and assessment of PROs are of the essence for safeguarding patient-centeredness, particularly for therapies whose main aim is to reduce pain and improve quality of life.

325 – MIXED TREATMENT COMPARISONS IN REVISION

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Background: Mixed Treatment Comparison (MTC) meta-analysis is a generalization of traditional meta-analysis that allow all evidence to be taken into account whether direct or indirect. The potential of the use of MTC methods in HTA has been recognized in various countries (UK, Canada and, more recently, US) as demonstrated by increasing number of published studies. However, MTC methods were developed under the Bayesian statistical approach and have been presented mainly to a statistical methods audience. Objectives: To disseminate Bayesian MTC methods and assist researchers and decision-makers in understanding the key characteristics of this new methodology. Methods: This work reviews the Bayesian MTC models comparing their methodology with standard pair-wise comparisons and showing the flexibility of the models through the understanding of their characteristics and assumptions. A discussion regarding a key assumption of MTC models (consistency between direct and indirect evidence) and why we should care about it is presented. The node-splitting method to checking consistency is highlighted and, also, the posterior plots (posterior densities of the treatment effects obtained using MTC) as a visual tool to assess the agreement of the two types of evidence. We use a practical example involving the comparison of different doses of statin in preventing acute myocardium infarct. Conclusions: Bayesian MTC combines the results from all sources of evidence providing narrower interval estimates when direct and indirect evidences are both available. The flexibility of the models allows to incorporating trials with more than two arms, get results from comparisons where head-to-head trials are not available, include trial level data and work with homogeneous between trials variability. The node-splitting method is very helpful to understand how MTC is pooling the evidences and identify lack of consistency. When faced with evidence of inconsistency researchers can not rely on results from full MTC and should reconsider all evidence.

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434 – ISSUES IN THE RAPID REVIEW OF HEALTH TECHNOLOGIES: GUIDANCE BASED ON A QUALITATIVE STUDY OF MANUFACTURERS' SUBMISSIONS TO THE UK NICE SINGLE TECHNOLOGY APPRAISAL PROCESS

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Objectives: The assessment and application of new health technologies is crucial to the sustainability of health systems. The rapid review is increasingly a part of international health technology assessment. In the UK NICE rapid Single Technology Appraisal (STA) process, manufacturers present the clinical and cost effectiveness of new technologies in their evidence submissions. These submissions are critically appraised by Evidence Review Groups (ERGs) who produce a report which forms part of the evidence considered by the Appraisal Committees. Early on in the process the ERG requests more information from the manufacturer via a clarification letter. The purpose of this research was to develop guidance for manufacturers based on common problems or issues identified in manufacturer submissions (MS). Methods: Two sources of evidence were used in this study: the first 30 completed ERG reports and 21 of their available associated clarification letters. Qualitative approaches were used to analyse both sources of evidence to identify common issues and concerns. Findings Issues and concerns identified included: conduct of the systematic review within the MS; criticisms relating to the data being used; failure to perform a necessary analysis and poor reporting. The population and comparator represented the key items in the decision problem assessed by the ERGs as being inadequately addressed by manufacturers. The majority of clarification points related to the economic data analysis and covered issues such as clarification of data sources and selection, queries about modelling decisions and requests for additional analyses. Internal inconsistencies between the clinical and economic sections of the MS, and inconsistencies within the economic section of the MS were also identified as particular problems. This analysis was used as the basis for the development of 13 recommendations for manufacturers. Conclusion Much can be done by manufacturers to improve the quality of MS in the NICE STA process.

713 – A NEW VERSION OF THE "METHODOLOGICAL GUIDELINE FOR ELABORATING RAPID HTA (RHTA)": WHAT'S NEW?

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The "Methodological Guideline for Elaborating Rapid HTAs" is a Brazilian Ministry of Health (MoH) tool whose aim is to guide and contribute to the standardization of RHTA elaboration, which is the first step in the process of evaluating the requests for the incorporation of new technologies into the Unified Health System (SUS). This Guide has been widely utilized in the MoH since 2007, when its first edition was published and disseminated through workshops at state health secretariats, hospitals and universities throughout Brazil. The 3rd edition, which will be published in 2011, was developed based on the suggestions from 150 participants from workshops conducted in 2009 and in the first semester of 2010, from RHTA users themselves (SUS technicians and managers), and from Health Technology Assessment Center members. The final version was approved by the experts of the Brazilian Network for Health Technology Evaluation – REBRATS. Suggestions focused on improving methodological quality, attempting to meet the manager's information requirements and to assist with the limitations technicians experience when formulating Rapid HTAs. New elements in the third edition are: more information regarding the analysis of health equipment and products; a definition of which electronic databases are considered to be obligatory and which are optional when searching for scientific evidence, keeping in mind the limited access to certain private databases; more information on researching and analyzing data on drug safety; highlights from HTA study results conducted by HTA agencies; information on GRADE; a RHTA quality evaluation form; and a date for the RHTA review. It is expected that the Rapid HTA Guideline will contribute to the structuring and dissemination of HTA in Brazil. As a challenge, it will try to measure the degree to which this Guideline is used and the impact of Rapid HTAs on the health services in other governmental spheres.

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898 – SPECIFIC GUIDELINES AND METHODS FOR HTA OF ONCOLOGY PRODUCTS (CANCER HTA)

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Objectives: Guidelines for procedures and methods in health technology assessment (HTA) are heterogeneous across different countries and can vary for different diseases. This project aimed to identify guidelines for HTA of oncology products in order to determine characteristics and dissimilarities in relation to HTA guidelines for non-oncology products. Methods: We conducted a systematic research on the homepages of several HTA-organizations in Europe, Australia, North and South America. These were selected by their characteristics as leading and nationally operating agencies incorporated in a stable environment, that are financed mainly publicly and that publish either German or English documents. The homepages then were screened systematically for methodological documents. Documents with guidance on HTA evaluating oncology technologies were selected and data extracted using a standardized extraction sheet. In case of lacking information, agencies were contacted directly for further details or confirmation of our findings. Findings: Three documents, published by CADTH (CA), NICE (UK) and the German Cancer Society (DE) have been analyzed. NICE guidance focused on specific conditions for reimbursement for end-of-life treatments, while the other documents dealt with specific challenges using typical HTA framework for cancer drugs. It was found, that the selection of comparators in the assessment of oncology products appears to be complex. Furthermore, cross-over study designs chosen for ethical reasons can bias the effect estimators of the clinical efficacy results. The most commonly used clinical outcome measure overall survival (OS) does not capture toxicity. Therefore, a summary measure allowing weighing benefit and harm is needed. Surrogate outcomes, like progression free survival, must be extrapolated to OS and the type of relationship must be justified. Conclusion: Cancer specific HTA guidelines have identified special challenges in the evaluation of oncology products and partly recommended standards for a reference case. The included documents differed in their focus, hence these recommendations are incomparable.

237 – NEUROECONOMICS AND ORGANIZATION OF INTEGRATED CARE

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Background: Integrating fragmented care pathways represent the case of inter-organization collaboration which requires extraordinary horizontal operational collaboration. Neuroeconomics explains Frontal integration (C) as a dialectic process between the Mesolimbic reward system (L(x)) and recollected memories (R). Within C ventromedial PFC (c) controls both dorsolateral cognitive prediction (R*c) and orbitofrontal emotions (L(x)/c) to minimize prediction error / maximize utility. c↑ is associated with pragmatic prediction while c↓ enables imagination by empathy. A visuospatial Parietal sketchpad integrates Occipital memory mismatches by spontaneous AHA-experiences modeled as stochastic knowledge (ϵ). Formula C models decision-making: C = Rc2/L(x) + ε → 1 Purpose: To investigate how Formula C might support integrated care (IC). Method: Qualitative studies of the application of Formula C in EC-FP7-Homecare 222954. Results: 1. Integrated homecare (IHC) for anxious patients with C<1 has a comparative advantage to other forms of IC: BP declining 5-7 mmHg~L↓→C↑ as evidenced for stroke patients 2. Neuroeconomics is applied to build high-performance-teams in IHC: • L(x) is our social brain mirroring social relations by empathy. So, supportive team-relations elevate the mood of team-members to a more optimistic and productive level which has been evidenced as the Hawthorne effect of human-relations management. IHC has simple transparent guidelines on informal behaviour to minimize formal regulation • Prediction and empathy are complementary cognitive processes (c↑↓). IHC presupposes in accordance with organization research that the best workgroup effectiveness is achieved at a medium level of employee satisfaction with challenging but achievable work tasks 3. De-stressing from over-load (C>1) by Medical Meditation is hypothesized to support Frontal integration: c↓→L↑→C↓. Our user-inquiry by the Internet confirms that people perceive the same level of health benefits (i.e. reduced blood pressure and less smoking) from yoga and meditation as from physical exercise. Conclusion: Neuroeconomics is useful for the development and assessment of both the technological and organizational aspects of IC.

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372 – ESTIMATING THE SF-6D VALUE SET FOR A SOUTHERN BRAZILIAN POPULATION

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Objectives: SF-6D is a preference-based measure of health developed to estimate utility values from the SF-36. The aim of this study was to estimate a weighting system for the SF-6D health states representing the preferences of a sample of Southern Brazilian general population. Methods: A sample of 248 health states defined by the SF-6D was valuated by a sample of a southern Brazilian population using the standard gamble (SG). The SG responses were used to estimate regression models at the individual and mean levels to predict preference values for all SF-6D health states. The models were compared with those described in the UK study. Results: Five hundred twenty seven participants were interviewed, but 58 (11%) were excluded for failing to value the worst state. Data from 469 subjects were used to estimate the models, rendering 2696 health states valuations. Compared to UK data, Brazilian health state values were lower, leading to a lower constant term in the models. The best fit model for the Brazilian data was a random effects model using only the main effects variables, different from the UK SF-6D model, highlighting the importance of adopting a country-specific algorithm in predicting SF-6D health states values. The Brazilian model produced significant coefficients and presented a mean absolute difference between observed and predicted values of 0.07. Inconsistent coefficients were merged to produce the final recommended model. Conclusion: The results provide the first population-based value set for SF-6D health states in Brazil, making it possible to generate QALYs for cost-utility studies using regional data. Besides, utility scores based on Brazilian preferences values can be derived from existing SF-36 data set.

424 – A WORKED EXAMPLE OF "BEST FIT" FRAMEWORK SYNTHESIS: A PRAGMATIC FORM OF QUALITATIVE DATA SYNTHESIS FOR HEALTH TECHNOLOGY ASSESSMENTS

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Background: A variety of different approaches to the synthesis of qualitative data are advocated in the literature. The aim of this paper is to describe the application of a pragmatic "best fit" framework synthesis approach to qualitative evidence synthesis, within the scope and constraints of a UK health technology assessment (HTA) project. Methods: An evaluation of a novel version of framework synthesis as an approach to the qualitative systematic review of evidence. The case study was a HTA systematic review exploring adults' views about taking various potential agents for the chemoprevention of colorectal cancer. An existing model was identified from the literature that conceptualised attitudes of adult women to the taking of several of these agents. The model identified did not entirely match the topic under study, but it was a "best-fit" and provided a relevant pre-existing framework and themes against which to map and code data. Results and Discussion: Twenty papers from North America, Australia, the UK and Europe met the criteria for inclusion. Fourteen themes were identified a priori from the previously identified model, which were then used to code the extracted data. The synthesis required a combination of framework and secondary thematic analysis approaches and resulted in the generation of a more sophisticated model with additional themes. The work was conducted within a health technology assessment timeframe. Conclusion: The novel and pragmatic "best fit" approach to framework synthesis developed and described here was found to be fit for purpose. It offered a means to reinforce, critique and develop an existing published model, conceived for a different but relevant population, and produced a relatively rapid process when compared to more interpretative forms of synthesis. Future research should seek to test further this approach to qualitative data synthesis, especially within the parameters of health techonology assessment.

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946 – INTERMEDIATE OUTCOMES IN MEDICAL TEST ASSESSMENT: GUIDING PRINCIPLES FOR ASSESSING CHANGES IN PATIENT MANAGEMENT

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Background: HTAs of medical tests generally seek to determine whether the test is accurate and leads to improved patient outcomes, however direct evidence of the latter is rarely available. Our systematic review of medical test HTAs tests published from 2005 to 2010 found intermediate test outcomes, most commonly change in patient management, were considered in 61 of 149 (41%). However, appraisal and interpretation of this evidence was inconsistent and incomplete in 63% of HTAs. Test evaluation guidelines do not provide explicit criteria for assessing evidence about intermediate outcomes. Objective: To define a set of principles to guide the use and interpretation of evidence about intermediate outcomes, specifically patient management, for medical test HTAs. These principles are based on an evaluation framework that requires reviewers to specify the clinical pathway linking the use of the test to patient outcomes. Results: Key principles for HTA reviewers include: 1. Developing the research question and protocol: If a new test is claimed to improve outcomes by improving treatment or avoiding other tests: - Specify what changes in patient management are expected as a consequence of the test results and state whether evidence measuring these changes is needed or whether assumptions are straightforward based on established clinical protocols. - List key assumptions required to infer that these changes in patient management will improve outcomes. 2. Defining study inclusion criteria: When seeking patient management studies, include studies that report patient management in sufficient detail to estimate the proportion of patients who receive the pre-specified change in management following a positive or negative test result. 3. Using a structured quality appraisal method: Assess potential sources of bias when attributing changes in management to test results. Conclusions: We believe these principles will help improve the use and interpretation of evidence of patient management changes in medical test HTAs.

449 – INDICATORS FOR ASSESSING RESEARCH NETWORKS IN INNOVATION AND TECHNOLOGY IN HEALTH

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The research networks are organizational forms that enhance the activities of research groups, articulating different competencies. In addition to strengthening the production of knowledge, the network enhances the activities of knowledge transfer to society and of training of personnel. Considering the government investment in the formation of research networks, their operation must be evaluated. This project's aim was therefore to develop indicators for evaluating a research network on innovation and technology in health, able to assess the consistency between actions and goals of the network, integration strategies, and relations with the network partners. Four categories of indicators were proposed, comprising a matrix of evaluation: 1 – Network Consolidation: indicators of the internal dynamics of the network and its relationship with outside groups, articulated through the activities of research and publications in partnership; 2 – Research: indicators of activities of knowledge production, through the quantification of research projects conducted; 3 – Knowledge transfer to government, business sector and society: indicators of the actions of knowledge dissemination, technical cooperation and patent registration; 4 – Training of personnel: indicators of activity for training specialists, masters and doctors. This matrix was applied and seemed to be adequate to evaluate the network. The indicators led to the identification of the current stage of this network development, identifying strengths and weaknesses. Probably, the methods used in this evaluation can be adapted to assess other research networks.

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514 – EVIDENCE FOR DISINVESTMENT: CHALLENGES FOR HEALTH TECHNOLOGY ASSESSMENTS AND SUBSEQUENT POLICY FORMULATION

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HTA methods (including systematic review) are well established for assessing new/emerging technologies to determine their suitability for public funding; however, their applicability to the assessment of technologies for disinvestment purposes remains uncertain. After undertaking two disinvestment case studies utilising HTA methods (assisted reproductive technologies (ART) and vitamin B12/folate pathology testing), we identified a number of challenges in the direct application of HTA methods to the pragmatic assessment of entrenched technologies for disinvestment. The very specific manner in which systematic reviews are structured – with pre-defined populations, interventions, comparators and outcomes (PICO) – competes with the diffuse use of established technologies and intervention-focussed reimbursement schedules. In clinical practice, the use of technologies evolves over time and across populations, creating challenges in defining the characteristics of the target population and the intervention itself. B12/folate tests for example, are used across a hugely diverse population with a broad range of clinical indications, as both screening and diagnostic tools. ART is a complex intervention to define, due to constant evolution and multiple components, combinations of which are applied variably across populations. Establishing appropriate comparators is also difficult, particularly in technologies such as B12/folate tests, which have a range of potential comparators, but lack an adequately evaluated gold-standard. Defining relevant outcomes may also be problematic; in ART the most policy-relevant outcome (healthy live birth per initiated cycle) was not consistently reported in the literature. The issue of generalisability – always prominent in HTA – becomes even more apparent in disinvestment decisions, when evidence may not reflect a technology's clinical utilisation within a healthcare system. Two real-world disinvestment assessments (ART and B12/folate testing) have uncovered challenges around PICO definitions, technology evolution, and generalisability. Despite these challenges, and to progress disinvestment, best-practice HTA methods need to be integrated with new ways of identifying and analysing information critical

618 – NEW APPROACH TO IDENTIFY NEW AND EMERGING TECHNOLOGIES: VALIDATED BIBLIOGRAPHIC SEARCH STRATEGY

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Background: early warning systems need to handle a wide range of sources to identify new and emerging health technologies. The process is laborious, time consuming and the efficacy is unknown. This work aims to present an approach to simplify identification and enable an earlier detection. Objectives: 1) present a bibliographic search strategy to systematically identify new and emerging technologies, 2) determine the efficacy in comparison to perusal of journals, 3) establish the effectiveness for early identification. Methods: the search strategy consists of a combination of keywords that were identified by scanning 162 early warning systems reports (EuroScan). The search was run for 2009 and abstracts scanned to establish the efficacy to identify new and emerging technologies. For comparison purposes, all papers published during 2009 in six primary research journals and eight high impact surgery journals (impact factor greater than 4) were reviewed. Relevant technologies identified were backtracked to locate first publications and these results crosschecked with the search findings for that year. Results: After limiting for irrelevant fields, the search yielded 6228 abstracts of potentially new and emerging technologies in 2009. Of these, 968 were classified as new or emerging. The scanning of 12061 journal papers identified 50 new and emerging technologies (Endoscopy=20; Annals of Surgery=16; Lancet=6; others= 8). Of these, 38 (76%) were located through the automatized search during the first two years of publication. Of the 12 technologies missed, only 4 were relevant losses: 5 were modifications of existing technologies and 3 corresponded to the first study published. Conclusions: the search strategy proposed appears to be highly effective to identify relevant new and emerging technologies in the very early stages of adoption. The automatic running of the search in PubMed and Embase periodically can avoid scanning of multiple sources and save time and resources.

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684 – ESTABLISHING HORIZON SCANNING ACTIVITIES IN THE BRAZILIAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

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Horizon Scanning (HS) is an integral process of any Health Technology Assessment system, comprising the steps of identification, prioritization and evaluation of new and emerging technologies. This paper describes the process of establishing Horizon Scanning activities in the Brazilian Network for Health Technology Assessment (REBRATS). We analyzed the stages for preparing guidelines on horizon scanning and systematized the main activities conducted up to this point in order to implement an alert system in Brazil. The first stage in this process was to establish a work group (WG) to coordinate HS activities in the scope of REBRATS. The WG defined four tasks to be fulfilled in a period of two years: 1) review the literature in order to identify the applied methodologies by the most experienced institutions in the field; 2) prepare a basic text to support WG discussions concerning the main directives to develop a guideline on the subject; 3) organize a workshop to expand the discussion on the subject to other experts in the fields of HTA and technology innovation; 4) define a pilot study to start the process in real life. As a result, the WG defined that the HS activities within the ambit of REBRATS should focus on technologies in the initial adoption phase and that have a high priority for the Unified Health System (SUS). The main scanning prioritization criteria will be: magnitude of the health problem; health services impact; technology characteristics; social pressures; opportunity. Additionally, robotic surgery was pointed out as the target technology of a pilot study to evaluate its impact in the SUS. Moreover, it is necessary to further improve the definition of the methodology to be adopted and the process of sustainability of HS activities in the SUS.

784 – INVESTMENT AND DISINVESTMENT OF HEALTH TECHNOLOGIES: THE NEED FOR TWO COST-EFFECTIVENESS THRESHOLDS

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Objectives: The concept of a cost-effectiveness “threshold” has been adopted either explicitly or implicitly by health care decision makers in numerous jurisdictions. This paper demonstrates that, under very weak assumptions – applicable to all real-world health systems – decision makers ought to instead adopt two cost-effectiveness thresholds. Methods: A simple model of a hypothetical health care system is used to demonstrate the appropriate threshold(s) under various assumptions concerning: (i) the size of the health care budget; (ii) the extent to which technology, productivity and/or input prices change over time; (iii) whether the amount of information available to decision makers changes over time; and (iv) the fixity of the set of adopted health care technologies in the short term. Results: The assumptions which must hold for two thresholds to be appropriate are that: (a) there is some fixity in the set of adopted health care technologies in the short term; and (b) either (i) technology, productivity and/or input prices change over time, or (ii) the information available to decision makers changes over time, or both. Where these assumptions hold, one threshold ought to be used when appraising technologies with positive incremental costs (investment decisions), while a different threshold should be used when appraising technologies with negative incremental costs (disinvestment decisions). This is true regardless of the marginality of the technologies under consideration. Conclusions: This finding has profound implications for the practice of cost-effectiveness analysis, for ongoing and future empirical research into the nature of the threshold, and for health care policy making. It gives a theoretical underpinning to observations that the ICERs of technologies disinvested at the margin differ from those of technologies adopted at the margin. It also has implications for the interpretation of ICERs, for the appropriate calculation of net benefit, and for the conduct of value of information (VOI) analysis.

156 – CRITICAL INCORPORATION OF HEALTH TECHNOLOGIES IN PUBLIC HOSPITALS AND HEALTH CENTERS: THE EXPERIENCE OF ADAPTING PROCESSES AND TOOLS IN THE PROVINCE OF TIERRA DEL FUEGO, ANTARCTICA AND ISLANDS OF THE SOUTHERN ATLANTIC (ARGENTINA)

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From 2007 to 2010, a collaboration project was implemented between the National University of Lanús and the Ministry of Health of the Province of Tierra del Fuego, Argentina, for the purpose of sharing the findings of the research into the improvement of health technology management. A study of current official documents revealed that the rules governing the provincial system are historically linked to administrative resolutions relating to procurement. The decision-making process regarding the incorporation of health technologies basically took into account the purchase amount and available budget with little consideration to other technical aspects. Interviews were conducted with key sources from within hospitals, the Ministry of Health and other governmental areas to know their opinions about the different aspects of health technology incorporation. They agreed upon the lack of a process capable of guaranteeing a decision-making process based on the transparent use of the best information available, ready to deal with competitive pressures. A bibliographic review allowed for the identification of key players, stakes, methods of implementation, barriers and enablers, processes, proceedings and instruments, lessons learned and recommendations. These elements served as a platform for adapting the international experiences chosen to the provincial scenario. This adaptation was based on repeated adjustments after various stages of consultation and consensus with main local players and the contributions from experts in other countries. A pilot was conducted applying the designed process and instruments to the health technologies chosen by local health authorities which provided further elements for the ultimate fine-tuning. The proposal covered the process (introduction, implementation and development), the procedures involved and both essential tools as well as supporting ones. Local authorities have approved the proposed process and instruments and formed a specific team for their progressive implementation, accompanying the gradual standardization of administrative circuits and the development of institutional evaluation capacities.

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492 – SUSTAINABLE POPULATION HEALTH: THE CHALLENGE AND THE ROLE OF HTA

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Any policy, program or intervention is decision for resource allocation. Whatever intervention is implemented there always will be winners (people who benefit) and losers (people who benefit less), hence conflict of interests – who will benefit more. Choices or prioritizing competing demands are inevitable, since resources are limited and less than the needs. Always some claims are declined, therefore the challenge is: “Which claims will be declined?” and more importantly: “On what basis some claims will be declined?” While healthcare is personal services on individuals, aiming maximizing outcome for individuals, public health is complex interventions applied to whole populations, aiming maximizing outcome for whole populations. However, although that a population is sum of individuals, achieving highest attainable health for an individual and for whole population is not the same thing. When looking for value-for-money decision-makers should be aware that even for healthcare cost-effectiveness varies depending on local context in terms of: organization of services provided; considered costs to individuals, families, employers, communities and society; cultural specificities. For interventions on populations there is one important extra aspect of the local context – the distribution of the benefit – which HTA should consider. Then, what HTA can/should do when different segments of the population respond very differently to identical interventions? I’ve established that evidence for interventions on populations is relative and depends on the distribution of the benefit in any specific case. The appraisal of such interventions should start with analyzing this distribution at local level. I’ve identified nine combinations of previous and new winners and losers leading to different results for population health. Once this is sorted out, HTA can evaluate possible alternatives for given distribution and can identify the best value-for-money in specific cases in order to maximize the outcome for whole populations, which is premise for sustainable population health.

425 – HEALTH TECHNOLOGY ASSESSMENT IN A BRAZILIAN PRIVATE HEALTH INSURANCE COMPANY

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In Brazil, private health insurance system is regulated by the Federal Government. The increased requests of new health technologies do not necessarily mean higher quality care to population health. On the other hand, costs rise exponentially, with a significant risk of compromising the viability of the health system. The adoption of strategies for assessing health technologies, ethical and technically justified, may be one way to ensure quality of care to society in a sustainable health system. We present the three years experience in a brazilian private, non-profit health insurance company, with more than half million users and about five thousand doctors. There were 103 assessments of requests for incorporation of health technologies, in almost all cases, were performed technical notes for quick review (mini-HTA), evaluating scientific evidence on safety, effectiveness and advantage of the new technology over the standard treatment. As part of the evaluation process, there were more than fifty meetings with the requesters doctors seeking to clarify the criteria and technical procedures adopted and spread knowledge on technology assessment in health. In a significant number of cases, after discussing the method, the physicians chose to not attend meetings and withdrew the request. Of all evaluations using this method, only three have resulted in lawsuits demanding the provision of technology. No procedure ethical or disciplinary action was brought as a consequence of the assessments. The inclusion of requesters physicians in the process of evaluation of health technologies and explaining about the ethical and technical criteria adopted resulted in a significant reduction in litigation on specific new health technologies in the company.

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429 – INDIRECT TREATMENT COMPARISONS AND NETWORK META-ANALYSIS: A REVIEW OF MANUFACTURERS' SUBMISSIONS TO THE NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE) SINGLE TECHNOLOGY APPRAISAL (STA) PROCESS

Matthew Bending, University of York, United Kingdom; John Hutton, University of York, United Kingdom; Clare Mcgrath, Pfizer, United Kingdom

Objective: Indirect Treatment Comparisons (ITC) and Network Meta-Analysis (NMA) can provide valuable information for decision-makers, especially when direct comparisons between medicines are unavailable. The objective of this study is to investigate the methods and impact of ITC and NMA submitted by manufacturers in the NICE Single Technology Appraisal (STA) process on the committee's appraisal of pharmaceuticals. Methods: A search of the NICE website was conducted for manufacturers' submissions that reported to contain either an ITC or NMA since 2006. Data were extracted and analysed for the type of network meta-analysis, number of trials, head-to-head trial evidence available, disease area, treatment comparisons, study selection justification, sensitivity analysis of trial selection and outcome(s). The impact was assessed by analysing information on Evidence Review Group (ERG) review of evidence synthesis, Appraisal committee's comments and final decision. Findings: The search identified 24 submissions that included either a ITC or NMA. The issues most frequently raised by the ERG were lack of reporting of trial characteristics, description of methods and quality assessment of all trials included. The most frequent validity concerns were both clinical and statistical heterogeneity between trials, inappropriate methods of analysis, exclusion of relevant trials and sparse numbers of trials in the network. The committee considered all evidence and reported the analysis to be plausible on one occasion, stated concerns with the validity in 18 appraisals and did not directly comment on 5 occasions. Fifty eight percent of appraisals including an ITC or NMA resulted in a restricted decision. Conclusions: ITC and NMA has provided additional useful information for NICE appraisals but there has been wide variation in the reporting and validity of analysis performed. Reimbursement agencies should establish guidelines for the conduct of network meta-analysis to reduce this variation.

895 – INTRODUCTION OF NEW TECHNOLOGIES IN URUGUAY: THE TECHNOLOGY ASSESSMENT AS A TOOL FOR DECISION-MAKING IN A NEW HEALTH CARE SYSTEM

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The Integrated National Health System of Uruguay (SNIS) created in 2007 introduced new policies to promote the rational use of health resources. Any new introduction of technology must be approved by the Ministry of Public Health (MSP) taking into account scientific evidence regarding its usefulness, the need for its use and the rationale for its geographical location. In this context, the Department of Health Technology of the Ministry of Public Health starts in 2009 a comprehensive analysis of all requests for incorporation of new technologies. Health care providers or institutions require to ask for authorization in any case of new incorporation of High Porte Equipment and Health Services of medium and high complexity. A questionnaire was developed specifically for the evaluation of applications presented for the technical analysis conducted by the MSP. Reports may arise to: no recommendation of the incorporation requested, recommendation after incorporation of amendments and suggestions, or recommendation for inclusion under the terms established in the request. Up to now, 61 applications have been analysed, 43 related to the incorporation of medical equipment and 15 for health services incorporation. Up to now, 12 new technology additions after technical analysis have been approved. This methodology to incorporate new technology has been an innovative experience for the Department of Health Technology of the Ministry of Public Health since each analysis requires, before adding new equipment or services, to make an review of: epidemiological situation regarding needs of each technology, service use and the potentiality of share use with other providers. This innovative methodology of incorporation avoids duplication of services and promotes complementarity among health care providers and services and contributes to build a unique system that optimizes financial resources.

509 – COMPLEX SURVEY EFFECT IN ANALYSIS OF UTILITY INDEX

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Introduction: Utility values are outcome measures recommended nowadays for use in economic analysis. They generate an unit called QALY (Quality Adjusted Life Years) which aggregates quality of life and survival in one measure. Many studies use complex survey sample (CSS) in the cultural adaptations of this kind of instrument, but do not consider it when analyzing data. In QOL and utility studies the effect of CSS in the final models is unknown. Objective: Evaluate the effect of sampling plan in a study for cultural adaptation of the instrument SF-6D. Methods: Cross-sectional population-based study (n=469) made in Porto Alegre, through cluster sampling. SF-6D and Standard gamble have been applied. In order to estimate utility, 4 different models were adjusted, 2 Ordinary Lest Square (OLS) and 2 multi-level models. Design effect (deff) was calculated to evaluate the effect of cluster sampling and intraclass correlation coefficient (ICC) to evaluate the need of multi-level modeling. Results: For OLS models most of deff values were smaller then 1. ICC values indicate multi-level modeling is adequate in this study. Multi-level models had smaller standard errors then OLS models. Discussion: Multi-level modeling was better then OLS models, even when OLS models included the effect of cluster, showing how important is the inclusion of random effects. Among multi-level models, incorporating random effect of cluster improved model quality. Conclusions: It's recommended incorporating cluster sampling in analysis of utility data, through multi-level modeling Keywords: Cluster Sampling, Multilevel Analysis, Quality of Life

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571 – IS BACKWARDS THE NEW WAY FORWARDS?

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Trial based analyses generally model resource use and QoL values using panel data techniques. Data is typically segmented into time periods moving forward from randomisation with mean values per time period adjusted to taken into account right censoring (Lin et al(1)). However, QoL may decline as patients approach death in cancer (Sandblom, 2004(2)) whilst health care expenditure studies indicate that resource consumption may increase. A recent cost study in CRPC indicated resource use potentially tripled as patients approached death from $15,185 9-12 months before death to $44,203 0-4 months before death (Alemayehu, 2011(9)). This suggests panel data analyses based on time periods moving forward from baseline may capture patient resource use or QoL at different stages pre-death. This may result in higher variance in estimates, increasing overall uncertain in CE estimates and providing potentially biased or uncertain comparisons across therapies. This study presents results from an clinical trial in hormone resistant prostate cancer (HRPC) which provides EQ-5D evidence demonstrating that QoL reduces before death. A panel data analysis indicated that mean EQ-5D index scores reduce substantially from 0.79 13-16 months before death to 0.73, 0.67 and 0.52 for time periods 9-12, 5-8 and 0-4 months before death. The current study provides a further worked example which proves that modelling resource use and QoL by time before death reduces uncertainty and improves estimates. It is shown that applying a concrete clinical endpoint such as death allows costs and QoL estimates to be mapped from one trial to another in a potentially more accurate fashion than existing techniques. It is believed these methods may have scope to be generalised to other indications.

817 – TRIAL SIMULATION MODELING IN THE ERA OF COMPARATIVE EFFECTIVENESS RESEARCH

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Background: The comparative effectiveness research (CER) era has heightened focus on late-phase trials, emphasizing head-to-head comparisons, clinically-relevant endpoints, and appreciation for heterogeneity of treatment response. Trial simulation modeling has long been a valuable tool for trial planning, but is more complicated to perform in this context. Objective: The purpose of this paper is to discuss common challenges and plausible solutions for simulation modeling of CER trials. Methods: In contrast to traditional clinical trial design, hallmarks of CER trials include active- (not placebo-) controlled comparisons of the effectiveness (not efficacy) of drug and non-drug health interventions (not just pharmaceuticals), in terms of relevant health outcomes (not surrogate/intermediate endpoints), analyzed separately within clinically-relevant patient subgroups (not just averaged over all study subjects), in real-world (not experimental) settings. A trial simulation model needs to accurately reflect these elements of the pragmatic trial design, especially the defined patient subgroups, primary study endpoint(s), duration of follow-up, and planned analyses. When performed in a stochastic framework, the model can address a variety of important questions, including expected differences in study endpoints between treatment groups (both overall and within patient subgroups), the likelihood that the trial outcome will favor a given intervention, and statistical power for the planned sample size. Alternative-scenario ("what-if?") analyses can be performed to assess potential impact of changes to patient inclusion/exclusion criteria or other modifications to the trial design. Illustrative Example: A case study trial simulation modeling effort for a phase IV comparative effectiveness trial will be presented to highlight the fundamentals and strengths/limitations of trial simulation modeling in CER. Conclusion: Interest in CER has revitalized a range of methodologic approaches for comparative analysis of medical interventions, including phase IV pragmatic trials. Trial simulation modeling is a valuable tool to improve the design of CER trials for optimum usefulness of study results.

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894 – HEALTH TECHNOLOGY ASSESSMENT OF INFLIXIMAB WITH THE EFFICENCY FRONTIER APPROACH

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Objective: Growth in drug expenditure challenges the sustainability of the German health care system. In 2009, the TNF-alpha inhibitors adalimumab, etanercept and infliximab generated €940mn drug expenditure at a 23% annual growth rate. The German Institute for Quality and Efficiency in Health Care (IQWiG) developed the efficiency frontier (EF) approach for health technology assessment (HTA) in Germany. The objective of our analysis is to assess the suitability of IQWiG's EF method for HTA of TNF-alpha inhibitors in early rheumatoid arthritis. Methods: A literature search is conducted for trials comparing infliximab with conventional disease-modifying anti-rheumatic drugs (DMARDs). Effectiveness evaluation requires comparison with DMARD combination therapy as it has been shown superior to DMARD monotherapy. Cost evaluation is limited to calculation of German drug costs due to its dominating role in TNF-alpha therapy. Findings: One trial (the BeSt trial) was identified to match the search criteria. For first-line therapy, we measured effectiveness in terms of patient response, i.e. a sustained DAS44 score less than or equal 2.4 after two years. In the BeSt trial, methotrexate monotherapy achieved 33% response at €230 cumulative drug expenditure. Initial combination therapy with methotrexate, sulfasalazine and prednisone achieved 58% response at €790 drug expenditure. Infliximab was superior with 72% response but caused €30,640 drug expenditure. Therefore, infliximab is plotted right of the EF which is defined by the conventional alternatives. By definition, the EF cannot be constructed with conventional DMARDs for second-line therapy. Conclusions: The EF method gives useful results for evaluation of first-line therapy in early rheumatoid arthritis, rendering infliximab inefficient as it is plotted to the right of the EF. Due to the lack of a global measure of health outcomes, the EF cannot achieve comparison of infliximab with conventional DMARDs in second-line therapy, stressing the need for complementary analyses like IQWiG's budget impact analysis.

437 – ASSESSING THE IMPACT OF MEDICATION ADHERENCE ON HEALTHCARE COSTS IN ULCERATIVE COLITIS

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Objectives: Increased adherence may reduce relapse frequency in ulcerative colitis (UC) patients, which may impact overall costs to payers. A budget impact model was constructed to estimate the influence of 5-ASA adherence rates on total annual direct costs in UC patients. Methods: Assuming a US payer's perspective and a 1-year horizon, the model assessed healthcare costs and utilization in adult patients (≥18 years) with newly diagnosed or relapsing mild-to-moderate UC. Average market share from June 2009–May 2010 for 5-ASA medications including Asacol, balsalazide disodium/Colazal (BD), Lialda, and Pentasa was assumed to be the default health plan share. Adherence rates were obtained from published literature. Annual UC-related pharmacy costs were calculated using net wholesale acquisition cost, while additional direct costs for patients with/without relapse based on medication possession ratio of <0.8 or ≥0.8 were from published literature (claims analysis). Sensitivity analyses were performed to estimate the impact of alternative assumptions on total annual health plan savings. Findings: Average annual costs for Lialda patients ($12,771 per patient/year) were lower than other 5-ASAs (Asacol:$13,005,BD:$13,331,Pentasa:$13,912). Inpatient and emergency room(ER) costs were lower for Lialda. Pharmacy costs were highest for Pentasa ($3,306), followed by BD($3,129), Lialda($2,927), and Asacol ($2,707). Incremental pharmacy costs of Lialda compared to Asacol were offset by cost savings in hospitalizations and ER visits. A health plan with 1 million lives (assuming 23% UC prevalence rate) could save $300,070 by switching all Asacol patients to Lialda. Sensitivity analyses suggest that Lialda adherence rate was highly influential in impacting annual health plan savings, as were inpatient costs for non-adherent patients who relapse. Conclusions: The primary driver for inpatient cost differences was reduction of relapse frequency because of greater adherence with medication. Choice of drug by therapeutic value (adherence) rather than costs may improve patient care and reduce costs, such as from hospitalizations and ER visits.

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884 – PROPOSAL OF BRAZILIAN GUIDELINES FOR CONDUCTING BUDGET IMPACT ANALYSIS FOR HEALTH TECHNOLOGIES

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Health technology assessment is still a developing field in Brazil. Guidelines for cost effectiveness analysis have been issued in 2009. The proposed Brazilian guidelines for budget Impact analysis (BIA) on health technologies are introduced in this presentation. Recommendations are made on how to conduct BIA for drugs, medical devices and other health technologies. Spreadsheet based BIA are taken as the base case for most BIA, but acknowledgment is made as for the need of more sophisticated techniques in specific circumstances. Recommendations include one to five years time horizon, adjustment for inflation not routinely employed, estimation of population size from epidemiological data or from reimbursement requests data, consideration of direct costs and scenario sensitivity analysis. Validation is still in development as expected for any tool recently issued. These guidelines are being developed by the Brazilian Institute for Health Technology Assessment (IATS), along with Brazilian Ministry of Health and the National Agency for Health Surveillance (ANVISA).

922 – HOW CAN HEALTH ECONOMIC EVALUATION OF CLINICAL GUIDELINES SUCCESSFULLY BE PERFORMED?

Ch. Markos Dintsios, Institute for Quality and Efficiency in Health Care (IQWIG), Germany; Nina Breyer, Institute for Quality and Efficiency in Health Care (IQWIG), Germany; Andreas Gerber, Institute for Quality and Efficiency in Health Care (IQWIG), Germany

Introduction: Health economic evaluation of clinical guidelines (GL) as complex interventions requires a specific methodological approach in contrast to single technology economic appraisal. Until now no methodological standards for the economic evaluation of GL have been presented. Objective: Our objective was to identify methodological approaches for health economic evaluation of GL and to compare them in order to detect methodological differences between the economic evaluation of single technology and GL. Methods: We performed a systematic literature search. An extraction form was specifically tailored to this study. Results: 42 publications were included into our study. Among the retrieved health economic analyses of GL were pre-post-comparisons, cluster randomizations, prospective cohort studies, and health economic models covering various phases of GL development. Cost-effectiveness, cost-utility, and cost-minimization studies as well as cost studies were found. Third party payers', societal, and in-hospital care perspectives were applied. The studies did not give a rationale for the selection of alternative implementation strategies. Process indicators or measurement of behavioral change were primarily used as endpoints. Overall, the studies lacked methodological rigor and often exhibited deficits in documentation. Discussion: In order to assess the efficiency of the implementation of GL a break-even point needs to be calculated where the savings based on the reduction of under- and overuse are in balance with the costs to develop, implement, and use the GL. Yet, no study delivered an analysis of the exact status of health care delivery that would be necessary. A separate health economic evaluation of single phases of GL development without considering the real health care delivery is at risk of neglecting important resources in the determination of cost-effectiveness. Conclusions: For GL influence upon complex health care delivery processes effects of single components are blended that need to be assessed in a methodologically standardized approach despite the well-known difficulties.

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948 – HTA AS AN INSTRUMENT FOR AN APPROPRIATE SELECTION OF A MEDICAL DEVICE

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It is a general problem how to select an appropriate medical device with suitable parameters, and how to justify its purchase. Taking patient lung ventilators as an example, this study describes how HTA can help to select the appropriate device. Our study analyses three types of ventilators used in newborns. The standard ventilator that is the commonest type in Czech hospitals, the modern so-called iron lung that is non-invasive and thus particularly very well tolerated by newborns, and the high frequency ventilation with admixture of heliox, using a closed circuit. Heliox is mixture of helium and oxygen that is better breathable for patients due to its low molecular weight. The use of heliox was very expensive, and so a closedcircuit was developed, in which patients breathe heliox back. To assess these three ventilators, the following methods were used: Primary patient data were statistically processed and used in modelling. A cost-benefit analysis and a cost-effectiveness analysis were performed. Finally, the method of value engineering was used to identify optimum functions and characteristics of the device. The study was conducted in the Motol University Hospital in Prague and in the Thomayer University Hospital in Prague, in both cases in the nowborn unit of the intensive care ward.

208 – THE POTENTIAL OF EARLY MODELING OF NEW TECHNOLOGIES TO HELP INFORM DECISION-MAKING

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Objective: An objective of a publicly-funded health service is to maximise health from the available resources. Decision-makers have to judge whether the relative advantages of using a new technology are worthwhile given the alternative uses that could be made of the scarce health care resources. Economic evaluation can help inform these decisions. We advocate that the incorporation of economic measures and economic analysis should be considered at every level of the development of the evidence-base of a technology. Using a case-study, we illustrate that early modeling may help inform decision-making and whether further research will be worthwhile. Methods: Using interventional treatments for snoring we assessed the feasibility of providing effectiveness and cost-effectiveness estimates. Methods: included linear exponential models to extrapolate long-term outcomes from primary studies and Markov models estimating life time costs and benefits. Findings: It was possible to generate information that allowed extrapolation of outcomes to the longer-term, include relevant comparators and provide a focus for future data collection. Three questions were addressed: -given the available evidence on effectiveness and cost-effectiveness, should decision-makers consider introducing a treatment for snoring? -given that decision-makers decide that a treatment for snoring should be offered to patients, which treatment is worth introducing? -would further research in this area be worthwhile? Although the evidence-base had limitations and there was uncertainty surrounding the data used, the results are very stable over a range of plausible deterministic and probabilistic sensitivity analyses, meaning that it was possible to provide meaningful information. Conclusions: Early modeling was possible and potentially useful. Although there is a time commitment associated with this task we will show that for this case-study the cost of conducting this research was worth the effort and we echo arguments that economic evaluations should be conducted ‘early and often’.

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456 – HEALTH ECONOMICS RESEARCH IN LATIN AMERICA: A BIBLIOMETRIC ANALYSIS

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Introduction: Bibliometric analysis is a descriptive, quantitative research method, used to identify and compare research patterns and trends. This project analyzes Latin American Medline-indexed research in Health Economics. Methods: Using “economics” as MeSH term (key word) and/or MeSH subheading we identified research linked to each Latin American country in the 25-year time period 1985-2009 in PubMed website. We describe time trends and main topics for the region and for each of the main countries, as well as prioritized topics of economic research. Results: The country with the largest number of papers published in the 25-year period was Brazil (with 1370), closely followed by Mexico (1299). At a distance come Argentina (314), Chile (292) and Colombia (288). In a third level fall Peru (210) and Cuba (200) and somewhat behind Costa Rica (116) and Venezuela (115). The main topics in Brazil have been HIV, vaccines and mental disorders, while for Mexico, pregnancy, obesity and smoking have had the most interest, from an economic perspective. Main topics for other countries have been vaccines and myocardial infarction for Argentina, infant mortality and pregnancy for Chile, contraception/fertility and health care reform for Colombia, social class and poverty in Peru, and vaccines and pregnancy in Cuba. Overall, the peak in the number of publications in the region occurred in the late 80s and early 90s, when Latin American countries published, on average, three times more per year than in the last ten years. Discussion: Publications on health economics in the region are scarce, if compared with more developed countries. Brazil, the first country in the region, would be 14th in a world ranking, behind Switzerland, and followed closely by India and Belgium. The main topics of research, however, are aligned, in general with the Millennium Development Goals.

617 – LOOKING FOR A COST-EFFECTIVENESS THRESHOLD IN KOREA

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Objectives: To investigate a cost-effectiveness threshold range in Korea METHODS: A survey questionnaire was developed to measure willingness to pay (WTP) for QALY in Korea. A general population sample of 1,017 people was interviewed face-to-face and web-based survey on four interest groups: decision makers, industry, providers, and academia, was also conducted. Each person's WTPs were elicited by four scenarios chosen from 3-item EQ-5D scenarios (<1 QALY) and additional scenario with extended year in perfect health (=1 QALY). The same WTP questions were also repeated for a family member for general public, a patient for providers, and a third party individual for the other groups. Also a question on appropriate WTP for a QALY in Korea (Policy-WTP) was added for the interest groups. The questionnaire included questions on demographics, disease status, and a visual analog scale (VAS) measure of each scenario presented. Consistency of each respondent was checked by matching ranks of five scenarios between WTPs and QALY improvements either by VAS or Korean EQ-5D tariff. Results: Of 1,017 persons surveyed, 933 persons passed consistency test. For those who passed consistency and not in medical assistance program, the average WTP for a QALY calculated from the open questions was 19.5 million KRW. WTP for family member were consistently higher than self. Of 73 respondents from the interest group survey, 67 passed consistency test. The average WTPs were highest in industry (median=51,460,000 KRW, IQR=[20,000,000, 93,020,000]) and followed by providers(median=60,510,000 KRW, IQR=[36,430,000, 10,830,000]), decision makers(median=19,160,000 KRW, IQR=[11,540,000, 29,060,000]) and academia(median=1,384,000 KRW, IQR=[3,730,000, 22,220,000]). Those who answered positively for knowledge of Incremental Cost Effectiveness Ratio (ICER) showed consistently higher WTPs. The Policy-WTP with ICER knowledge showed a narrower range of 15-55 million KRW. Conclusions: WTP for QALY was estimated as 19,500,000 KRW (23,700 USD considering purchasing power) from general public, however, industry and providers

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959 – FIVE-YEARS FOLLOW-UP OF CONGENITAL HEART SURGERY AT THE HEART INSTITUTE OF THE CLINICS HOSPITAL, SÃO PAULO UNIVERSITY MEDICAL SCHOOL, INCOR-HC/FMUSP

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Methods Prospective cohort of consecutive congenital heart surgery cases, operated for repair or palliation, between January the 03rd, 2005, and December 14th 2010. The information system, SI3, harmonized the STS Nomenclature of the primary procedure documented by the surgeon, allied bar codes data collection and electronic prescription of drugs. Prospective Risk level stratification by Aristotle Basic and Complexity Scales: groups level 1 (scores 3 to 5.9), 2nd level (6 to 7.9), 3rd level (8 to 9.9) and level 4 (scores of 10 or more), where morbidity and mortality were documented. Estimated costs of hospital care (materials, medications, procedures, tests, operating theatre hours and the ICU or ward rate per day) used Micro-costs methods. Physician fees were excluded. A clinical team ensures lifelong post-operative follow-up, with periodic visits and

facilitated access for all required care. Results: - At 5 years of follow-up, absolute mortality rate of 1.5%, 4.0%, 8.1% and 15,3% were observed, with scores lower than 6, the 2nd stratum, 3rd level and level 4, respectively. Patients with the highest scores, 4th stratum required the double of the length of stay and ICU use than the 2nd stratum, as well as more than double the number of diagnostic tests and therapeutic procedures required. Thus, costs for the hospital admissions have increased three fold from the 2nd stratum until the 4th level of scores. - Presence of infection before surgery tripled costs regardless of age group or risk levels. - Post-operative infection tripled costs for neonatal and adolescents and doubled it particularly for patients with the highest scores. - Longitudinal follow-up is warranted. Conclusion: - Five Brazilian Reference Centers for Congenital Heart Surgeries: Ceará , Pará, São Paulo, Paraná and Rio Grande do Sul are developing Chapters of the multicenter study with the Brazilian Cardiology Society, Brazilian Health Ministry and São Paulo State.

240 – IS SIMULTANEOUS PANCREAS KIDNEY TRANSPLANT THE MOST COST-EFFECTIVE TREATMENT FOR TYPE 1 DIABETES PATIENTS WITH RENAL FAILURE? A COST-UTILITY ANALYSIS

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Objective: Cadaveric simultaneous pancreas kidney (SPK) transplant has been shown to improve quality of life, reduce long-term diabetic complications and prolong survival in Type 1 diabetes patients with renal failure (IDDM-RF). The objective of the current study was to assess its cost-effectiveness compared with other treatment strategies for IDDM-RF prior to establishment of a pancreas transplant programme in Singapore. Methods: A decision analysis model was developed using TreeAge Pro for IDDM-RF treatment strategies, consisting of cadaveric kidney transplant (Ktx-CD), living donor kidney transplant (Ktx-LD), SPK and dialysis. We conducted a cost-utility analysis from a health service perspective based on a 5-year model. Singapore cost and survival data were used except for all SPK survival variables where American data from the United Network for Organ Sharing and Scientific Registry of Transplant Recipients were used. Sensitivity analyses were performed to evaluate the impact of uncertainties around key variables. Findings: In the baseline analysis, Ktx-LD was the most cost-effective strategy with the lowest cost per quality-adjusted life year (QALY) gained. Cost per QALY for Ktx-LD was SGD69,381; SPK, SGD72,905; Ktx-CD, SGD81,674 and dialysis, SGD177,341. The Ktx-CD was dominated strategy being both less effective and less efficient as measured by a higher incremental cost-effectiveness ratio (ICER). ICERs with dialysis as a reference for Ktx-LD and SPK strategies were SGD33,715 and SGD45,379, respectively. Both strategies are considered highly cost-effective under WHO guidelines (less than GDP per capita for Singapore in year 2009, that is, SGD53,900). In the sensitivity analysis, with an 8% increase in kidney graft survival or 8% increase in patient survival, would make SPK the most cost-effective strategy. Conclusions: Both Ktx-LD and SPK are highly cost-effective strategies in the treatment of IDDM-RF. SPK is potentially the most cost-effective strategy if an increase of 8% in graft or patient survival is achieved.

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276 – DIAPS79: A COST-UTILITY ANALYSIS OF SAXAGLIPTIN AS AN ADD-ON THERAPY TO METFORMIN IN TYPE 2 DIABETES PATIENTS FROM THE BRAZILIAN PRIVATE HEALTH SYSTEM

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Objectives: This is a cost-utility analysis of saxagliptin (treatment group) vs. thiazolidinediones (control group) as add-on therapy in type 2 diabetes (T2DM) patients not achieving appropriate glycaemic control with metformin, from the Brazilian private health system (PHS) perspective Methods: A discrete event simulation model based on UKPDS68 study was developed in order to simulate 40 years for a cohort of 1,000 patients. Safety and efficacy data were obtained from a systematic review and meta-analysis of published literature. Epidemiological and costing data were obtained from DIAPS79, an outcome study of the treatment patterns and costs of T2DM patients in the Brazilian PHS. Pharmaceutical costs were based on Brazilian official factory price. Insulin plus metformin was defined as rescue therapy. An annual discount rate of 5% was applied to both costs and benefits. Deterministic and probabilistic sensitivity analyses were conducted to assess the robustness of the results. Results: According to the model, the lipid profile benefits from thiazolidinediones did not translate into long-term vascular benefits when compared to saxagliptin (vascular fatal events risk reduction of -0.0034 vs. pioglitazone). Saxagliptin was dominant when compared to both pioglitazone as the add-on therapy of choice to metformin (costs savings per patient of USD 1,810 vs. pioglitazone; incremental 0.13 QALY per patient vs. pioglitazone). In the deterministic sensitivity analysis, HbA1c level was the

most impactful parameter in the model, but saxagliptin remained the dominant option in all cases. In the probabilisitc sensitivity analysis, saxagliptin had a greater than 90% probability of being cost-effective for a willingness-to-pay of zero. Conclusion: Saxagliptin is associated with lower costs and increased quality-adjusted life expectancy compared to thiazolidinediones as add-on therapy in T2DM patients failing to achieve adequate glycaemic control on metformin monotherapy.

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465 – COST-UTILITY ANALYSIS OF PHARMACOLOGICAL TREATMENTS FOR THE PREVENTION OF BONE FRACTURES IN OSTEOPOROTIC POST-MENOPAUSAL SPANISH WOMEN

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Objective: To assess cost-utility of the most employed pharmacological treatments in Spain for the prevention of bone fractures in osteoporotic post-menopausal Spanish women. Methods: We evaluated the efficiency of alendronate, risedronate, ibandronate, raloxifene, and strontium ranelate in preventing bone fractures in Spanish osteoporotic post-menopausal women, as compared to using calcium plus vitamin D, or placebo. The societal perspective was adopted. We built a Markov model, preferably incorporating Spanish data. The target population is made up of Spanish osteoporotic women over the age of 50. The efficacy information came from randomized controlled clinical trials that were monitored between one and three years. Those efficacy data were adjusted to represent a partial treatment adherence. Both, treatment duration and offset time were five years. The time horizon was until death or 100 years old. Results: Assuming partial treatment adherence, the Incremental Cost-Effectiveness Ratios (ICER) of the evaluated drugs in comparison with calcium plus vitamin D or placebo were higher than 30,000 € per additional QALY gained for women starting treatment before the age of 69. Only alendronate, starting treatment at an age of 69 or above, obtained ICER values less than 30,000 €. To gain an additional QALY from a 5-year intervention with alendronate in comparison with calcium plus vitamin D or placebo, starting treatment at the age of 69, and with partial adherence was estimated to cost 26,248 € per patient. Conclusion: In comparison with calcium and vitamin D, or placebo, treating with alendronate, risedronate, ibandronate, raloxifene or strontium ranelate is not efficient for the prevention of bone fractures in osteoporotic post-menopausal Spanish women when they start treatment before the age of 69. However, if women start treatment at an age of 69 or above, alendronate would be efficient.

360 – THE COST-EFFECTIVENESS OF EXERCISE REFERRAL SCHEMES IN PRIMARY CARE

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Objectives: To examine the cost-effectiveness of exercise referral schemes (ERS) in comparison to usual care. Methods: Using a decision analytic model that was developed from a UK NHS/ PSS perspective, the costs of ERS and the quality-adjusted life-years (QALYs) gained were modelled over the patient's lifetime. The model was populated primarily with data drawn from the systematic reviews undertaken as part of the research project. Deterministic and probabilistic sensitivity analyses investigated the impact of varying ERS cost and effectiveness assumptions. A discount rate of 3.5%was used and costs were expressed in £2010 prices. Findings: Compared to usual care, the mean incremental cost for ERS was £169 and the mean incremental QALY was 0.008, with the base-case incremental cost-effectiveness ratio (ICER) for ERS at £20,876 per QALY in sedentary individuals without a diagnosed medical condition. There was a 51% probability that ERS was cost-effective at £20,000/QALY and 88% probability that ERS was cost-effective at £30,000/QALY. The ICER was £14,618 per QALY in sedentary obese individuals, £12,834 per QALY in sedentary hypertensives and £8,414 per QALY for sedentary individuals with depression. However, findings suggest small incremental costs and QALYs, and ICERs were therefore highly sensitive to variations in the relative risk for change in physical activity and cost of ERS. Further developments of this model to incorporate short-term benefits in health related quality of life associated with ERS reduced the base case ICER to £17,032 /QALY. Conclusions: The cost-effectiveness of ERS is uncertain because of limitations and gaps in the clinical effectiveness evidence base. Sensitivity analyses show that the cost per QALY associated with ERS can change markedly with plausible changes in model effectiveness and cost inputs, indicating that robust evidence on the cost effectiveness of ERS cannot currently be provided.

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369 – USING VALUE OF INFORMATION ANALYSIS IN COMBINATION WITH AN EARLY STAGE MODEL OF AORTIC STENOSIS TO INFORM FUTURE RESEARCH NEEDS IN PATIENTS WHO ARE CURRENTLY ELIGIBLE FOR AVR BUT COULD SWITCH TO 'COREVALVE'

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Objective: Aortic Stenosis (AS) is a severe cardiovascular condition the treatment of which often involves a major operation to replace the aortic valve (AVR). 'CoreValve', a novel procedure for this condition, is less invasive and allows for the implantation of a replacement valve in this patient group. Since information is not yet available on key clinical parameters, we modified an existing early stage economic model to perform a value of information analysis to inform the prioritisation of future research. Methods: An Excel based Markov model with a ten year time horizon was used in this analysis. Treatment options were CoreValve and AVR with parameters derived from published literature. All costs were taken from the most recent published sources. Decrements were applied to age-specific EQ-5D population norms to generate QALYs. A probabilistic sensitivity analysis was used to inform the global Expected Value of Perfect Information (EVPI) calculation. Deterministic analyses were used to select the variable groups and individual parameters on which partial EVPI (EVPPI) calculations were performed. Annual incident population estimates were derived from information in a national database. Results: Assuming a decision horizon of 10 years, an annual incident population of 4,900 and a willingness to pay threshold of £30,000 per QALY gained the population EVPI is £77.5 million. EVPPI estimates were generated for procedure costs, utility decrements, intensive care length stay, device lifetimes and treatment effects. Of these, the VoI for ICU length of stay and the AVR procedure cost were greatest (£36.2 million and TAVI: £3.5 million, AVR: £3.5 million respectively). The VoI for all others was negligible Conclusion: Further information on cost or resource use estimates in the comparator arm would potentially have the greatest impact on decision uncertainty. Thus, a new clinical trial may not be required and a registry may be more appropriate.

882 – COST-EFFECTIVENESS OF ABDOMINAL AORTIC ANEURYSM SCREENING IN FINLAND

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Background: Abdominal aortic aneurysms (AAA) are responsible for up to 2% of deaths in men aged 65 or more. Majority of the AAAs are asymptomatic until rupture, and the risk for rupture depends on the size and growth rate of the aneurysm. AAA can be detected non-invasively, using ultrasound. Objectives: This study aims to estimate the cost-effectiveness of AAA screening in both, men and women, in Finland compared to current practice with no systematic screening. Methods: Cost-effectiveness analysis was done from the health care provider's perspective using a time horizon of the expected lifetime. A previously constructed and published model was used for the analysis. Model input values were taken from a systematic review, national registries (mortality and resource use data) and expert opinion. Both costs and effectiveness were discounted by 3%. Uncertainty of the model and the parameters was analysed by probabilistic sensitivity analysis. Findings: According to the preliminary results, the screening of AAA seems to be effective and cost-effective in men. For women, however, the screening is not cost-effective but also the data available is limited. The final results will be available for an edited version of the abstract and presented at the conference. Conclusions: Screening for AAA can be seen cost-effective for men aged 65. For women no evidence on cost-effectiveness was found.

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961 – COST-EFFECTIVENESS AND PUBLIC HEALTH AND BUDGET IMPACT OF FRACTIONAL FLOW RESERVE-GUIDED PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH MULTIVESSEL DISEASE IN GERMANY

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Background and Objectives: The FAME Study, an international multicenter RCT (n=1005), demonstrated significant health benefits for patients undergoing multivessel percutaneous coronary intervention (PCI) guided by fractional flow reserve (FFR) measurement compared with PCI guided by angiography alone (ANGIO). The aim of our study was to determine the cost-effectiveness as well as the public health and budget impact for Germany and other European countries. Methods: All analyses were performed for patients with multivessel disease comparing FFR vs. ANGIO, based on the original patient-level data of the FAME Study (Tonino et al., NEJM2009). In the prospective cost-effectiveness analysis, we calculated the incremental cost-effectiveness ratio (ICER) in Euro per QALY gained during 1 year adopting the societal perspective. Utilities were measured with German EQ-5D. Costs were based on German prices and DRGs. The public health and budget impact analysis was based on PCI registries and performed from the payer's perspective. Variability was estimated using the Bootstrap method (n=5000 samples) and extensive sensitivity analysis. Findings: For the German health care context, the cost-effectiveness analysis resulted in an ICER of 1000 EUR/QALY gained. Bootstrap simulation indicated FFR being cost-effective in 87% at a threshold of 50,000 EUR/QALY gained. Under different scenarios, the public health impact due to the use of FFR ranged from 14-842 QALYs gained during a 2-year period. The 2-year budget impact ranged from total cost savings of 4.7 million EUR to additional costs of 0.6 million EUR. Sensitivity analyses showed that prices of FFR pressure wire and drug-eluting stents were most influential, determining whether FFR is cost-effective or cost-saving. Further results will be presented for other European countries (e.g., UK, France, Italy). Conclusions: FFR-guided PCI in patients with multivessel coronary disease substantially reduces cardiac events, improves QALYs and is very cost-effective compared to other well accepted technologies in health and medicine.

163 – COST-EFFECTIVENESS ANALYSIS AND BUDGETARY IMPACT OF THE COMBINATION CETUXIMAB-RADIOTHERAPY VERSUS RADIOTHERAPY ALONE FOR LOCALLY ADVANCED HEAD-AND-NECK SQUAMOUS CELL CARCINOMA: THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM (SUS) PERSPECTIVE

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Objectives: To perform a cost-effectiveness analysis from the Brazilian Public Health System's (SUS) perspective, of cetuximab combined to radiotherapy (CRT) versus radiotherapy (RT) alone for the treatment of patients with locally advanced head-and-neck squamous cell carcinoma (HNC), who are not candidates to cisplatin and RT combination therapy. Methods A Markov model simulating the progression of HNC through the different stages of the disease was designed and divided in time frames of four months. The base study used for efficacy data was from Bonner et al and its recent 5-year survival update. The costs of resources utilization were collected from the following sources: Banco de Preços em Saúde-BPS (Healthcare Prices Database), Sistemas Gerenciais da Tabela de Procedimentos –SIGTAP (Management Systems of the Table of Procedures) and Revista SIMPRO (SIMPRO magazine). The comparative strategies results were measured by the Incremental Cost-Effectiveness Ratio (ICER), considering a 5% discount/per year for costs and benefits. We conducted interviews with decision makers and physicians in six of the main HNC treatment center in the country. Results Considering the cost of cetuximab in Brazil (R$ 562,12 - Ex-factory price without VAT) the ICER for 5 years, 10 years and life-time were R$ 43.836,06, R$ 22.421,06 and R$ 15.909,95, respectively. Estimating in 8% the number of HNC patients non-eligible for cisplatin and radiotherapy, therefore eligible to receive cetuximab in addition to radiotherapy the budgetary impact of the combined therapy compared to radiotherapy alone was R$ 8.463.849,85 in one year. Conclusion The addition of cetuximab to radiotherapy demonstrated significant higher efficacy in terms of overall survival and loco-regional control without increase of adverse events when compared to RT. The association of CRT was associated with higher costs than RT alone, however the ICER was inferior to the suggested threshold of 3 GDP per capita per year.

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252 – COST-EFFECTIVENESS OF EPIDERMAL GROWTH FACTOR RECEPTOR GENE MUTATION TESTING IN THE SELECTION OF FIRST-LINE THERAPY FOR PATIENTS WITH ADVANCED NON-SMALL CELL LUNG CANCER IN ONTARIO, CANADA

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Objective: To assess the cost-effectiveness of epidermal growth factor receptor (EGFR) gene mutation testing for guiding the application of gefitinib as first-line therapy in patients with advanced non-small cell lung cancer (NSCLC) living in Ontario. Methods: A decision analytic model was developed to compare EGFR gene mutation testing strategy versus no testing strategy in patients with advanced NSCLC. Under the testing strategy, patients tested positive for mutation would receive gefitinib as first-line therapy. Under no testing strategy, patients would receive conventional chemotherapy as first-line therapy. Probability variables were estimated through literature review. Utility variables were estimated from a multivariate linear regression analysis taking into account of the clinical responses and side-effects associated with treatment for NSCLC. Cost variables were based on two Ontario cost studies for NSCLC. Both benefits and costs were discounted at 5% per annum. Results: Compared to no testing strategy, the incremental cost-effectiveness ratio for EGFR gene mutation testing was $46,021 per life year or $81,071 per quality adjusted life year (QALY). The cost-effectiveness of EGFR gene mutation testing was sensitive to the cost and efficacy of gefitinib. The budget impact analysis projected that EGFR gene mutation testing would cost Ontario health care system $4.6M, $7.0M, $7.9M, $8.1M, and $8.1M more a year in the next five years. Conclusion: EGFR gene mutation testing would not be cost-effective in patients with advanced NSCLC in Ontario until willingness-to-pay was above $81,000 per QALY. The efficacy and cost of gefitinib significantly affected the cost-effectiveness of EGFR gene mutation testing.

375 – COST EVALUATION OF INTRAOPERATIVE RADIOTHERAPY (IORT) FOR BREAST CANCER: DIFFERENT PERSPECTIVES MAY YIELD OPPOSITE CONCLUSIONS

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Context: IORT is an intensive radiation treatment that delivers a concentrated beam of radiation to tumors at the time of surgery, while sparing normal surrounding tissue. It replaces the 7-week ambulatory radiotherapy program usually following breast-conserving surgery. Objective: To assess the incremental cost impact of introducing IORT in place of ambulatory radiotherapy within three perspectives: hospital, third-party payer and healthcare system. Method: Economical data are derived from the cost accounting and prices of Lausanne University Hospital (CHUV). IORT has no impact on DRG assignment. It requires the acquisition of a dedicated radiotherapy system and the presence of a radio-oncologist during the intervention. The duration of the surgical intervention is increased by 30 minutes. Findings: The depreciation charge of the IORT system amounts to CHF 5'635 per patient and the incremental operating costs amounts to CHF 4'456 per patient. The 7-week ambulatory radiotherapy program's marginal cost is CHF 3'219 and is charged CHF 9'970 per patient. The adoption of this new technology represents an incremental cost of CHF 16'841 per patient from the perspective of the hospital, an incremental cost of CHF 6'872 from the perspective of the healthcare system and an incremental benefit of CHF 9'970 from the perspective of the third-party payer. Conclusions: For the hospital, the adoption of IORT lead to higher hospitalization costs without any compensation through the DRG payment system and a loss of profitable ambulatory services. This could dissuade it from adopting a promising new technology, which is much less costly if we consider other perspectives.

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401 – COST-EFFECTIVENESS OF 1ST LINE TREATMENT FOR METASTATIC COLORECTAL CANCER IN THE BRAZILIAN PUBLIC HEALTH SYSTEM

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Objective: In August 2010, the Brazilian Ministry of Health reviewed values for the public financing of colorectal cancer treatment, in order to incorporate modern chemotherapy regimens, with higher efficacy. The aim of this study was to estimate the cost-effectiveness of 1st line treatments available before and after the review process. Methods: A Markov model was developed to predict disease progression, mortality, and costs of colorectal cancer patients with metastatic disease treated with 5-fluorouracil and leucovorin (Mayo regimen), or oxaliplatin, infusional 5-fluorouracil and leucovorin (FOLFOX regimen). The model was developed using data from randomized trials, projecting outcomes for a ten-year period. The cost-effectiveness estimates were made from Brazilian public health system perspective. Data on resources utilization and associated costs were obtained from price tables regulated by Brazilian Ministry of Health. The incremental cost per life year gained was calculated comparing both strategies to supportive care. Future costs and benefits had an annual discount of 5%. Findings: Extrapolating benefits for a ten-year follow-up, the 'old strategy' (Mayo regimen) showed an estimate of 0.17 LY gained with chemotherapy compared to clinical support only, with a cost-effectiveness ratio showing an increment of R$ 50,156/LY. The 'new strategy' (FOLFOX scheme) showed an estimate of 0.91 LY gained, compared to clinical support only. The cost-effectiveness ratio showed an increment of R$ 78,188/LY. Conclusions: Both strategies for 1st line treatment for patients with metastatic colorectal cancer are not cost-effective from a Brazilian public health care system perspective. The use of new price tables to permit the incorporation of new regimens, despite the higher efficacy, worsened the cost-effectiveness ratio.

657 – ECONOMIC EVALUATION OF THE COLORECTAL CANCER SCREENING POGRAMME IN THE ABRUZZO REGION

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About 38.000 new cases of colorectal cancer (CRC) are yearly diagnosed in Italy. Abruzzo Regional estimates report 902 new cases, 378 deaths and 4.686 prevalent cases for 2008. 20% of patients are no longer surgically operable at the time of diagnosis, as the generic symptomatology is often cause of a late awareness. Therefore, early detection programmes have become a priority for Regional decision makers in Italy. The aim of this study is to estimate the Cost-effectiveness ratio of the public CRC screening programme implemented in Abruzzo. We performed a Cost-effectiveness evaluation in the Regional Healthcare Service perspective. Background information was found through a literature research performed on Pubmed, while organisational data about the current screening programme were collected through a field survey. Markov-transition model involved two arms: 1) Abruzzo screening programme based on biennial FOBT, colonoscopy as second level test and positive patients treatment; 2) Treatment of symptomatic patients according to the stage of the neoplasm. The model was filled with non symptomatic 50 to 74 years old people. Transition probabilities were weighted for accuracy of tests and incidence of CRC. DRG charges and field collected data were used to estimate costs. Preference data were derived from a previous published study. Costs and benefits were discounted at a rate of 3.5%. The impact on results of compliance percentage, discount rate and tests' accuracy was explored through both one way and multivariate deterministic sensitivity analysis. The public screening programme is dominant for each level of compliance, discount rate and tests' accuracy. Benefits due to early detection appear in terms of duration of survival and Qol.

181 – COST-UTILITY OF THE INTRODUCTION OF ROTAVIRUS VACCINATION IN THE SPANISH INMUNIZATION PROGRAMME

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Rotavirus is the major cause of diarrhea in children under 5 years and it is responsible for around half-million deaths each year worldwide. Rotavirus-related mortality is very low in western countries, but it causes a significant morbidity from gastroenteritis: primary care visits, hospitalization and nosocomial infections. There are two orally-administered vaccine preparations against rotavirus available in Spain but rotavirus vaccination is not included in the Spanish immunization programme. Aim: To assess the cost-utility of the introduction of a vaccination programme with Rotateq® or Rotarix® against rotavirus in the Spanish paediatric population. Material & methods: Using a Markov model, we compared costs and utilities of the vaccination programme with each vaccine preparation to those of non-vaccinated in a hypothetical birth cohort followed over five years. Data on incidence and costs came from Spanish sources of information. Data on vaccine efficacy and loss of quality-adjusted life years (QALYs) were obtained from the international scientific literature. A univariate sensitivity analysis was conducted to explore the effect of uncertainty in the input values of vaccine coverage, efficacy and price. Results: Rotateq® resulted in an incremental cost-effectiveness ratio of 300,190 €/QALY gained from a public health-care service perspective and of 228,826 €/QALY gained from a societal perspective. The values for Rotarix® were 235,367€/QALY and 159,993 €/QALY gained, respectively. In the sensitivity analysis, the model was robust for changes in vaccine coverage and efficacy. The cost of the vaccine was the most influential variable. A decrease at the vaccine price below 60€ for Rotateq® and 70€ for Rotarix®, would render the vaccination programme cost-effective. Conclusion: Rotarix® accomplished a better cost-utility relationship than Rotateq®. However, according to our current analysis, the introduction of a universal vaccination programme against rotavirus in Spain using any of these vaccines would not be recommended unless market prices would be significantly lower.

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312 – COST EFFECTIVENESS OF OPTIMAL® RAPID DIAGNOSTIC TEST FOR MALARIA IN REMOTE AREAS OF THE AMAZON REGION, BRAZIL

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Background: In areas with limited structure in place for microscopy diagnosis, rapid diagnostic tests (RDT) have been demonstrated to be effective. Method: The cost-effectiveness of the Optimal® and thick smear microscopy was estimated and compared. Data were collected on remote areas of 12 municipalities in the Brazilian Amazon. Data sources included the National Malaria Control Programme of the Ministry of Health, the National Healthcare System reimbursement table, hospitalization records, primary data collected from the municipalities, and scientific literature. The perspective was that of the Brazilian public health system, the analytical horizon was from the start of fever until the diagnostic results provided to patient and the temporal reference was that of year 2006. The results were expressed in costs per adequately diagnosed cases in 2006 U.S. dollars. Sensitivity analysis was performed considering key model parameters. Results: In the case base scenario, considering 92% and 95% sensitivity for thick smear microscopy to Plasmodium falciparum and Plasmodium vivax, respectively, and 100% specificity for both species, thick smear microscopy is more costly and more effective, with an incremental cost estimated at US$549.9 per adequately diagnosed case. In sensitivity analysis, when sensitivity and specificity of microscopy for P. vivax were 0.90 and 0.98, respectively, and when its sensitivity for P. falciparum was 0.83, the RDT was more cost-effective than microscopy. Conclusion: Microscopy is more cost-effective than OptiMal® in these remote areas if high accuracy of microscopy is maintained in the field. Decision regarding use of rapid tests for diagnosis of malaria in these areas depends on current microscopy accuracy in the field.

329 – HEALTH TECHNOLOGY ASSESSMENT OF CHILDHOOD VACCINATION AGAINST ROTAVIRUS INFECTION

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Objective: To evaluate the relative efficacy and cost-effectiveness of rotavirus vaccination with Rotateq® or Rotarix® in order to inform the Norwegian government on whether or not to include rotavirus vaccination in the national childhood immunization programme. Methods: We developed a Markov model with four health states. The model followed a hypothetical cohort from birth to death. Estimates of vaccine-efficacy were taken from our systematic review of the literature. Epidemiological data were provided by the Norwegian institute of public health and costs were collected from national tariffs. The analyses were performed both from a societal and a health care perspective. A discount rate of 4 % was applied to both costs and health outcomes. In order to assess decision uncertainty, we performed a probabilistic sensitivity analysis. Findings: We found Rotarix® and Rotateq® to be efficacious in preventing infections, with a RR of respectively 0.22 (0.17-0.28) and 0.26 (0.21-0.33), of preventing hospital admission RR respectively 0.04 (0.01-0.17) and 0.04 (0.02-0.01) and of preventing visits to a general practitioner RR respectively 0.10 (0.07-0.15) and 0.14 (0.07-0.26). When Rotarix® and Rotateq® are each compared to placebo; they will yield respectively 0.00117 and 0.00112 additional QALYS at an incremental cost of respectively US $ 131 and US $140 from a health care perspective. From a societal perspective the incremental cost were reduced to US $ 2.30 for Rotarix® and US $ 14.2 for Rotateq®. From a health care perspective, Rotarix® had a 14 % probability of being cost-effective, assuming a willingness-to-pay of US $ 83 500. However, when the societal perspective was applied the probability increased to 95 %. Conclusions: Including routine rotavirus vaccination with Rotarix® in the childhood vaccination programme in Norway is likely to be considered cost-effective from a societal-, but not from a health care perspective.

924 – COST-EFFECTIVENESS ANALYSIS OF THREE LEPROSY CASE DETECTION METHODS IN ADAMAWA STATE, NORTH-EAST NIGERIA

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Background: Increasing child proportion and grade 2 disability cases of leprosy in Nigeria suggest continuous spread of the disease and the need to review detection methods to enhance identification of early cases for more effective control and prevention of permanent disability. The study evaluated the cost-effectiveness of three leprosy case detection methods to identify the most cost-effective method for more efficient leprosy control in Adamawa state north-east Nigeria. Methods: The study was retrospective undertaken in routine practice setting, from a sample of six randomly selected endemic and non-endemic local government areas with a population of about 757,140 people. Primary and secondary data were collected from routine practice records and the Nigerian Leprosy Control Programme between 2005 and 2010. All costs and effects were measured from both providers' and patients' perspectives. Effectiveness was measured as number of new leprosy cases detected and outcome was expressed as cost per case detected. Incremental approach, using routine passive case detection (PCD) method as reference was used to measure the additional cost per new case detected as incremental cost-effectiveness ratio (ICER). All costs were converted to the US Dollar ($) at 2010 exchange rate. Sensitivity analysis was carried out to evaluate uncertainties around the ICER. Results: Cost-effectiveness varied according to leprosy contact levels in the study areas. At incremental cost of $4,300 Household contact Examination generated additional 20 new cases leading to ICER of $215 per additional new case detected making it the most cost-effective method in non-endemic areas, while Traditional Healers referrals generated ICER of $430 per new case detected as the most cost-effective in endemic areas. Conclusion: Combination of HCE and RVS complementing routine practice was most cost-effective at all contact levels. Further robust and implementation studies are required to establish the acceptability and feasibility of the methods in other leprosy areas.

51 – COSTING OF THE FREE MATERNAL HEALTH SERVICES UNDER THE NATIONAL HEALTH INSURANCE SCHEME IN GHANA CHALLENGES AND IMPLICATIONS FOR SUSTAINABILITY IN GHANA

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Costing of free maternal health services under the National Health Insurance Scheme in Ghana Challenges and Implications for sustainability in Ghana EMMANUEL ANKRAH ODAME1 1 SCHOOL OF PUBLIC HEALTH UNIVERSITY OF GHANA, LEGON, GHANA Reducing the maternal mortality rate of 451/100,000 live births in Ghana to meet the MDG 5 target by 2015 remains a challenge. Several factors including the lack of financial access pose a challenge. A free maternal health policy was therefore launched in 2008 with a grant from the British government to improve financial access to maternal services. The main objective of this study was therefore to examine the cost of the free maternal health services to the southern part of Ghana and explore factors that contribute to these costs. Available routine financial claim records for 2009 were used to compile the cost information for the various maternal services using a compilation sheet for the three national insurance scheme accredited facilities and the scheme office in the area. The financial cost of antenatal, postnatal, delivery, abortion and the overall costs of all the maternal health services were obtained by facility type for both services and drugs. Among other findings, we found that the financial cost of antenatal care was GH¢289,094.96(US$199,375.83), postnatal care was GH¢159,913.34(US$110,285.06) and spontaneous vaginal delivery was GH¢205,452.58 (US $141,691.44). GH¢1,358,647.98(US$936,998.61) was spent in 2009 this represented 7.7% of expenditure of the British Grant. This study also showed that unit costs of maternity services were consistently higher at hospitals. The lower health facilities were under utilized. Cost savings can be made if services such as antenatal care and normal deliveries which form the bulk of maternal health services are done with the Levels C and B facilities, for the free maternal health services to be sustained. Keywords: Maternal health care, Costs, insurance, sustainability, Ghana

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176 – PLANNING FOR SUSTAINABILITY OF ARV PROVISION. A STUDY IN PERU, BOLIVIA AND MOZAMBIQUE

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The provision of ARVs is central to HIV/AIDS programs, because of its impact on the course of the disease and on quality of life. Although first-line treatments costs have declined, treatment-associated expenses are steeper each year, not only due to more PLWH in need of treatment, but also in face of new and costlier patented medicines incorporated to treatment guidelines. Provision sustainability is therefore an important variable for the success of treatment programs and should be acknowledged during planning and implementation of programs or of provision schemes. The literature was reviewed for sustainability issues. A conceptual framework on sustainability of ARV provision was developed, followed by data collection instruments. The pilot study was undertaken in Brazil. Three countries - Bolivia, Peru and Mozambique, were visited. Investigation of sustainability issues related to ARV provision involved implementation and routinization events of programs/provision schemes. Key informants were identified and interviewed. Evidence of greater sustainability potential of the program was observed in Peru, where provision is implemented and routinized by the National HIV/AIDS program and expenditures met by the government. In Mozambique, provision is almost totally dependent on donations and external aid. A large effort is being undertaken to incorporate ARV provision and care to routine healthcare activities. Bolivia, in addition to external dependence on financing and management of drug supply, presents problems regarding implementation and routinization of ARV provision activities. The conceptual framework was useful in recognizing events that may influence sustainable ARV provision in these countries. Planning ahead for sustainable provision, considering the epidemic profile and population needs, is essential and without it financing sources and mechanisms are not enough. Furthermore, country programs/provision schemes must consolidate themselves in the structure of health services provision as a whole, especially in limited resources settings.

206 – REGULATION ON ACCESS TO THE OUTPATIENT CLINIC OF A UNIVERSITY HOSPITAL FOR SUS SUSTAINABILITY

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For the Brazilian public health system, regulation of patients flow between health services and hospitals in regionalized care networks is a challenge to overcome. In 2000, HCFMRP-USP proposed to decentralize scheduling of new patients and organized Centers of Regulation of Elective Visits with the Regional Health Departments (DRS). Objective: To assess the impact of the implantation of centers of regulation on the patients flow and the effective designation of HCFMRP-USP as tertiary unit in the regional service network. Methodology: To assess the effective designation of HCFMRP-USP as tertiary unit, the coherence between the complexity of the referred cases and the mission of the Hospital was analyzed. A descriptive quantitative study was conducted using secondary data from 2000 to 2005. A cross-sectional investigation was conducted at two times, 2000 and 2005, sampling new visits scheduled via Centers of Regulation and held at the Hospital. Results: None of the DRSs took advantage of the total number of vacancies. Scheduling rate was 66.2% and absenteeism rate was 22.4%. Overall utilization rate was 37.9%, showing that of 309,573 visits made available, only 192,245 were absorbed for follow-up at the Hospital. Cases of low complexity represented 41.5% in 2000 and 39.3% in 2005; coherence between referrals and access protocols was 74.0% in 2000 and 75.5% in 2005; 31.3% of patients with visits scheduled via Centers of Regulation were not accepted. Conclusions: Implantation of Centers of Regulation of Elective Visits was barely reached, although has provoked discussion between managers and the Hospital, and assigned to the municipalities and the regional centers the responsibility for referring patients to the tertiary level. It was also an important action regarding humanization of the health services, but still needs continued and integrated assessing and planning.

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826 – COST EFFECTIVENESS ANALYSIS OF THE PRENATAL SCREENING STRATEGY FOR DOWN'S SYNDROME IN CHINA

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Objectives: To evaluate the cost-effectiveness of the prenatal screening strategy for Down's syndrome (DS) in China and provide evidence-based information to policy makers. Methods: Based on field surveys in 12 selected cities with different socio-economic status in China and literature review, the economic evaluation of the prenatal screening strategy for DS from a societal perspective was conducted by cost-effectiveness analysis with the decision tree model. The strategy is mainly maternal serum screening with α-fetoprotein (AFP) and human chorionic gonadotrophin (hCG), followed by the diagnostic karyotyping by amniocentesis (AC). Direct medical costs included screening, genetic counseling, AC, karyotype analysis, etc. The costs per DS case detected were analyzed among cities. Results: In current clinical practice in 12 cities, for a cohort of 10,000 pregnant women, the screening strategy could detect 0.152~4.937 DS in different cities. The city of Zhuhai, Guangzhou and Huzhou took the leads in the effectiveness among 12 cities. In the setting of ideal circumstance, the strategy could detect 7.8 DS cases in every 10,000 pregnant women. The cost per DS detected by the prenatal screening strategy varied 182,592~710,578 RMB Yuan (27,750~107,991US$) in different cities. The gaps in term of cost-effective among cities were explored. Sensitivity analysis showed that the prenatal screening could be more cost-effective if the management of screening improved, such as coverage of the strategy, uptake rate of AC for patients with positive serum tests, etc. Conclusion: The similar prenatal screening strategy demonstrated a large deviation among cities in terms of effectiveness and cost-effectiveness evaluation in the real world. It could reflect that the management of screening in different cities influenced the effectiveness and cost-effectiveness of such a strategy, and it inferred that health delivery system factors were important determinants of the technology's effectiveness and efficiency. Keywords: cost-effectiveness analysis prenatal screening Down's syndrome

196 – JUDICIARY BRANCH AND SCIENTIFIC EVIDENCE: AN ANALYSIS OF JUDICIAL DECISIONS INVOLVING THE DRUG GALSULFASE

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Background: The judiciary branch, in Brazil and other countries, has been an active actor in public health policies, especially regarding drug policies. In the present paper, we will evaluate the judicial response to cases regarding Galsulfase, a recombinant form of human N-acetylgalactosamine 4-sulfatase, designed for the treatment of patients suffering from mucopolysaccharidosis type VI. Objective: To identify the prevalence of scientifically grounded judicial decisions and the knowledge of Brazilian judges about Evidence-based medicine. Methods: We searched the electronic database of the Supreme Court (STF), the Superior Court of Justice (STJ) and all Federal Regional Courts (TRFs), looking for the keywords \"naglazyme\" OR \"galsulfase". Results: We found 31 judgments, including collegial judgments (5, 16.12%) and monocratic decisions (26; 83.87%). Of these, 9 were excluded due to procedural reasons (29.03%) and 22 met the eligibility criteria. Out of them, 20 (90.09%) decisions determined the government to supply galsulfase. Only 1 decision (4.54%) considered it improper to deliver the drug due to lack of evidence about its effectiveness. And 1 decision (4.54%) determined the performance of forensic expertise. Out of the 22 decisions examined, 18 (81.81%) were not substantiated by scientific evidence. Other 2 (9.09%) referred to evidence-based medicine (EBM), without, however, taking it as a plea for the decision-making. Only 2 decisions (9.09%) considered EBM as the basis of the decision-making process. On the other hand, 7 decisions (31.81%) referred to medical expert opinion. Medical outcomes incompatible with the administration of galsulfase were found in 7 decisions. Conclusions: The judiciary ignores scientific evidence as an aid to the decision-making process. In order to preserve the right to health and sustainability of the system, it is necessary that judicial decisions find ground on high-grade medical evidence. Therefore, it is imperative that the Judiciary branch becomes more pragmatic and less ideological.

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997 – EVALUATION OF JUDICIAL REQUESTS FOR CHEMOTHERAPEUTIC AGENTS TO MINISTRY OF HEALTH OF BRAZIL

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Brazilian public health system is totally free. However, in some sectors like oncology, there are also private services that complement the public one, but both can be provided by the government. These oncology services have provided different treatments across the country using, preferably, cheaper protocols. In the last years, there has been an increase in the number of legal actions requesting chemotherapeutic agents not provided by the government. The Ministry of Health has to analyze the indications of use of such drugs through technical notes made by consultant specialists. These notes can help the Judiciary to give its decision. Objectives: Analyze the lawsuits requesting chemotherapeutic agents throughout Brazil in 2009 and 2010. Methods: A review of all technical notes issued through 2009 and 2010 performed by consultant specialists, describing the drugs most requested and their indications. Findings: About 880 notes in 2009 and 920 notes in 2010 were reviewed, showing an increase of 4%. It happened most from states of the south and southeast regions of the country. The most requested drugs were traztuzumab prescribed for breast cancer, rituximab for non Hodgkin lymphomas, temozolamide for tumors of the central nervous system, sunitinib for renal cancer, sorafenib for liver cancer, bevacizumab for several types of cancer, erlotinib for lung cancer, bortezomib for multiple myeloma and imatinib for chronic myeloid leukemia. In many cases the indication of use was incorrect, experimental or incomplete. Many protocols prescribed did not have any references in literature. Conclusions: These findings suggest that health technology assessment has been little spread and discussed in Brazil. The evaluation of new health technologies is the bottom of any health system, which needs to be sustainable. Almost all of the chemotherapeutic agents described are high cost medications and its misuse may constitute a threat to economic sustainability.

911 – CHARACTERIZATION OF LAWSUITS FOR THE SUPPLY OF ESSENTIAL MEDICINES IN THE STATE OF RIO DE JANEIRO, BRAZIL

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Introduction: Recognition of the right to health in Brazil raises a practical issue: the government''s ethical and legal duty to ensure comprehensive health care and citizens' recourse to legal action to guarantee this right. Objectives: This study focused on lawsuits to demand essential medicines, filed at the State Court of Appeals in Rio de Janeiro, Brazil, in 2006. Design and Setting: descriptive study including lawsuits brought by citizens against the government. The source of information was the data bank of the Courts of the State of Rio de Janeiro where judicial decision on lawsuits demanding medicines and which had already followed an appeal were researched for the terms "medicines" and "essential". Results: 185 suits were examined. The claims were granted in all but three cases. Defendants included, in 36.8% of suits, more than one government entity. Median times between filing the suit, the injunction, first ruling, and appellate ruling were 7, 239, and 478 days respectively. Of the 316 identified medicines 35.8% were present in the Brazilian National Essential Medicines List (Rename). In 80.6% of the 98 suits in which the specific medicines could be identified, at least one did not belong to any publicly funded list of medicines. This could indicate that lawsuits demanding essential medicines were motivated not only by problems in procurement, distribution, and dispensing but also by non-inclusion of medicines in official lists. Most of the medicines demanded were for conditions involving the cardiovascular and nervous systems ailments. Conclusions: Reasons that lead to judicial decisions are centered in the explicited need of the plaintiff, expressed solely by the petition itself and by a medical prescription. In the perspective of the health sector "essential" expresses the meaning in the essential medicines concept, while for the judicial sector, "essential" is related to the plaintiff´s need of the medicine.

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944 – ANALYSIS OF MEDICINES DISPENSED BY COURT ORDER IN THE COURT OF RIO DE JANEIRO: THE APPLICATION OF SCIENTIFIC EVIDENCE IN DECISION-MAKING PROCESS

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Introduction: The Brazilian law guarantees the right to pharmaceutical assistance, but there are still gaps in the effectiveness of citizens access to medicines of the state, which in turn have led to lawsuits of medicines. Objective: To assess the medicines present in the lawsuits from the county Rio de Janeiro from July 2007 to June 2008, compared to therapeutic alternatives present in the public lists and with scientific evidence. Methods: This is a retrospective sectional study. The unit of analysis was the patient, the author of the judicial process and was analyzed the medicines registered in the Central of lawsuits in SESDEC/ RJ referring to 281 patients. Results: There were 804 requests for medicines, corresponding to 356 medicines, with an average of 2.8 medicine per patient. With regard to the medications required, there was also a myriad of categories when considering the available evidence and existing information. Most of the medications they needed was not financed by the health system and between them stands out: 1) medications required with health information registered in the National Sanitary Agency (ANVISA) with scientific evidence and that presenting alternative therapies funded by the system, 2) medicines for which the evidence in long term are not yet well established, 3) medications for indications not approved by ANVISA, 4) medicines unregistered at Anvisa and 5) there are medicines without evidence for use or are not recommend for use. Conclusion: The search for scientific evidence is extremely important for the medicines that are not present in the public lists and who also have no therapeutic alternatives. In confronting the phenomenon, especially regarding the lawsuit of medicines, the approximation of the SUS with the Judiciary is essential to guarantee the right to health without compromising the principles of the SUS and the management of pharmaceutical services.

154 – APPLYING A DISINVESTMENT LENS TO THE ROLE AND VALUE OF DIAGNOSTIC PATHOLOGY TESTS: CURRENT EVIDENCE CHALLENGES RISING USE IN SERVICES

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Background: In the pursuit of more sustainable health systems, governments are increasingly engaging with HTA to consider strategies for disinvesting (partially or completely) from existing services with limited evidence of (cost-) effectiveness. For diagnostic pathology services, this evidence primarily relates to the accuracy of a given test. Longstanding controversy surrounding the diagnostic accuracy of serum B12, serum folate (SF) and red cell folate (RCF) tests has done little to restrict their use in Australia, with annual government expenditure now exceeding $57M on 1.5 million tests (population: 22 million). In recognition of this controversy coupled with rising utilisation, we conducted a systematic review of the diagnostic accuracy of serum B12, SF and RCF tests, as the first step in a disinvestment framework. Methods: Based on a protocol, a standardised search strategy was applied to six databases. Included studies underwent standardised quality assessment and data extraction. Summary estimates of sensitivity and specificity (and summary positive and negative likelihood ratios) were determined using the bivariate model along with hierarchical summary receiver operating characteristic curves. Results: The search identified 57 studies comparing serum B12, SF and RCF tests with a reference standard(s). For serum B12, results demonstrated highly variable estimates of sensitivity (0.13-0.91), specificity (0.45-1.00), positive (1.23-3.70) and negative (0.34-0.90) likelihood ratios. Similar results were found for SF while the evidence base for RCF tests was more limited. Extensive heterogeneity existed, particularly in test methods, threshold values, clinical indications and study quality. Conclusions: Estimates of the diagnostic accuracy of serum B12, SF and RCF tests from this study suggest these services have poor discriminatory power across patient subgroups and are therefore, strong candidates for further disinvestment exploration. This case study highlights the potential for disinvestment initiatives to add value to pathology-related medical decision making and clinical practice.

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260 – INFORMING POLICY MAKERS WITH AN ENHANCED EVIDENCE-BASE FOR DISINVESTMENT: FINDINGS FROM A MULTI-STAGE STAKEHOLDER ENGAGEMENT

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Background: Programs of disinvestment from services that lack evidence of effectiveness are being considered internationally to support quality and sustainability reforms. HTA has been central to these efforts, offering best-practice in the assessment of safety and effectiveness. However, to identify those factors operating at mid- and micro- levels to sustain entrenched, relatively ineffective health care practices, an enhanced evidence-base is needed. Methods: A series of evidence-informed, deliberative stakeholder engagements were undertaken with community, consumer and clinical groups around a case study on removal/ restriction of public subsidy for assisted reproductive technologies. Data from these engagements were combined with results from a systematic review, along with ethical and cost analyses. This enhanced evidence-base was then presented to policy advisors for exploration in the context of a disinvestment policy agenda. Results Evidence of differential effectiveness gained from the systematic review was not seen by policy advisors as the sole factor influencing disinvestment decisions; other parameters may be used to identify and prioritise services as candidates for disinvestment. Across policy portfolios, advisors valued stakeholder perspectives as evidence and interpreted them in a number of different ways, including as: confirmation of existing perceptions; warnings of possible tensions associated with policy change; and potential stakeholder support for disinvestment. There were

concerns about the transferability of this model of enhanced evidence to 'real world' funding debates, where opinions of strong special interest groups may overpower those of more disinterested stakeholders. Conclusions: The complexity of disinvestment decisions requires a range of evidentiary inputs. Informed stakeholder engagement is valued as part of an evidence-base by policy advisors, although requires further integration in 'real world' contexts. Non-traditional constructions of evidence add value to established HTA methods and will play an important role in understanding and improving decision-making within a disinvestment context.

412 – SUSTAINABILITY OF DRUG REIMBURSEMENT SYSTEMS: A COMPARISON OF THE AUSTRIAN, BELGIAN, DUTCH, FRENCH AND SWEDISH SYSTEM

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Objectives: Sustainability of drug reimbursement systems is under pressure by rising health care expenditures. The aim of our study is to compare five European drug reimbursement systems to obtain insight into the strengths and weaknesses of these systems and to identify opportunities to improve system efficiency and sustainability. Methods: The analytical Hutton Framework was used for comparing and assessing "fourth hurdle" drug reimbursement systems in Austria, Belgium, France, the Netherlands and Sweden. We investigated policy documents, explored literature and conducted 57 interviews with policy-makers and representatives of the pharmaceutical industry. Results: All systems aim to balance three main health system objectives: system sustainability, equity and quality of care. Nevertheless, system impact is mainly assessed on drug expenditure and all systems have an open-ended pharmaceutical budget. All countries have a centralised decision body, even though financial responsibility may be regional (Sweden). All countries make efforts to increase transparency in the decision-making process. Policies to deal with uncertainty vary between countries: financial risk-sharing agreements by price/volume contracts –France and Belgium– versus outcome-based agreements for expensive inpatient drugs – the Netherlands. The reimbursement level depends on disease severity in France and Belgium, whereas in the other countries drugs are fully reimbursed. All countries attempt to consider cost-effectiveness in decision-making. However, no country is explicit about the relative importance of cost-effectiveness nor applies a strict threshold value. Case-by-case decision-making and lack of systematic group revisions result in uncertainty about value for money of many currently reimbursed drugs. Conclusions: This study reveals that while there is a convergence in scientific evaluation processes, important differences remain between the Austrian, Belgian, Dutch, French and Swedish regulatory frameworks. All countries recognise that cost-effectiveness is relevant, enhancing value for money, but experience difficulties in defining its weight in the decision-making process, next to quality of care and equity.

184 – WHAT DO MANAGERS AND PRESCRIBERS OF THE BRAZILIAN HEALTH SYSTEM THINK OF ESSENTIAL MEDICINES? PRELIMINARY RESULTS OF A NATIOWIDE QUALITATIVE STUDY: "FALA ESSENCIAL"

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The adoption of the concept of essential medicines by health systems starts with the development and use of essential medicines lists (EML). In Brazil there are legal provisions for the development of EML in the health sector of the three levels of government and in health institutions. Objective: To describe, analyze and discuss the knowledge and perceptions of managers and prescribers of the Brazilian Health System (SUS) in regard to the essential medicines concept and to the national, state and local EMLs. Methods: We propose an exploratory qualitative study. Twenty state and federal managers and sixty SUS prescribers from the five administrative regions of the country were sampled through a national health facilities database. Data was collected during the second semester of 2010. Analysis was done using content analysis technique. Results (preliminary): Thirty health facilities were visited, in 15 different municipalities. Of these, fifteen were hospitals of different levels of care, and fifteen were primary health care units. Five state managers, 15 municipal managers and 61 prescribers were interviewed. Managers and prescribers associate essential medicines to primary health care, especially for treatment of hypertension and diabetes. Managers have some knowledge regarding the Brazilian National EML, but the importance given to essential medicines is mainly related to their financing quotas. Prescribers apparently do not employ the EML in their daily practice and do not recognize its value. Perceptions are that the lists are a restriction to prescribing, with perceived gains only for management and not for clinical practice. Conclusions: Great effort has been channeled to the development and review of EMLs and to the adoption of the essential medicines concept throughout Brazil in the past 12 years. Nevertheless, adherence to these is still lacking. Further analysis is needed to understand which strategies have been useful may enhance adherence to the list.

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236 – EXCEPTIONAL HIGHER ALLOWED PRICE OF MEDICINES IN SLOVENIA. DOES HTA FIT IN?

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Background: In Slovenia, the maximal allowed price (MAP) for medicines at the wholesale level is determined by the use of external reference pricing model (AT, FR, DE). The regulations define the criteria and procedures for setting the ceiling prices (MAP or exceptional–higher-allowed-price (EHAP)). For the national authorities, the characteristics of small sized market represent a continuous confrontation with the limited number of medicines on the market and pressures from the pharmaceutical industry to increase the prices due to the small economies of scale. Methods: To keep the appropriate national portfolio of medicines on the market, while maintaining the national cost containment policies, the Committee for EHAP was established in 2009. Its main task is to assess the compliance of the applications for EHAP received from the industry. It works on the basic HTA principles; it evaluates the public health interest of the product, risk assessment of potential exit from the market, relative effectiveness and pharmaco-economics. A scoring model enables a quantitative allocation of EHAP. Results: The Committee assessed >500 medicines (some in repeated semi-annual evaluations). The EHAP asked for by the industry was proposed in 25 % of cases, lowered (MAP-EHAP interval) in 50%, and denied in 25 % of cases. The analysis shows that the mechanism of EHAP amounted for by 1.68 Mio EUR annually, which accounts for less than 0.5% of the public expenditures for pharmaceuticals. Discussion: The mechanism of EHAP preserves on the market those medicines, which would leave Slovenia otherwise, and thus enables the continuous supply of the medicines to the population. In December 2010, a novel version of pricing bylaw, which substantially reduces the access of to the EHAP mechanism by stricter qualifying criteria for submission of applications, was implemented. HTA is viewed as a critical component of the future EHAP mechanism.

379 – MULTIPLE DEMAND SIDE MEASURES NEEDED TO ENHANCE PRESCRIBING OF GENERICS FOR SUSTAINABLE HEALTHCARE: EXPERIENCES FROM ABU DHABI

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Introduction: Potential savings from generics reduced if only limited demand side measures combating industry pressure on physicians to increase their prescribing of patented products in a class once multiple sourced products are available. HAAD recently introduced the 'Unified Prescription Form' (March 2009) mandating INN prescribing alongside a comprehensive Generic Drug Policy (August 2009) to enhance the prescribing and dispensing of generics. However, there are currently limited demand side measures directing physician prescribing. Objective: Document the outcome of recent generic policies in HAAD and suggest potential reforms to achieve desired results. Methods: One year (12 months up to end September 2009 vs. 12 months up to end September 2010) pre and post policy analysis of the impact of the two generics policy in HAAD on utilisation patterns for PPIs, stations and ezetimibe in ambulatory care (2 highest expenditure classes in 2009). Changes in utilisation patterns measured by converting packages dispensed (IMS data) to 2010 DDDs. Results: a) PPI utilisation increased by 8.4%. Single sourced esomeprazole and pantoprazole increased by 33% and 27% respectively versus 10% reduction for multiple sourced omeprazole - increasing overall expenditure by 11.5%. b) Statin utilisation increased by 14%. Atorvastatin/ rosuvastatin utilisation increased by 14% (87.5% of total statins in 2010) with simvastatin increasing by 13% (7% total statins in 2010). Utilisation of ezetmibe also increased. Total expenditure on statins and ezetimibe increased by 11%. These changes in utilisation patterns mirror those among Western European countries with only limited demand measures where again see increased utilisation of patented products once multiple sourced products available in a class. Conclusions: Anticipated efficiency savings from generic availability in a class have not materialised in HAAD. Future policies are being considered based on favourable activities/ experiences among European countries implementing multiple measures. These include educational and economic activities, and prescribing restrictions.

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448 – POLICY FRAMEWORK FOR TIERED PRICING TO IMPROVE ACCESS AND AFFORDABILITY OF MEDICINES IN LOW AND MIDDLE INCOME COUNTRIES

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Key words: globalization, public policy, corporate strategy, pharmaceuticals, access and pricing, sustainability. Problem statement: Access to medicines is dependent on availability, affordability, adoption, and appropriate use. In low and middle income countries the main barriers include poor health care infrastructure, understaffed work force, lack of financial resources, high customs and tariffs, and the cost of developing new medicines. These factors combined slow down the achievement of the Millennium Development Goals. On the other hand, incentives need to be created at different stages of the value chain to spur research and development of innovative health technologies and medicines that reduce the burden of disease and mortality in poor countries or deprived population groups and ultimately improve the quality of life and wellbeing of millions of people. Objective: To propose a model for differential and equitable pricing of medicines that will facilitate better and faster access to medicines for larger groups of poor or uninsured citizens in emerging and developing economies. This policy framework helps countries achieve the MDG's and thus greater equity in health, while at the same time preserving incentives for research and development of new and innovative medicines. Design: Conceptual framework for country segmentation and differential pricing that improves access and affordability of medicines at both a global and country level is based on a multi-dimensional approach. Socio-economic and health system indicators are being used to identify and prioritize countries where coverage of medicines tthrough the formal health care system could be improved. Conclusions: Tiered pricing benefits in particular transitional economies including low, lower-middle and upper-middle income countries. Whereas value-based pricing remains the corner stone for pricing and reimbursement in high income countries, tiered pricing and price/volume trade-offs ensure the inclusion of underserved populations in the public health care system of emerging economies and developing countries.

660 – MANAGEMENT MODEL TO REPLACE AN ORIGINAL HIGH COST DRUG FOR A GENERIC FORMULATION. EVALUATION, MONITORING AND RESULTS

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High cost medicines and treatments are funded, in Uruguay, by one institution which manages a national insurance mandatory to all citizens. It provides universal coverage based on protocols built according to based-evidence medicine and to equality and sustainability criteria. Tacrolimus is financed for immunosuppressive treatment in solid organs transplantation. The original trademark was exclusively provided until May 2009, when a generic was introduced with a significant cost reduction. This was resisted by patients and physicians and a process was designed to follow up the change. The new trademark was given to new patients and to those already in treatment who accepted the change. Drug's plasmatic measures for patients who changed are paid by the institution (otherwise, patients pay for them). Results are registered online to the institution's data base. If they are out off therapeutics levels, a mail is automatically sent to a physician who does the following up who resend it to treating physicians. At four and ten months after starting the generic formulation all available data of patients who changed were analyzed. In 93 patients analyzed there was a significant drop in Tacrolimus plasmatic levels (7.62/6.14 ng/ml, $p<0.001$) explained by a drop in given dose (5.59/4.81 mg, $p<0.001$). In a recent evaluation that included 408 patients receiving both trademarks, differences between consecutives plasmatic measurement (2172 cases) were compared with correlatives differences between doses. An ANCOVA test was run. Plasmatic values decreased with both trademarks (0.094 ng/ml the original and 0.099 ng/ml the generic) which was associated with a dose decrease (0.1147 mg, $p<0.001$) rather than with the trademark ($p=0.972$). Considerations: There are now 143 patients with the original and 330 with generic. With available information, we haven't found differences in plasmatic values between both trademarks. More time is needed to evaluate the impact on grafts and patients survival.

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816 – THE EFFECT OF HTA ON REIMBURSED PHARMACEUTICAL PRICES – PRELIMINARY RESULTS FROM AN INTERNATIONAL EMPIRICAL ANALYSIS

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Introduction: The number of countries introducing HTA requirements has grown steadily around the world over the past two decades. HTA is principally used to determine whether and how new medicines receive public subsidy. This presentation reports the first part of a research project which aims to measure the relationship between health care policies and pharmaceutical prices. Methods - This analysis examines the relationship between HTA policies and the prices paid by Governments for first, a widely used off-patent lipid lowering medicine (simvastatin) and second, an on-patent novel oncology treatment. Counties were categorised as requiring mandatory HTA, encouraging HTA and using no HTA. A sample of 21 countries was included in the simvastatin analysis and 15 in the on-patent novel oncology treatment analysis. The study normalised ex-factory prices to a per mg/ml basis in US dollars at the January 2011 exchange rate. Multivariate regression analysis was used to explore potential relationship. A number of variables were controlled for, including formulation strength, mix of public/private funding and total healthcare expenditure. Findings – The median price for the off-patent drug was highest in countries where HTA was mandatory for reimbursement, second highest in HTA encouraged countries and lowest when no HTA was used. Prices in the no HTA group were only 57% of prices in the mandatory HTA group. Conversely, for the on-patent oncology drug, the median price was highest in the no HTA countries, followed by HTA encouraged countries and lowest in mandatory HTA countries. The price in the mandatory countries was 78% of the price in the no HTA countries. Conclusions - This initial pilot analysis shows that reimbursed prices can be compared between countries. Further, HTA may control prices of new innovative drugs but may not effectively reduce prices following patent expiry.

444 – THE IMPACT OF HEALTH TECHNOLOGY ASSESSMENT ON DRUG PRESCRIBING IN THE FIELD OF DIABETES

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Aim: Assessment of health technology (HTA) plays an important role in health care systems by providing structured, evidence-based input to policymaking. The value of HTA in a health system depends on its contribution to improved health status or increased efficiency. We assessed the impact of HTA on prescribing patterns regarding a selection of diabetes drugs that have been assessed by HTA agencies in nine European countries, the USA, Canada and Australia. Methods: We developed a research framework to measure the impact of HTA. The strategy included doing two case studies in the field of diabetes (e.g. Levemir®). After reviewing HTA (-related) reports on these cases from the different HTA agencies, we assessed the impact of HTA on prescription patterns using statistical (regression) analyses on sales data. Results: The HTAs undertaken resulted in a mix of recommendations among the involved countries. One of the reasons for the variation is the appraisal of the evidence collected even though the evidence is based on robust scientific data. Also, the agencies differ in the criteria that are used when making reimbursement decisions. The statistical analysis showed that irrespective of an HTA publication or the reimbursement decision, all countries show a comparable increase in sales on the long-term. In the short term, we found an effect in some countries having a clear link between the appraisal and the pricing and reimbursement decision. Conclusions: The reason for this limited impact is probably because many factors determine the uptake of medicines, including the role of reimbursement policies. In order to document the impact it would be important to update the effects periodically after a HTA report is finished. For this purpose, developing a (inter)national database that could be added to over time would be useful.

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594 – EVIDENCE BASED ESSENTIAL MEDICINES AND HERBAL MEDICINES SELECTION: TRAINING OF BRAZILIAN EXPERT COMMISSIONS

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Objective: to describe the training process for evidence-based decision-making in Technical and Multidisciplinary Commission of Updating of Brazilian Essential Medicines List (COMARE). and Technical and Multidisciplinary Commission for Elaboration and Updating of Brazilian Essential of Medicinal Plants and Herbal Medicines List (COMAFITO). Methods: in 2010, two workshops were held, involving the members of these committees (n= 38). The workshops focused on the following topics: formulation of a clinical question that it is feasible to answer; essential epidemiological issues; construction of search strategies; types and levels of evidences; searches in sources that are oriented towards the best level of evidence; critical assessment of scientific information; and application of the existing evidence in the decision-making process. Results: from the training, the committees developed instruments for standardization and assessment of expert reports for analyses on requests from the lists mentioned. The coordinated discussions in the meetings subsequent to the training were of effective and problem-solving nature, and brought clarity and greater rigor to the decision-making process. The search for scientific evidence (to minimize publication bias) and the specific quality criteria of clinical trials involving phytotherapeutic medications constituted the main focus of changes in how analyses were conducted in COMAFITO. Conclusions: lists of essential medications and phytotherapeutic medicines are the scientific and public health basis for development of the pharmaceutical sector. With the understanding that scientific evidence is one of the parameters that guides the selection process, development of skills relating to location and critical assessment of the literature may ensure quality in decisions on selecting these medications.

706 – THE ROLE OF DECIT ON DECISION MAKING ABOUT INCORPORATION OF HEALTH TECHNOLOGIES IN BRAZILIAN HEALTH SYSTEM IN 2010

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In 2006, the Commission for Health Technology Incorporation (CITEC) was created at the Brazilian Ministry of Health to appraise requests for inclusion, alteration or exclusion of health technologies into the Brazilian Public Health System and to formulate recommendations to the Ministry of Health on this subject. CITEC's recommendations are founded on the impact caused by the inclusion of technologies on the public health system and on their technological relevance based on the best available scientific evidence. The Department of Science and Technology (DECIT) of the Brazilian MoH gives support to CITEC by elaborating studies on scientific literature review or by funding research on new technologies. In the year 2010, in order to support the decision-making process regarding requests for the inclusion of 24 technologies into the public health system, CITEC used 18 appraisals developed by DECIT and 2 researches commissioned by them, totaling 20 studies, with some of them evaluating more than one technology. Of these 18 studies prepared by DECIT and assessing the scientific evidence on efficacy and safety, 13 were Rapid Response Report, four were Rapid Health Technology Assessments (HTA) and one was an HTA Bulletin elaborated jointly by DECIT, the National Agency for Health Surveillance and the National Supplementary Health Agency. The two researches commissioned by DECIT were a cost-effectiveness study and a randomized clinical trial. Among the 24 evaluated technologies, 19 were drugs (18 for treatment and one for prevention), three were diagnostic techniques and two were medical devices. CITEC's decisions regarding the incorporation of 24 technologies were in accordance with the recommendations coming from the DECIT studies conducted on 17 (71%) technologies. Regarding the remaining seven technologies, DECIT did not recommend inclusion into the health system since they lacked high quality methodological evidence.

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886 – HEALTH TECHNOLOGY EVALUATION FOR INCLUSION OF A NEW ANTIRETROVIRAL IN A PROGRAM OF AIDS VADEMECUM

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Introduction: Since 1990, Argentina's Ministry of Health implemented the free provision of antiretrovirals and other drugs for AIDS-related conditions through the AIDS Direction. - In the last years, a new antiretroviral drug has been developed as a therapeutic alternative, called maraviroc. Description of the technology: Maraviroc is a selective blocker of the human CCR5 receptor, and is approved only for use in persons with CCR-5 tropic viruses exclusively. - The Ministry of Health requested a technical evaluation of the effectivenes of maraviroc in HIV1-infected antiretroviral-experienced and antiretroviral-naive patients. Research questions: Is there enough scientific evidence to sustain the inclusion of maraviroc in the AIDS Direction's vademecum? - Is maraviroc effective in reducing HIV-1 viral load in patients with HIV/AIDS, antiretroviral-experienced or not; compared to other antiretrovirals? Search strategy: A bibliographic search was performed initially in different databases: Medline, Tripdatabase, UptoDate, and agencies of evaluation of Health Technologies; for full-text articles (2004-2010). The search produced three systematic reviews and two randomized controlled trials. Results: There is evidence of the effectiveness of maraviroc associated to protease inhibitors (PI) for the treatment of antiretroviral-experienced patients, compared to PIs combined with placebo - The cost of the tropism test must be taken into account, since maraviroc es effective only for patients with CCR-5 tropic viruses exclusively. - Maraviroc didn't prove to be superior to efavirenz in antiretroviral-naive patients. Conclusions: Maraviroc showed to be effective for the treatment of experienced HIV/AIDS patients, but didn't prove to be superior to efavirenz for naive patients. - The price of the drug, determined by the manufacturer, is similar prices observed in United States and Canada, which is acceptable for the approved budget for new drugs of the AIDS Direction, and thus could be incorporated in its vademecum for use in antiretroviral-experienced patients.

304 – EVALUATION OF IMPLEMENTATION PROCESS OF PRENATAL SCREENING IN FINLAND

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Background: In Finland, a statute on screening for foetal abnormalities was given in 2007 to unify prenatal screening methods and promote equity of care. The statute was based on an HTA report and contained general ultrasound (US), screening for chromosomal abnormalities by a combination of nuchal translucency measurement and blood test, and US screening for structural anomalies. Local authorities organize screening and had to comply with the statute by the end of 2009. The National Screening Board commissioned Finohta (Finnish Office for HTA) to support the implementation of the statute. Methods: Finohta assembled an expert group to produce information materials for professionals and for pregnant women. The 3-year process was externally evaluated using surveys and interviews, listing product sales and downloads, and reviewing documents including press debates. Results: For professionals, the implementation group arranged three full-day sessions targeting trainers in municipalities, produced education materials and a guide concerning interaction and risk communication. Two booklets were made for expectant parents. A website was launched providing all materials downloadable free of charge in Finnish and Swedish, and booklets for expectant parents also in English (1). The proportion of the municipalities organizing screening as defined in the statute increased from about 60% in 2007 to 80% in 2009. The members of the expert working group considered their work process successful; they particularly valued that the client perspective was included. Lack of both resources and commitment to unify the screening programme remain the major obstacles of the implementation. Discussion: The practices of prenatal screening have become more uniform in Finland, at least partly due to a successful national implementation process. Continuous local training, as well as marketing and updating of the national support materials are needed.

1. www.thl.fi/fi_FI/web/fi/aiheet/tietopaketit/seulonnat/sikioseulonnat/oppaat_perheille

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460 – TELEMEDICINE SUPPORT ON MATERNAL AND NEWBORN HEALTH IN REMOTE PROVINCES OF MONGOLIA

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Background: Telemedicine is an application of modern technology and telecommunications for delivering the health care services, dissemination of knowledge and experience between different parts of the country and regions and a mean to provide continuous education for medical personnel. Therefore, telemedicine support on Maternal and Newborn Health in remote provinces of Mongolia is initiated since 2007. Objective: To assess achievement of its overall objective to improve the quality of maternal and newborn services for rural population. Methods: We conducted qualitative research comprising of observations of supplied medical equipments, in-depth interviews and focus group discussions of service providers engaged in Telemedicine based health services. Findings: In 2008, this health technology initiative has established four aspects of clinical networking between reference and rural hospitals, namely prenatal diagnostic ultrasound, high risk antenatal care, fetal monitoring and colposcopy based cervical screening networking. In total, 714 cases were discussed on a Web based iPath software platform, out of which, 64.2% of consulted cases were obstetric disorders, 21.7% were gynecological cases and the remained 14.7% were neonatal cases. As a result of the newly applied medical technology, the early antenatal care and quality and accessibility improved due to upgrading of equipment, distance consultation and training of relevant professionals in the selected provinces. Conclusions: The telemedicine system as an open source based communication for relevant personnel at the selected hospitals, and provision of high technology medical equipments have significantly contributed to the provision of quality maternal and new born care. A number of complicated clinical cases that previously could have referred to the upper level of care in the capital city were managed locally and it is cost effective intervention. Effective implementation of Telemedicine based initiative has led to intensive involvement in the formulation process of the E-Health Strategy within the E-Mongolia National Program.

518 – REVIEW OF DECISION-ANALYTIC MODELS IN CHRONIC MYELOID LEUKEMIA

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Background: Equal access to cost-effective cancer therapies especially in personalized medicine challenges sustainability of health care systems all over the world. Therefore, decision-making about different treatment options in this emerging area requires appropriate methods in decision-analytic modeling and health technology assessment (HTA). Objectives: To give an overview of published decision-analytic models evaluating different treatment strategies in chronic myeloid leukemia (CML). We sought (i) to describe and analyze the structural and methodological approaches used and (ii) to derive recommendations for future CML models. Methods: We performed a systematic literature review in electronic databases (Medline/PreMedline, EMBASE, and others; updated January 2011) to identify published studies evaluating CML treatment strategies using mathematical decision models. Models were required to compare different treatment strategies and to comprise relevant clinical health outcomes such as life-years gained or QALYs over a defined time horizon and population. We used standardized forms for data extraction, description of study design, and methodological framework. Results: We identified 15 different decision-analytic modeling studies including 14 economic evaluations. The modeling approaches varied substantially and comprised decision trees, Markov models, Monte Carlo simulations, and mathematical equations. Time horizons ranged from two years to lifetime. Health outcomes included survival, life expectancy, and QALYs. Compared treatment strategies comprised bone marrow or peripheral blood stem cell transplantation, conventional chemotherapy, interferon-alpha, and tyrosine kinase inhibitors (TKI). Only one model evaluated a second-generation TKI (nilotinib). None of the models evaluated comprehensive personalized medicine strategies. Conclusions: We identified several well-designed models for different CML treatment strategies. However, there was a substantial variation in the quality of reporting, in the choice of model assumptions and input parameters. We recommend that future models should include new treatment options and subgroup evaluations for a more personalized decision making. Already available models with a short time horizon could be up-dated with new survival data.

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707 – USE OF THE MINI-HTA TOOL TO ASSESS MANAGEMENT DECISIONS RELATED TO THE PURCHASING OF MEDICAL EQUIPMENT IN SELECTED PUBLIC HOSPITALS IN SOUTH AFRICA

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HTA offers an excellent opportunity to enhance technology use in the health care delivery platform. In a hospital setting, it is often necessary to take relatively quick decisions for acquisition of health technologies such as drugs, devices, instead of going through a lengthy and elaborate HTA processes. The Danish Centre for Evaluation and Health Technology Assessment had developed a mini-HTA-tool to address this issue. However, this was not tested in a developing country setting like South Africa. Objective: To adapt and use the mini-HTA tool to assess decisions made by hospital-managers for procurement of selected medical devices. Methodology: This was a cross sectional survey using the adapted mini-HTA-tool relating to decision making in South African public hospital setting. 21 hospital managers who attended a HTA course in our University participated in the study. Results: Although 81% of the decisions assessed referred to medical devices, few participants consider clinical needs or risks and only a few took decisions based on evidences. About half of them were aware of the impact of these devices on staff workload. Approximately half of these managers did some assessments on the effects of these devices on their organization and aware of this information at their facilities. 10% were able to estimate annual costs of related consumables and additional cost per patient/unit. The findings of this study demonstrated the deficiencies in medical device decision-making and the need

for a decision-tool to inform this process. All of them believed the mini-HTA-tool could be used as a valuable tool for future decision-making. Conclusion: This study has demonstrated use of mini- HTA-tool in assessing the quality of decisions and, highlighting the management information gaps. This tool could also be useful in future decision making to support hospital managers with respect to medical devices procured/ purchasing.

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736 – REVIEW OF STUDIES ON ECONOMIC EVALUATION OF TREATMENT FOR OSTEOPOROSIS POSTMENOPAUSAL

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The use of economic evaluation studies has been increasingly common to support decision-making on health policies, incorporating new technologies and development of guidelines for health, especially in the field of osteoporosis, in which there is wide variation effectiveness and costs of therapeutic strategies. Aiming to identify relevant studies, there was complete review of economic evaluations, conducted in Brazil and abroad, focusing on the treatment of postmenopausal osteoporosis. There was a search on PubMed and national scientific journals until August 2010. We used the keywords {osteoporosis} and {postmenopausal or post-menopausal} and {cost effectiveness or cost benefit or cost utility or Economic Evaluation}. Found 107 titles and abstracts. After careful selection, 10 articles remained for analysis. We found great variability in the methods of the studies related to issues specific to each country (demographic and epidemiological), associated with the perspective adopted, the prices, the valuation of health states by population (utility) and according to factors inherent in economic modeling . Most studies that compared treatment strategies with no treatment, they found an incremental cost-effectiveness ratio (ICER) reasonable, according to the willingness to pay of each country. The interventions have become more cost-effective with increasing age, decreased bone mineral density and presence of previous fractures. In general, bisphosphonates were the most valued and strategies that resulted in better ICER's. Teriparatide was not cost effective. Studies evaluating hormone replacement therapy found good ICER, but call attention to the increased risk of breast cancer. Vitamin supplementation, strontium ranelate, raloxifene, and denosumab were evaluated and showed variable results depending on the perspective, of the country and the assumptions. There was no possible to extrapolate the results to the population of Brazil, limiting its use to decision makers in different locations.

214 – NORTH-SOUTH AND SOUTH-SOUTH HTA TRANSFERABILITY: THE EXPERIENCES OF LATIN AMERICAN RESEARCHERS AND DECISION-MAKERS IN USING HTA REPORTS FROM OTHER JURISDICTIONS

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Introduction Most HTA agencies, especially in developing countries, are under-resourced and unable to produce the volume of outputs desirable. Adapting or using HTA reports (HTAr) from other jurisdictions is an alternative used formally or informally with the intention to save time and resources. Objective to explore HTA “transferability” experiences in Latin-America (LA): are decision makers (DM) using HTAr from other jurisdictions to guide decisions? Are researchers using or adapting other HTAr when developing local reports? How useful is the information found in HTAr from other jurisdictions? Methods A web-based survey was sent to 13031 HTA researchers and DM in LA. Results Between 05-12/2010 we received 657 responses from 19 LA countries. DM reported using HTAr from other jurisdictions to guide decisions in the majority of the situations: 50% HTAr from other regions (eg Europe, Canada), 27% from other LA countries, and in only 23% HTAr from their own countries. 64% of researchers reported using HTAr from other jurisdictions as a source for local HTAr. Usefulness scored significantly higher for HTAr from other jurisdictions as compared to local HTAr (7.1 vs 5.9 in a 1-10 scale, p<.01). Both DM and researchers considered more applicable the information regarding description of the technology, safety and effectiveness and less so the information regarding social aspects, budget impact or economic evaluation. Barriers that limit transferability scored significantly different for HTAr from other LA countries as compared to HTAr from regions outside LA (i.e poor methodological quality 5.3 vs 6.6, different epidemiological context 7.3vs6, all p<.01). Conclusions LA DM and researches are using in most cases HTAr from outside the region. However, both DM and researchers agreed to identify HTAr from LA with the greatest potential for transferability provided that certain barriers such as lack of transparency, lower methodological quality and lower production, will be overcome.

393 – INNOVATIVE HEALTH TECHNOLOGIES: CRITERIA AND INCENTIVES IN FRANCE

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Definition of innovation is context specific. In the field of medicine, the definition of what constitutes an innovative health technology (HT) differs in the context of development, regulatory approval and HT assessment at national level . Up to now, most attention has been given to innovative medicines, as opposed to innovative medical devices and interventions, where specific definitions lack. In line with recommendations of the High-Level Pharmaceutical Forum to Member States to ensure timely access to valuable innovations and orphan medicines and to set clear rules on what innovation is considered valuable, the French Health Technology Assessment body, the Haute Autorité de Santé, has elaborated criteria for selection of innovative HT eligible for temporary coverage with evidence development (CED). These criteria are the part of a step-wise process comprising adequate identification of an innovative HT based on a priori defined set of criteria, scientific advice for developers to discuss clinical studies designs and data needed for reimbursement and establishment of incentives aimed at CED. The criteria take into account not only the novelty of the molecule (new therapeutic class/mechanism of action/formulation/mode of administration or new target population for medicinal products) or the novelty of medical device and/or medical intervention (bearing an important impact on the organisation or the structure of health care potentially beneficial for health professionals), but also the existence of data in favour of direct clinical benefit for patients . The latter is defined as either fulfilment of an unmet medical need in chronic, debilitating or life-threatening diseases or added therapeutic value of a new technology as compared to existing technologies in the management of target patient population (better efficacy, safety or access to a technology). Handicap compensation and improvement of quality of life might also be considered as clinical benefit in the context of HT assessment.

462 – ACCOUNTABILITY FOR REASONABLENESS OF DRUG REIMBURSEMENT SYSTEMS: COMPARISON OF THE AUSTRIAN, BELGIAN, DUTCH, FRENCH AND SWEDISH SYSTEM AND DEVELOPMENT OF A TRANSPARENCY FRAMEWORK FOR DECISION MAKING

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Objectives: In a democratic health system, decision makers should be accountable for the reasonableness of their decisions, i.e. decisions should be in line with public values. The aim of our study is to evaluate five drug reimbursement systems against an ethical theoretical framework for accountability for reasonableness and to develop a tool to help increasing systems' accountability for reasonableness. Methods: The framework of Daniels and Sabin, defining four requirements for accountability for reasonableness (transparency, relevance of the rationales, revisability and enforcement), was used to evaluate the Austria, Belgian, French, Dutch and Swedish drug reimbursement systems. A transparency framework was developed based on an in-depth analysis of the organisation, structure and procedures of the five systems. Results: We identified five key questions and possible decision criteria that need to be answered and justified in order to increase the transparency of drug reimbursement decision processes and the relevance of the decision rationale. The criteria considered relevant for the decision are similar between systems, but their operationalisation varies and their relative importance and role in the appraisal process is not always clear. Transparency of appraisal processes varies between the systems and justification with explicit criteria is generally limited. Revisions occur ad hoc in all countries and systematically for specific drugs (the Netherlands, Belgium) and all drugs (France). Only Sweden and France revised the complete list of reimbursable drugs. Appeal against reimbursement decisions is possible in all countries. Evaluation of reimbursement processes is limited to (ad-hoc) external (parliamentary) audits. Outcomes of drug reimbursement systems are mainly evaluated by pharmaceutical expenditure. Conclusions: to enhance accountability for reasonableness, drug reimbursement systems could increase the transparency of their appraisal procedures by using our transparency framework with five explicit questions, each of them involving value judgements. Answers should be publicly justified using relevant, socially acceptable and explicit criteria.

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870 – HEALTH TECHNOLOGY ASSESSMENT (HTA) IN MEXICO: EXPERIENCES, ACHIEVEMENTS, AND CHALLENGES

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Since 1991, HTA was introduced in México as an institutional effort through different instances like Mexican Health Foundation A.C. (FUNSALUD), the National Council on Science and Technology (CONACyT), the Mexican Social Security Institute (IMSS). Additionally, since 2004 the National Center for Health Technology Excellence (CENETEC), a government agency from Mexican Ministry of Health (MoH), creating an HTA specialized area, with two subareas, one for development of clinical practice guidelines, while the second one responds to HTA requirements of the General Health Council, State Health Services and MoH. HTA was included as a public policy in the National Health Program (2007-2012) and the Specific Health Action Program, since 2007. The objectives were to standardize the methodology to perform HTA in the Mexican Health System, to generate HTA reports and to encourage the use of HTA in the decision process to incorporate innovative health care technologies. Currently, CENETEC is member of INAHTA and a WHO Collaborating Centre in Health Technology. Its recommendations in HTA are considered to include or exclude medical equipment and medical devices in the Basic Frame and Catalogue of Inputs of Health Sector of the General Health Council. CENETEC had participated as a member of the Economic Evaluation group of the Negotiating Committee for Drugs Prices. One of its main achievements is the establishment of a HTA work group that includes the main National Health Institutes. Current challenges faced by CENETEC related to HTA include training at various levels: individual, institutional, and academic and rising awareness of the importance of HTA among the health policy makers. However, the most important challenge is to expand the HTA Sector Network, in which all institutions of Mexican Health System should be included.

899 – HTA: THE ANCHOR IN A SEA OF POLITICAL CHANGE

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Background: The National Institute for Clinical Excellence (NICE) was established in April 1999 by the new Labour government to ensure equal access to medical treatments and high quality care from the NHS in England & Wales. Over the following 11 years NICE's remit expanded to cover public health, becoming the National Institute for Health and Clinical Excellence in 2005. In 2010, with the election of the Conservative and Liberal Democrat Coalition government, NICE experienced a change in health policy. At the heart of the Coalition's health policies are the notions of patient-centred care and choice, and a focus on clinical outcomes. Commissioning responsibilities and budgets are to be devolved to general practitioners, who are envisioned as having a better understanding of the needs of their local communities. Discussion: For NICE the change in health policy has resulted in a new emphasis on producing quality standards and a remit expanded to include social care. NICE quality standards are a set of specific, concise statements that act as markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions. This emphasis on quality standards may also signal a change in the status and influence of NICE's guidance recommendations. The future will see the introduction of value-based pricing as a means of reforming how the NHS pays for medicines, which will require new methods for valuing the benefits of technologies and assessing their cost-effectiveness. Conclusion: In 2012 NICE will become the National Institute for Health and Care Excellence with a broader remit and new products for a new policy environment. However, HTA will still be at the heart of its new role and will remain the basis on which its guidance and quality standards will be derived across clinical topics, technology appraisal, public heath and social care.

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945 – INSTITUTIONALIZING HTA IN BRAZIL: A COMPARATIVE ANALYSIS WITH THE UK, CANADA AND AUSTRALIA

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In recent decades, developed countries with strong health public systems, such as Australia, Canada and United Kingdom have adopted the health technology assessment (HTA) to support decision making about reimbursement of new technologies, mainly medicines. Brazil, more recently, has also made efforts to adopt this criterion. The aim of this study was to compare the use of HTA on decision making for technologies reimbursement in Brazil to these 3 countries. The scientific literature on HTA was reviewed at the databases Medline, Lilacs and Scielo and at the sites of HTA agencies from these 4 countries, INAHTA and HTAi. The HTA institutions from Canada and UK are independent from their MoH. In Australia and Brazil, HTA areas were created in their own MoH, but the decision making about reimbursement is made by different areas. About the incorporation of new drugs, Australia, Canada and UK follow the same steps: HTA followed by reimbursement definition. In Brazil, after license approval, the economic regulation area of National Health Surveillance Agency (ANVISA) produces scientific and economic evaluations of drugs and, then, the Board for Regulation of Drug Market (CMED) defines their prices for the market and allows the commercialization. After that, technologies with request for incorporation in the public health system pass through another stage of technical evaluation (HTA) conducted by the Department of Science and Technology (DECIT) of the MoH, which sends its recommendations to the Commission for Health Technology Incorporation of the MoH (CITEC) about the incorporation of the drug in the public sector. In Brazil, an overlapping of governmental activities in HTA is apparent and indicates the need to reform the current institutional model by creating an independent HTA agency that would be able to unite HTA activities and human resources, aiming to optimize financial and human resources in the HTA field.

374 – STRATEGIES TO ENROLL PATIENTS TO AN INTEGRATED PROGRAM FOR BREAST CANCER CARE – A PARTNERSHIP BETWEEN HEALTH SERVICES, SCHOOLS AND A NON-GOVERNMENTAL ORGANIZATION

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In November 2009 an Integrated Program for Breast Cancer Care started its activities at Administrative District of Mooca, São Paulo, Brazil, with the aim of offering to 14,000 women older than 40 years. This Program includes educative activities, health promotion, screening for breast cancer (medical evaluation, mammography, ultrasound), diagnosis and treatment, if it would be necessary. It is developed by Hospital Alemão Oswaldo Cruz as a project to Ministry of Health in Brazil in this area during 3 years. Initially women attended at four community health centers (Unidades Basicas de Saude, UBS) located in this area and maintained by Brazilian Public Health System could be accepted by this Program. This catchment strategy wasn't so effective: between January and June 2010 the Program received 2,152 women, corresponding to 62.2% of expected for this period. One of reasons to explain this is the lack of experience in partnerships involving public and private health services in Brazil. Three strategies were used to optimize the catchment of women from July 2010: (1) Agreement with the Secretary of Health for inclusion of three more of the UBS coverage area of the project.(2) Stocks education in public schools in the municipal and state levels, focusing on raising awareness among students by offering the service for breast cancer screening for women of their family through the health passport.(3) Training of UBS community agents and "Se Toque" Non-Governmental Organization members to capture women in the community through the health passport. Mean of attended women per month grew up from 359 (s.d.: 80.8) before these actions to 600 (s.d.: 146.1) after their implementation (p = 0.007). This is an example of partnership between public and private institutions that proved effective in terms of active recruitment of women, contributing to the organization and execution of a public health program.

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430 – INTRODUCING PATIENTS' PERSPECTIVE IN HEALTH TECHNOLOGY ASSESSMENT AT THE LOCAL LEVEL: A QUALITATIVE STUDY AMONG HTA PRODUCERS AND HOSPITAL MANAGERS

Marie-Pierre Gagnon, Faculty of Nursing, Laval University, Canada; Marie Desmartis, Quebec University Hospital Research Centre, Canada; Johanne Gagnon, Faculty of Nursing, Laval University, Canada; Michèle St-Pierre, Department of Management, Laval University, Canada; Marc Rhainds, Quebec University Hospital Centre, Canada; Randa Attieh, Faculty of Nursing, Laval University, Canada; France Légaré, Department of Family Medicine, Laval University and Quebec University Hospital Research Centre, Canada

Objective: To explore current practices and perceptions of health technology assessment (HTA) producers and hospital managers regarding the integration of patients' perspectives in local HTA activities. Methods: We conducted semi-directed interviews with HTA producers and hospital managers from the Province of Quebec (Canada). An interview guide was used to explore respondents' current practices and their preferences about patients' involvement in HTA (e.g. type and level of patients' involvement). Perceptions of barriers and facilitators, impacts, and conditions for successful patient's involvement in HTA were also assessed. Interviews lasted one hour on average and were audio recorded. Verbatim were analysed using the NVivo software. Codification of interview content was first performed by a research associate whereas two researchers independently reviewed codification and identified emerging themes. These themes were validated during a work session involving six members of the research team. Findings: We conducted a total of 21 interviews (involving 24 individuals). Few experiences on patients' involvement in HTA have been conducted until now in Quebec. However, HTA producers and hospital managers agreed on the need to enhance the patients' perspective in HTA. Respondents also agreed that involving patients in HTA requires a structured approach and proposed that a methodological framework should be developed to help decision makers to determine why, when (at what stage of the process, for which technology), and how patients may be involved in HTA activities. Conclusion Results from interviews provide key elements to facilitate future developments of a structured approach for incorporating patients' perspective in HTA activities at the local level. Based on a systematic review of international experiences of patients' involvement in HTA and on the findings from this study, a framework to guide patient involvement in HTA activities will be proposed and validated.

956 – ETHICS AND POLICY IN HTA: PATIENT PREFERENCES AT ODDS WITH HTA- THE EXAMPLE OF AUTOLOGOUS BLOOD DONATION FOR SPINAL FUSION

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Autologous blood donation has been used to limit patient exposure to blood borne pathogens (e.g. HIV and hepatitis) and avoiding transfusion reaction in spinal fusion. Technology assessments have indicated the cost effectiveness of autologous blood donation, cell saver and hematopoietic stimulants in various fusion procedures. However, these assessments have not included value input from a key stakeholder group - the patients. This ethical and policy shortcoming was highlighted by a quality assurance review at our medical center showing that many autologous blood units were being wasted/discarded. In a review of 100 consecutive posterior lumbar spine fusions, it was found that 55 units of autologous blood were discarded. The majority were associated with the 85 one level fusions (50/55 units). Bank blood was required in 9.4% of the one level fusions. One level fusions thus became the primary focus of a remedial QA effort. One principle challenged was the surgeons' assumption that all patients would choose to donate autologous blood. Thus, autologous blood donation had been a routine part of fusion pre-op protocols for many years. The QA findings precipitated a pilot program for autologous blood donation for one level fusions based on patient preferences and shared decision making. Patients were told that autologous blood donation was not routine for a one level spinal fusion and the frequency of transfusion using bank blood was about 10%. Risks of bank blood from the American Association of Blood Banks were given (HIV-1/1,930,000, Hepatitis B-1/137.000, Hepatitis C-1/1,000,000, HTLV-1-1/641,000, death 1/1,000,000). To the utter surprise of the surgeons, the 30 patient pilot resulted in autologous blood donation by exactly ZERO patients. This review highlights the potential differences in the value systems and appraisal of risk between physicians and patients. Where such differences exist, it is particularly important to incorporate patient input into decision making.

172 – BRAZILIAN CLINICAL TRIAL REGISTRY PLATFORM

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The Brazilian Clinical Trials Registry (REBEC) was launched on December 2010. This is the first Clinical Trial Registry Platform available in Portuguese. Registration process is a fully web based task. REBEC system was developed with open software, and is available to download and use at no cost. In order to be in compliance with the World Health Organization´s International Clinical Trial Registry Platform (WHO/ICTRP) best practices, registration must be in English and the registrant must complete all the 20 required fields. In order to allow a better information dissemination, on the Brazilian Registry, all Brazilian studies must have all data entered also in Portuguese. The system is already prepared to receive studies in Spanish. Clinical Trials submitted are reviewed and after its approval are published on REBEC´s website (http://www.ensaiosclinicos.gov.br). On this presentation we are going to make a brief explanation on REBEC´s operation and a balance of its first months.

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242 – EROS: A NEW SOFTWARE FOR EARLY STAGE OF SYSTEMATIC REVIEWS

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Introduction Sometimes, the workload involved in performing a sound systematic review (SR) is underestimated. The screening and quality assessment of studies, usually done by pairs of independent reviewers, is not only time-consuming, but it also is complicated, tiresome, and prone to mistakes. A computer-software designed to cope with the initial phases of a SR would be of great help. There is a generalized lack of development in this regard, and the available options are not very accessible or affordable. The objective of this study is to show the advances in the development of EROS (Early Review Organizing Software), a web-based software to serve in the initial phases of a SR process. Methods We developed an online software that helps in performing the first stages of a SR: importation of citation from a reference manager software or directly after a search in several medical electronic databases (PubMed, EMBASE, LILACS, etc), screening by title/abstract, first agreement, uploading of full-text, screening by full-text (tracking exclusion reasons), quality assessment (second and third agreement respectively), and distribution of full-text for data collection. Results EROS is currently being used in the simultaneous conduction of 10 systematic reviews requested to IECS (4-8 reviewers, 1 librarian and 240- 1550 cites per SR). Its main characteristics are: a) ability to manage multiple projects; b) differentiation of roles assigned to reviewers, administrators and librarians; c) multi-language environment in each review; d) adequate, equitable and timely delivery of full-texts for evaluation and data abstraction; e) real-time tracking of the whole process for each role; f) building the study flowchart; g) possibility to work simultaneously in different SR's stages; h) configurable inclusion/exclusion criteria and other relevant features. Conclusion A computerized SR tool in the initial phases like EROS saves time, reduces workload for each involved role, and probably enhances SR's methodological quality.

244 – AN APPLICATION TO IDENTIFY HEALTH DEVICES BASED ON TECHNICAL ATTRIBUTES

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There is a great interest to organize the information available for health devices so that similar devices can be compared for the purpose of acquisition, for instance. However, to the best of our knowledge, the existing health device terminologies do not have the level of technical details to group devices with similar characteristics. The objective of this study is to develop an application that allows the identification of products according to their technical attributes. This application focused on cardiovascular devices: stents, pacemakers and implantable cardioverter-defibrillators (ICD). A review of the literature and consultations with user guides were performed to recognize the distinguishing characteristics of these particular items. An initial proposal was created and validated with experts. The final proposal was adapted to Protégé which is a freeware, widely used in the area of ontology and do not require programming skills. A questionnaire was elaborated to evaluate the application content and interface and answered by potential users. The attributes that apply to all devices are indication of use, anatomic localization, manufacture, device model and lifetime. Besides, each type of device has its own technical attributes. Stents included the following attributes: deployment method, construction material, coating, active drug, graft material and shape. The technical attributes for pacemakers and ICDs are pacemaker programming parameters defibrillator programming parameters and connections. The values for each proposed attribute were standardized according to the terms and definitions of SNOMED and other nomenclatures. Protégé was a useful tool to create the environment. It allowed the standardization of the terms used, has a simple interface to create and store queries and also enables to export the information to several formats. The users' evaluation showed that the application was important to organize the devices according to their work needs, however they had some difficulty identifying icons and accessing tabs.

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454 – RESEARCH PRIORITY SETTING IN HTA: THE BRAZILIAN EXPERIENCE USING THE DELPHI METHOD

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Background: In 2009 the Ministry of Health began an updating process of the National Priorities Agenda on Health Research (NPAHR) using the Delphi method as a starting point. Delphi is a tool for qualitative research that looks for opinion consensus of a group of experts about future events. Objectives: Update the research priorities in health technology assessment using the Delphi method. Methods: We used the Delphi method using electronic survey based on two questions. Results: The work was completed in two stages: the first e-mailed the questions to 2,800 persons and received 543 answers (20%). In total 5430 responses were examined by using a clustering procedure presented to the HTA theme 7 citations for the first question and 72 for the second. For the second stage of the process, we selected topics that have reached at least 5% of citations. In the second stage of the process 543 respondents of the first phase received the results grouped by topics and items in each topic were asked, every one, which gives priority from 1 (highest) to 5 (lowest). The most frequent topics were: clinical interventions therapeutic effectiveness assessment, evaluation of innovation cost-effectiveness, evaluation of new technologies and inputs in health effectiveness, life cycle of health technology, development of criteria to guide the technologies incorporation, development of new diagnostic therapies: more practical, efficient and cheap, pre-qualification development systems, continued surveillance inputs and supplies, competitiveness studies and technological innovation prospection according SUS needs, studies regarding the financial costs from technology incorporation. Conclusion: The Delphi methodology was a first step in the NPAHR reviewing process. It serves as a base to make future prospecting. However, its use associated with other methods gives more robust results.

723 – SYSTEMATIC REVIEWS AS PART OF THE HEALTH TECHNOLOGY ASSESSMENT - BRAZIL, 2006 TO 2010

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The perspective HTA area of the Department of Science and Technology (DECIT) is that systematic reviews (SR) provides information that is more consistent for making decisions because they increase the magnitude and precision of the outcomes evaluated. Therefore, since 2004, DECIT has a partnership with the Cochrane Center of Brazil and, also, makes use of the international reviews registered at the Cochrane Library in order to elaborate DECIT´s HTA reports. However, the full scope of the use of these reviews for MoH decision-making has not yet been analyzed. Objective: to describe the use of SR from the Cochrane Collaboration when composing DECIT´s HTA reports and in MoH decision-making. Results: between 2006 and 2010, 66 SR from the Cochrane Collaboration of Brazil were requested by DECIT and 54 were concluded. Twenty-four of these (44%) were sent to the Commission for Health Technologies Incorporation (CITEC) and to the group elaborating the Practice Clinical Guidelines and 21 were focused on the efficacy and safety of drugs. Seven (32%) reviews were used directly for CITEC decisions and seven were used to compose DECIT´s rapid HTA and rapid response reports. In regards to the use of Cochrane reviews from the Cochrane Library, 54% (26/48) were used for DECIT´s rapid HTA and 18% (31/226) for creating rapid response reviews. Discussion: the use of SR for rapid HTA depends on the search strategy, on the study's availability in relation to relevant clinical outcomes, and on the clarity of results. In the case of utilizing SR to support MoH decisions, the generating element is the policymaker's priority. Conclusions and recommendations: systematic reviews confer greater consistency when evaluating outcomes. From this perspective, the challenges are: to reduce SR elaboration time, to improve the clarity of conclusions and to measure the economic impact of the reviews

419 – APPROPRIATENESS OF PROSTATE SPECIFIC ANTIGEN TEST IN A HEALTH MAINTENANCE ORGANIZATION – UNIMED BH

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Background: Prostate cancer is the most common non-skin cancer in male gender worldwide and is the second leading men's cause of death from cancer in Brazil, after lung cancer. Several recent publications have questioned the benefits and harms of prostate specific antigen (PSA) test for prostate cancer screening. Objectives: To evaluate the appropriateness of PSA test, its overall expenditures in Unimed BH and the potential savings if PSA tests were performed according to an evidence-based protocol. Methods: All PSA tests recorded on Unimed BH database from August 2008 to July 2010 were analyzed. Indications were classified as appropriate - according to a local protocol - when PSA tests were performed yearly for all men between 41 and 74 years old if not associated with ICD-10 code C61 (prostate cancer); and a maximum of four exams yearly if associated with ICD-10 code C61 recorded on the database. Results: There were 198,302 PSA tests recorded on the database, performed in 191,301 men. The total expenditure with PSA tests was R$ 6.2 million (U$3.7million). Overall, 52% of PSA test were considered inappropriate, 29.2% related to patients' age range and 22.8% to excessive number of tests associated or not with ICD-10 code C61 recorded on the database. The estimated total expenditures with inappropriate PSA test indications was R$ 2.8 million (U$1.6 million), with a potential saving of R$3.4 million (U$2.0 million) in two years. Conclusions: PSA test indications were largely inappropriate in this cohort. Adherence to a simple evidence-based protocol could result in significant savings. However, even according to protocols, patients' benefit with PSA screening is a matter of debate worldwide.

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601 – KNOWLEDGE DISSEMINATION IN HEALTH TECHNOLOGY ASSESSMENT

Kellee Kaulback, Medical Advisory Secretariat, Canada

The translation of evidence into policy cannot occur unless knowledge is disseminated widely, particularly to decision-makers with the power to implement change. Unfortunately, the excellent work that is done by health technology assessment bodies around the globe to generate unbiased evidence is often buried in that state of semi-publication known as "grey literature." Grey literature is generally not published commercially or indexed by major databases, making it a challenge to disseminate to the right people at the right time. This invisibility can lead to a lack of relevance, duplication of effort, and an overall lack of sustainability in health technology assessment. One solution is to ensure the inclusion of HTA reports in major databases such as PubMed/Medline, and Embase, which are regularly consulted by researchers internationally. The Cochrane Collaboration, the Blue Cross/Blue Shield Technology Evaluation Center, and the National Institute for Health Research have all taken the step of disseminating their HTAs through at least one of these major databases. Following their lead, the Medical Advisory Secretariat (MAS) in Toronto, Ontario, Canada began the process of transforming their reports into a series in 2008. A number of challenges were identified and surmounted to create the Ontario Health Technology Assessment Series (OHTAS), and ensure that it met the stringent selection criteria of the world's major indexers of medical information. OHTAS is now indexed in EMBASE, and has been accepted for indexing by MEDLINE, exponentially increasing exposure to the excellent work done at MAS and demonstrating a concrete commitment to knowledge translation and dissemination.

620 – BRAIN INJURY REHABILITATION – A HEALTH TECHNOLOGY ASSESSMENT

Britta Bjerrum Mortensen, National Board of Health - Dacehta, Denmark; Lisa Von Huth Smith, National Board of Health - Dacehta, Denmark; Tove Borg, Center for Neurorehabilitation - Hammel, Denmark

Objective: to critically assess and discuss five hypotheses on factors promoting positive results in brain injury rehabilitation. The hypotheses are related to: Client-centered approaches, working with goal-setting, strategies for learning, strategies for transferring knowledge and skills and the importance of multidisciplinary services. Methods: a systematic review of the multidisciplinary interventions with positive results included in this HTA's section of assessment of effects supplemented with a systematic review of qualitative studies. . Results: Moderate evidence indicates that a strong alliance between the rehabilitation team and the person with acquired brain injury improves the probability of positive results. Strong evidence demonstrates that the best way for multidisciplinary rehabilitation to achieve positive result is to strive towards activity based goals that are determined jointly with the patients and relatives. One multidisciplinary intervention finds positive results of using two specific strategies for learning. Strategies for transferring knowledge and skills are to a lesser degree investigated in the multidisciplinary interventions. The review identify three principals for determining the composition of the multidisciplinary interventions:1) specifying the target group or programmes; 2) individualizing the services; 3) special ideas or theories, such as in holistic neuropsychological interventions, which structures the intervention. Conclusions: Even though rehabilitation often claim the importance of the five mentioned hypothesis as part of rehabilitation, strategies for transferring knowledge and the importance of multidisciplinary intervention needs more research. Further the hypotheses need to be incorporated in practice to obtain positive results.

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708 – ASSESSING THE DIFFUSION OF MEDICAL TECHNOLOGIES IN PRIVATE HEALTH SYSTEM IN BRAZIL: THE CASE OF POSITRON-EMISSION TOMOGRAPHY (PET)

Hudson Pacifico da Silva, Universidade de São Paulo, Brazil; Ana Luiza D'Avila Viana, Universidade de São Paulo, Brazil

Objectives: To analyze the determinants of diffusion of positron-emission tomography (PET) into a selected set of private health care organizations and health plans companies in Brazil. Methods: Qualitative case study, with data collection conducted through in-depth interviews (N=9) with representatives of four private organizations of health care providers located in different Brazilian states and pioneer in incorporating biomedical technology into their respective jurisdictions, and three health care insurance companies of different size and institutional form. Results: Decisions to adopt the technology are made by managers of hospitals and clinics that adopt a differentiation strategy based on technological leadership. The factors influencing this decision are: history of pioneering in the adoption of new biomedical technologies; pressure of clinical staff; reputation of the physician or area demanding the technology; availability of financial resources; facilitating access to technology; competition among health care providers; availability of evidence; and return on investment. Third-party payers in the public and private systems have little influence in the diffusion process. Conclusions: Current policy instruments used to manage the diffusion of medical technologies in the Brazilian health care system have little influence on decisions of private health care providers, whose activities are not necessarily related to the health needs of the population or with the priorities of health policy. In order to balance the institutional and professional desire to practice a modern and expensive medicine in a context of health inequalities and basic health need, Brazilian government needs to strengthen its role in managing medical technology diffusion by adopting a set of policy instruments capable of influencing decisions of private agents.

845 – EXPLORING THE ROLE OF PROFESSIONAL NETWORKS ON THE DIFFUSION OF MEDICAL TECHNOLOGIES: AN EMPIRICAL STUDY ON ROBOTIC SURGERY

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Objective: Medical technologies are significant components of healthcare costs. Literature indicated that organizational and professional factors play role to understand patterns of diffusion, but there is still a scant of knowledge on how professional factors influence the adoption. This study aims to understand how inter-physician relations affect the adoption of a robotic surgical system in the Italian National Health Service (NHS). Methods: This study is part of the Research Project financed by the Italian National Agency for Regional Healthcare (Age.Na.S) entitled "Tools and methods to regulate the processes of technological, clinical and organizational innovation in the NHS. An integrated system of research". Through a systematic literature review we identified the specialties using the surgical system. We sampled potential adopters, submitting a sociometric questionnaire to medical directors. We gathered data on physicians' attributional characteristics, first and current use, perceived determinants of adoption and the social networks through which information are exchanged. Forty physicians completed the questionnaire. Descriptive statistics and social network analysis techniques were used. Results: Professional ties play a major role for technology adoption and diffusion. The first adoption is influenced by "word of mouth" and scientific articles, suggesting the attitude towards evidence-based medicine. The current level of adoption is significantly correlated to the ties with colleagues. Our analysis unravels the presence of opinion leaders in the network and the variability in the year of first adoption and the patterns of diffusion. Conclusion: Our study provides contribution to the healthcare management literature. Firstly, the integration should enhance the diffusion and sustainability of innovation within healthcare organizations. Secondly, policy makers who easily identify opinion leaders should implement strategies to facilitate the diffusion of technologies as well as to hinder the adoption of those whose effectiveness appears questionable. We greatly acknowledge Thomas Jefferson, head of the Age.Na.S research project.

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857 – USE OF A RESEARCH TOOL TO ASSESS CARDIOVASCULAR HTAS PUBLISHED BY FOUR INTERNATIONAL ORGANIZATIONS

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Background: Worldwide, cardiovascular disease is a leading cause of death. International Health Technology Assessment (HTA) organizations prioritize reviews to improve cardiovascular quality of care while seeking to optimize value. This study assessed variability in perceived prioritization of target study populations and outcomes across four leading international HTA organizations with respect to cardiovascular assessments. Methods: Using a proprietary research tool, we examined completed and published cardiovascular HTAs conducted by U.S. (AHRQ), Canadian (CADTH), German (IQWIG), and U.K. (NICE) organizations between 2007 and 2010. Search terms were selected to be inclusive of cardiovascular therapies. Studies were reviewed and compared based upon the cardiovascular condition, target population examined, and outcomes assessed. Results: We assessed a total of 44 completed cardiovascular-related reports published by the organizations. AHRQ and CADTH commissioned reports for a variety of conditions, including atrial fibrillation (AF), hypertension (HTN), hyperlipidemia, and coronary artery disease (CAD). By contrast, a majority of IQWIG reports focused on HTN. NICE focused on CAD with a few reports exploring AF and dyslipidemia. Target populations and outcomes assessed varied across organizations. AHRQ most frequently assessed sub-populations of interest (e.g. elderly, African-Americans) in its reports. Additionally, NICE and CADTH examined cost-effectiveness as an outcome more frequently than AHRQ and IQWIG. Conclusions: These four HTA organizations appear to establish different priorities in their approaches to conducting cardiovascular therapy assessments, as evidenced by the wide variation in key study elements that we found. Organizations differed on specific conditions, approaches to cost-effectiveness, and sub-populations of interest. Further investigation of the key factors that drive these approaches may help improve the effectiveness of research by optimizing resource use for cardiovascular assessments of interest.

90 – THE USE OF RESEARCH EVIDENCE IN MUNICIPAL HEALTH SERVICES AND SYSTEMS MANAGEMENT: A CASE REPORT

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Health systems sustainability increasingly relies on optimum governance, financial and delivery of healthcare services. Evidence derived from health technology assessment (HTA) is key for the incorporation of cost-effective, safe, equitable, ethical, and socially accepted interventions into local health care systems. Although HTA has been promoted at the national level in Brazil, Piripiri, a municipality of 62,000 inhabitants, located in the country poorest region pioneered by launching Brazil's first evidence-to-action municipal unit in January 2010. The 'Piripiri Centre for Health Evidence Use' promotes the production and use of evidence –including from HTAs– for local decision-making. It is also a venue for deliberative dialogues where interested stakeholders (e.g., municipal healthcare managers, clinicians, researchers, and civil society representatives) exchange their views and experiences in relation to pre-circulated evidence briefs. We present the center's vision, members, mandate, and activities. We discuss the context under which the center was developed including the involvement of the Evidence-Informed Policy Network-Brazil, Latin American and Caribbean Center on Health Sciences Information (BIREME/PAHO), federal and municipal government, researchers, and organized civil society groups. We also present its preliminary results and impact. In brief, the center has produced one evidence and one policy brief, and held one deliberative dialogue. These initiatives have informed local decision-making and promote social appropriation of research evidence. We are monitoring and evaluating these outputs and the preliminary results are promising and may lend themselves to scale up and use in other health systems in Brazil and abroad.

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809 – SOCIAL ACCEPTABILITY AND PATIENT'S CONFIDENCE IN TELEHEALTH

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Objective: To assess social acceptability and patient's confidence in telehealth in the province of Quebec. Method: We conducted a survey using a questionnaire assessing social acceptability and confidence level in telehealth. Two strategies were used: (1) Written questionnaires were sent in two Quebec's hospitals; (2) online questionnaires were sent randomly by a survey specialized firm using their database to a representative population of the province of Quebec. Inclusion criteria were to be a resident of Quebec and to be 18 years of age or older. Questions were scored using a four-level Likert scale. Findings: 1813 questionnaires were analyzed (226 written and 1738 online questionnaires). Our sample is representative of the Quebec population since no significant difference in demographic data (age, sex, education, working status (part time vs. full time employment), income) was found between our sample and data provided by Statistics Canada. Overall, social acceptability scores at 77.9% and patient's confidence at 65.8%. We found a significant difference ($p<0.05$) between written and online questionnaires regarding patient's confidence (64.6 % vs. 74.8%). Conclusion: Our results suggest that the Quebec population encourages the development of telehealth for real time diagnosis and treatment at distance for regions deprived of healthcare professionals in order to improve quality of care.

876 – SURGEON'S VIEWS OF HEALTH TECHNOLOGY ASSESSMENT (HTA) PROCESS IN AUSTRALIA

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Objective: The aim of this study was to explore the views and perceptions of surgeons about the current national health technology assessment process for new medical technologies and procedures conducted by the Medical Services Advisory Committee (MSAC). Methods: A survey was distributed by the Royal Australasian College of Surgeons to it members over a four week period. The survey asked about participants' knowledge, use and views of the MSAC process. Descriptive statistics were used to summarise the data. Frequencies and proportions were calculated with their 95% confidence intervals. Results: Fifty five surgeons completed the survey of these 79% were males, 31% were age between 36-45, 60% reported their primary work place as public hospital and 49% were involved in making decisions about the adoption of health technologies or treatments at their institution. Twenty five percent of the participants reported that they had never heard of MSAC and 37% stated being aware of the process but don't really understand it. A third of respondents (33%) considered the process as a way to ensure that decisions about new technologies are evidence-based. The Commonwealth Government and committee members were seen as having a high impact on the MSAC decision making process while the general public had a low impact. Forty five percent reported that surgical procedures are most likely to be introduced in the Australian health care system at the public hospital level (which is beyond MSAC's scope). Conclusions: The results of this study suggest that knowledge and understanding of the MSAC decision making process is limited amongst surgeons. Public hospitals are still perceived as the entry point for the introduction of new surgical procedures. The influence that MSAC decisions have on clinical practice; especially in areas beyond MSAC's scope (e.g. public hospitals) appears to be limited.

301 – MULTIPLE TECHNOLOGIES ASSESSMENT IN CHRONIC WOUNDS AND BURNS BACKGROUND

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The treatment of chronic wounds and burns is a challenge with great impact on quality of life of patients. Objective: provide information to support governmental decision makers about new technologies in chronic wounds and burns treatment and dressings with high costs and significant budgetary impacts. Search: The search for the best available evidence on efficacy and safety of technologies was performed through the following databases: Medline, The Cochrane Library, Trip database, Centre for Reviews and Dissemination (CRD), Embase, Bandolier and National Institute for Clinical Excellence (NICE), CINAHL, Up-To-Date, Web of Science and Lilacs. The search identified a total of eight systematic reviews and four randomized controlled trials (RCT). High quality sistematic reviews were used. Others indications of the listed technologies were not included. The quality of evidence was classified as HIGH, MODERATE, LOW AND VERY LOW and recommendations in STRONG or WEAK following the GRADE System. Recommendations: Incorporate / Strong: hyperbaric oxygen therapy for wounds in the lower extremities of patients with diabetes (HIGH QUALITY) (reduction in risk of amputation, accelerates wound healing in the short term 2-4 weeks). Incorporate / Low: skin substitutes based collagen or silicone (very low quality) Against Incorporation / Low: Silver Dressings (LOW QUALITY), skin substitutes based on bacterial cellulose (very low quality), ozone therapy (very low quality), wound closure by negative pressure (LOW QUALITY). Security Technologies that presented more risks were: wound closure by negative pressure, causing bleeding and organ injury, and hyperbaric oxygen therapy as having the most common complication of ear barotrauma. Additional recommendations Cellulose Skin substitutes: Recommendation to conduct clinical trials in Brazil facing the possibility of favorable results and the interest of investment in domestic industry. Negative Pressure Wound Dressings: in front of the possibility of using the device \"homemade\", recommendation to conduct a pragmatic randomized clinical trial.

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490 – META-ANALYSIS OF MORTALITY WITH COMBINED CARDIAC RESYNCHRONIZATION AND IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR THERAPY IN HEART FAILURE: DOES RECENT EVIDENCE CHANGE THE STANDARD OF CARE?

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Objectives: The present meta-analysis aims to assess the impact of combined cardiac resynchronization therapy (CRT) and implantable cardioverter-defibrillator (ICD) therapy on survival of heart failure (HF) patients. Background: The recent publication of the MADIT-CRT and RAFT trials has more than doubled the number of patients in which a direct comparison of the combination of CRT and ICD versus ICD alone was carried out. Methods: Medline, Embase, and the Cochrane Library databases were searched, and all randomized controlled trials of CRT alone or combined with ICDs in HF due to left ventricular systolic dysfunction were included. Main outcome was all-cause mortality. Summary relative risk (RR) and 95% confidence interval (CI) were calculated employing random-effects models. Results: Twelve studies were included, with a total of 8,284 randomized patients. For the comparison of CRT alone versus medical therapy, pooled analysis of 5 available trials demonstrated a significant reduction in all-cause mortality with CRT (RR 0.76, 95% CI: 0.64–0.9). Pooled analysis of 6 trials that compared the combination of CRT and ICD therapy to ICD alone also showed a statistically significant reduction in all-cause mortality (RR 0.83, 95% CI: 0.72–0.96). Stratified analysis showed significant mortality reductions in all New York Heart Association class subgroups, with greater effect in classes III–IV (RR 0.70; 95% CI: 0.57–0.88). Pooled estimates of implant-related risks were 0.6% for death and 8% for implant failure. Conclusions: Combined CRT and ICD therapy reduces overall mortality in HF patients when compared to ICD alone.

815 – IMPACT OF INTRAVASCULAR ULTRASOUND-GUIDED STENTING: SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CLINICAL TRIALS

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The aim of this systematic review and meta-analysis was to evaluate the impact of routine intracoronary ultrasound (IVUS)-guided coronary stent implantation as compared to angiographic-guided, on clinical and angiographic outcomes.Methods and results: A search of databases Medline/Pubmed, CENTRAL, Embase, Lilacs, Scopus e Web of Science, and references of published studies, until November of 2010, was conducted. Randomized trials (RTs) that compared IVUS-guided vs. angiographically-guided coronary stent implantation in patients with coronary artery disease were included.Minimum follow-up was 6 months and the outcomes assessed were death, myocardial infarction (MI), major adverse cardiac events (MACE), revascularization, angiographic restenosis, and stent thrombosis Two reviewers independently extracted data. Summary risk ratio (RR) and 95% confidence intervals (CI) were calculated with random-effects models. The GRADE approach was used to determine the quality of evidence for each outcome. Of 2.690 articles identified, 8 RCTs evaluating a total of 2.341 patients were included. There was a significant 27% reduction of revascularization (RR: 0.73; IC 95%: 0.54 – 0.99; I^2 = 55%),and no significant 27% reduction of angiographic restenosis (RR: 0.73; IC 95%: 0.54 – 0.97; I^2 = 51 %), no significant 27 % reduction of myocardial infarction (RR: 0.73; IC 95%: 0.43 -1.16; I^2 = 12%), no significant 14 % reduction of MACE (RR: 0.86; IC 95%: 0.70 – 1.07; I^2 = 55%),and no significant 10% reduction of stent thrombosis RR: 0.90; IC 95%: 0.37 – 2.22; I^2 = 0 %), in favor of IVUS-guided stenting vs. angiographically-guided stenting. However, there was a no significant 54% increase of mortality for all causes in IVUS-guided stenting group (RR:1.54; IC 95%: 0.85-2.78; I^2 = 0%).Conclusions: The present meta-analysis demonstrates that IVUS-guided stenting implantation has a neutral effect on death, myocardial infarction, angiographic restenosis, MACE, and stent thrombosis compared to an angiographically-guided stenting. However, IVUS-guided stenting significantly lowers 6-month revascularization.

284 – IMPACT OF STATIN DOSE ON MAJOR CARDIOVASCULAR EVENTS: A MIXED TREATMENT COMPARISON META-ANALYSIS INVOLVING MORE THAN 174,000 PATIENTS

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Background: The benefit of statins in reduction of vascular events has been demonstrated in several placebo-controlled trials. Their effectiveness according to regimen intensity is less established. Some trials have directly compared more versus less intensive statin regimens. Nonetheless, the number of patients studied in statin trials is immense, and analyses including trials comparing statins with placebo could add valuable information, by providing indirect evidence. Our objective was to compare different statin dosages in the reduction of cardiovascular events, combining direct and indirect evidence, through mixed treatment comparisons (MTC). Methods: We conducted a systematic review in MEDLINE and Cochrane CENTRAL. A random-effects model Bayesian MTC was used to combine placebo-controlled and direct statin comparisons trials. Statin dosages were classified according to their expected LDL-cholesterol reduction: <30% = low (e.g. Pravastatin 40mg), 30% to 40% = intermediate (e.g. Simvastatin 40mg), ≥40% = high (e.g. Atorvastatin 20mg). Inconsistency was assessed through the split-node methodology. Results: 46 trials were included (15 direct statin comparisons), totaling ≈174,000 patients. High intensity schemes reduced non-fatal myocardial infarction (nf-MI) by 27% (95% CI: 16%–35%) and by 14% (6%–21%) when compared to low and intermediate dosages, respectively. RR for nf-MI of intermediate versus low was 0.85 (0.76–0.96). High dosages also had an effect on coronary revascularization [RR versus low and intermediate dosage of 0.81 (0.69–0.95) and 0.87 (0.77–0.99), respectively; no difference between these two] and on stroke [RR of 0.83 (0.68–0.99) against low dosage]. No differences were observed in all-cause death [RR high versus low 0.92 (0.80–1.06), high versus intermediate 0.98 (0.88–1.07), intermediate versus low 0.95 (0.83–1.08)]. Results for coronary and cardiovascular death did not show difference between regimen intensities either. No statistical inconsistency existed in analyses. Discussion: In our study, which simultaneously analyzed all available evidence regarding statins, benefit of higher intensity regimens was restricted to non-fatal events.

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351 – REAL WORD EFFECTIVENESS AND COMPLIANCE OF HEPATITIS C TREATMENT IN BRAZIL: META ANALYSIS AND META REGRESSION

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Objective: To summarize the effectiveness of treatment for chronic hepatitis C (CHC) in Brazil and investigate the influence of compliance on sustained viral response (SVR). Methods: We performed a literature search in electronic databases (e.g., MEDLINE, Capes) to identify observational and experimental studies on CHC in Brazil. According to the Brazilian protocol we evaluated the data in five groups. Treatment with peginterferon-alfa plus ribavirin for 48 weeks: genotype 1 (A), HIV-HCV co-infection (B), relapses (C) and non-responders (D); treatment with interferon-alfa plus ribavirin for 24 weeks: genotype 2 or 3 (E). We excluded studies not reporting SVR and studies on identical study populations. We used a random effect model to estimate the pooled SVR with 95%CI for each treatment group and meta-regression to explain heterogeneity and evaluate the association between discontinuation treatment and no SVR. Results: From 64 studies, 20 satisfied all inclusion criteria and were included in the analysis. The pooled SVRs for treatment groups were: A (n=1775; SVR= 40.2%, 95%CI 34.5-45.8); B (n=59, SVR= 23.73%); C, gen 1 (n=68; SVR=60.0%, 95%CI 44.0-75.9); C, gen non1 (n=17; SVR=59.0%, 95%CI 32.9-85.1); D, gen 1 (n=230; SVR=18.3%, 95%CI 13.3-23.3); D, gen non1 (n=79; SVR=50.2%, 95%CI 33.4-67.0); and E (n=486; SVR=54.3%, 95%CI 39.3-69.3). The rates for discontinuation of treatment varied between 4.5% and 44.4%. The heterogeneity test was statistically significant ($p<0.05$) in treatments groups A and E. Meta-regression using discontinuation treatment as explanatory variable explained 26%

of this heterogeneity. An increase of discontinuation of 10% decreased SVR by 4.1%. Assuming 100% conclusion yielded 44.4% SVR. Conclusion: For all subgroups except for subgroup C, pooled SVRs were lower than those of clinical trials. According to our analysis discontinuation treatment is a major reason for this. Improving treatment conclusion rates could improve the rates of SVR and save lives in Brazil.

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512 – ERYTHROPOIESIS STIMULATING FACTORS (ESAS) FOR THE TREATMENT OF CHEMOTHERAPY INDUCED ANEMIA IN PATIENTS WITH HB<11G/DL. A SYSTEMATIC REVIEW (SR) AND META-ANALYSIS (MA)

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Objectives: Anemia is a frequent condition in patients receiving chemotherapy. This condition can be controlled by ESAs but many randomizaed clinical trials (RCTs) and SR have reached different conclusions about its safety and efficacy. Methods: We performed a systematic review and meta-analysis of studies that addressed the safety and efficacy of the use of ESAs according to the current on label indication: patients that are on anticancer chemotherapy and with a Hemoglobin (Hb) < 11g/dl. We measured the risk of a patient come to need a transfusion and the mortality rates according to the use of ESAs. Results: For the mortality analysis, we found 21 studies, with 4571 patients. There were 929 deaths among 2602 patients treated with ESA (35,7%) versus 775 deaths among 1969 patients in the control group (39,3%). The meta-analysis showed no increase in mortality rates associated with the use of ESA (Relative risk (RR) = 0.98; CI 95% 0.92 to 1.05; P=0.63; I2=0%). The risk of transfusion was obtained from many published RCTs and SR. The pooled data showed that use of ESAs in patients with Hb levels <11g/dl are linked to less transfusions (RR = 0.64; CI95% 0.53 to 0.73). Conclusion: The use of ESA in patients with chemotherapy related anemia and Hb levels below 11 g/dl appears to be effective and is not associated with an increase in mortality.

579 – MEASURES OF ABSOLUTE RISK OF INFLIXIMAB IN THE TREATMENT OF RHEUMATOID ARTHRITIS

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Objective: The objective is to update knowledge on the treatment of rheumatoid arthritis with the addition of infliximab, using measures of absolute risk, when compared with use of methotrexate. Methods: We conducted a search of articles in the PubMed, EMBASE and Cochrane, with an end date in 05/2010. Qualitatively evaluated by the Jadad scale, the percentage adjustment to the main CONSORT items and the level of evidence of the Oxford-CEBM. We did a reading of titles and summary for the initial exclusion of researches not related to the topic and we read the full texts remaining. We extracted data from articles by a spreadsheet developed based on the model suggested by SR_CRD York. Data were tabulated comparing infliximab in two dosages with methotrexate, measuring the ACR20, ACR50 and ACR70, by absolute risk in the control group (RAC) the reduction in the intervention group (ARR), CI95% and NNT. Results: 64 articles were retrieved through the search. Of this total, eight articles met the eligibility criteria and study design (RCT). Of these, five studies evaluated the dose of 3mg/kg, totaling 2197 patients and four studies examined the dose of 10mg/kg, totaling 1673 patients. One study looked at the two dosages. Statistically significant differences with 3mg/kg infliximab group were observed with ACR50 RAC=0.76, ARR=0.16, CI95%=0.12-0.20, NNT=6; ACR70 RAC=0.83, ARR=0.09, CI95%=0.05-0.12, NNT=12 and with 10mg/kg infliximab group, ACR50 RAC=0.77, ARR=0.21, CI95%=0.17-0.25, NNT=5; ACR70 RAC=0.83, ARR=0.13, IC95%=0.09-0.17, NNT=8. The ACR20 with both dosing schedules showed heterogeneity (I2 > 80%) besides its weak clinical relevance. Conclusion: There was a similar benefit in terms of ACR50 between the two dosages. The benefit of ACR70 was greater with 10mg/kg, but the approximate SUS (health public system) cost was US$ 31,000.00 person-year for the dosage of 3mg/kg, wich was triplicated with the dosage of 10mg/kg.

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650 – MYCOPHENOLATE MOFETIL VERSUS AZATHIOPRINE AS MAINTENANCE THERAPY FOR KIDNEY TRANSPLANT RECIPIENTS

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Background: incidence and prevalence of kidney disease are high and increase in Brazil and in the world, generating a growing number of patients that could be submitted to renal transplant (RT) and high costs for health systems. Objective: to conduct a systematic review with meta-analysis to summarize the data efficacy of mycophenolate mofetil (MMF) versus azathioprine (AZA) in the maintenance therapy of RT. Search strategy: was conducted a search in the MEDLINE, LILACS and the Cochrane Central Register of Controlled Trials and a handsearch to identify relevant randomized controlled trials (RCTs). Two reviewers assessed studies for eligibility and quality independently. Selection criteria: All RCTs which AZA was compared with MMF for the maintenance treatment of kidney transplant recipients. Data analysis: in the meta-analysis of 12 months the data were synthesized (random effects model) and results expressed as risk ratio (RR), values <1 favoring MMF in the case of acute rejection (AR), with 95% confidence intervals. The data of others studies were described. Findings: nine RCTs and 2107 kidney transplants were evaluated. The majority of the sample consisted of male patients, white, middle-aged and underwent his first kidney transplant. The median length of follow up was 12 months (range 12-60) and the studies were conducted in the period 1995-2002. At 12 months AR was significantly reduced in MMF-treated recipients (RR 0.62, 0.48 to 0.81) and were no differences in graft and patients survival. When considering AR and graft survival, the group that made use of MMF shows positive results (p>0.05). The results of patient survival in the studies were divergent and the findings were not significant. Conclusions: the evidence of difference in efficacy between MMF and AZA are questionable. Long-term hard-endpoint data from methodologically robust RCTs are still needed.

202 – IODINE-125 PERMANENT IMPLANT FOR LOCALIZED PROSTATE CANCER

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Objective: To evaluate the safety and effectiveness of I-125 permanent implant (PI) for treating localized prostate cancer compared with radical prostatectomy (RP), external beam radiation therapy (EBRT). Methods: First, we found the HTA report by MSAC (Medical Services Advisory Committee, 2005) so that we did a systematic review for the period between 2005 and August 2010. The searches were conducted via electronic databases including Medline, Embase, HTA websites, 8 Korean medical DB and retrieved 656 non-duplicate citations. Total 41 studies (8 comparative studies, 33 case series) were included for this review. Findings: PI is used as monotherapy, as boost therapy and as salvage therapy. - Safety: PI is comparable to or better than EBRT, RP in terms of bowel and sexual function. PI result in higher rates of urinary toxicity but severe urinary toxicity did not happen and it resolved by conservative treatment. However, two case series reported that salvage therapy result in higher rates of severe urinary toxicity. - Effectiveness 1) Effectiveness was evaluated by biochemical disease-free survival rate (bDFS). The evidence available does not demonstrate a difference in survival or disease progression between PI, RP, EBRT in patients with localized prostate cancer. Some studies commented on the effect of risk factors (T stage, Gleason score, PSA). In case series, 5-year bDFS of monotherapy was 91-98.2% for low risk group, 70-92.8% for intermediate risk group, 52-100% for high risk group. 2) A comparative study, boost therapy was associated with an increase in survival in high risk group. 3) There is insufficient evidence of salvage therapy to demonstrate effectiveness. Conclusion: On the basis of current data, we recommend that monotherapy is possible treatments for patients with low/intermediate risk group and boost therapy is possible treatments for patients with intermediate/high risk group.

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406 – PERCUTANEOUS SCLEROTHERAPY FOR VASCULAR MALFORMATIONS - A SYSTEMATIC REVIEW

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Objective: Sclerotherapy aims to eradicate or reduce abnormal vasculature through endothelial damage, inflammation, thrombosis, fibrosis and resultant obliteration of the lesion, with minimal invasiveness. Advances in the percutaneous sclerotherapy technique have been developed due to high recurrence rates and poor symptomatic and cosmetic improvement when lesions are surgically excised. The objective of the review was to determine the safety and efficacy of percutaneous sclerotherapy for patients with congenital vascular malformations via review of current peer reviewed literature. Methods: Literature was identified via systematic searches of electronic databases including PubMed, EMBASE, the York (UK) Centre for Reviews and Dissemination (CRD) and the Cochrane Library; and was conducted in December 2010. Only recently published (year 2000 onwards) peer reviewed publications with a minimum of 20 patients were included. Types of sclerosants utilised included ethanol, OK-432, sodium tetradecyl sulphate and doxycycline. Findings: A total of 17 articles were included for review: one systematic review, one RCT and 15 case series. Venous malformations comprised almost half of the patient population, followed by lymphatic malformations, arteriovenous malformations, arteriovenous fistulae and mixed malformations. The total number of reported adverse events was 369 of 1027 (36 percent) patients, including systemic and localised complications; the majority resolved without further intervention. Primary effectiveness outcomes included lesion regression, symptomatic, functional and cosmetic improvement, lesion recurrence; and results varied according to lesion type and location. Conclusions: Percutaneous sclerotherapy appears to be safe and effective for the treatment of congenital vascular malformations. Notably, treatment success was closely linked to the haemodynamic properties and histological structure of the lesion. Studies utilising a multi-disciplinary team achieved the greatest treatment success, highlighting the technical difficulty of this procedure.

559 – ENZYME REPLACEMENT THERAPY IN MUCOPOLYSACCHARIDOSIS TYPE II: A SYSTEMATIC LITERATURE REVIEW

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Mucopolysaccharidosis type II (Hunter syndrome) is an X-linked recessive lysosomal storage disorder caused by a deficiency of iduronate-2-sulfatase. It has multisystemic involvement, and a therapeutic option is enzyme replacement therapy (ERT) with idursulfase (dose= 0.2mg/kg/week). Methodology: In order to examine the efficacy and safety of ERT, a systematic literature review seeking studies comparing idursulfase to other intervention was conducted on Clinical Trials, The Cochrane Library, MEDLINE, EMBASE, and LILACS until October 30, 2010. The inclusion criterion was being a randomized controlled trial (RCT); in the absence of at least 5 RCTs, prospective case series with ≥5 patients that evaluated relevant outcomes were also included. The endpoints considered relevant had been previously defined by our research team. Results: Two RCTs comparing idursulfase to placebo and 2 open label trials were included in this systematic review. One RCT was a phase I/II trial of 12 patients for 72 weeks; the other was a phase II/III study of 94 patients for 54 weeks. Both RCTs demonstrated reductions in urine glycosaminoglycans and hepatosplenomegaly and an increase in the 6-minute walk test distance and the pulmonary function; however, at baseline, disease severity was heterogeneous between the groups; a small number of patients were evaluated for a short time; this hindered reaching consistent conclusions. Both open-label studies revealed analogous benefits as described by the RCTs; however, one was a 24-month extension study for the RCTs and the other evaluated only Japanese patients. Conclusion: MPS II is a rare disease, and some difficulties in the conduction of RCTs can occur. Idursulfase can bring benefits to MPS patients; however, the majority of the studies reviewed had surrogate endpoints, clinical heterogeneity, and few patients, thus limiting our conclusions. Additional studies should be conducted. Support: MCT/CNPq/MS-SCTIE-DECIT 037/2008.

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607 – META-ANALYSIS: EFFICACY AND SAFETY OF CETUXIMAB IN THE TREATMENT OF COLORECTAL METASTATIC CANCER

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Background: Cetuximab is one of the drugs that has already been registered in Uruguay for oncologic use but not yet included in the National Therapeutic Formulary (NTF) for the treatment of metastatic colorectal cancer. For this reason, the Ministry of Health of Uruguay has faced several legal claims from patients who request payment for oncologic treatment with this drug. Objective: To assess the efficacy and safety of cetuximab-based therapy vs non cetuximab therapy in patients with advanced or metastatic colorectal cancer in order to decide the inclusion of the drug in the NTF. Methods: A systematic search of the literature was performed in electronic databases with no language restrictions. Key words included were: cetuximab, metastatic OR secondary, colorectal, cancer OR neoplasm, limited by meta-analysis, clinical trial and randomized controlled trial (RCT). All studies comparing combined chemotherapy with cetuximab vs no cetuximab chemotherapy were included. Critical appraisal of the papers was done by two independent reviewers. Statistical analysis was performed with Review Manager 5.0. Sensitivity analysis and subgroup analysis for wild-KRAS condition were performed. Results . Two complete systematic reviews and seven RCT met inclusion criteria. Six of the RCT were included in the systematic reviews so meta-analysis was done again including all the studies. Global analysis showed a hazard ratio for overall survival of 0.93 (IC 95% 0.86-1.00) and grade 3-4 adverse events showed a OR 2, 25 (IC 95% 1.96-2.58) Conclusion: According to this global analysis, there is not enough scientific evidence to assure that the inclusion of cetuximab to the treatment of metastatic colorectal cancer can improve survival. Adverse effects increase with this drug. Further research is needed in order to recommend its coverage.

346 – THE IMPACT OF TACROLIMUS AS RESCUE THERAPY IN CHILDREN USING DOUBLE IMMUNOSSUPRESSIVE REGIMEN AFTER HEART TRANSPLANTATION

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Objectives: The aim of this study was to evaluate the clinical outcome of children undergoing heart transplantation who required conversion from a cyclosporine-based steroid free therapy to a tacrolimus-based immunosuppressive regimen. Background: Organ transplant recipients with refractory rejection or intolerance to conventional immunosuppressant may respond to rescue therapy with tacrolimus. Methods: We performed a prospective observational cohort study in 28 children who underwent conversion from a cyclosporine-based steroid free therapy to a tacrolimus-based therapy for refractory or late rejection or intolerance to cyclosporine. Results: There was complete resolution of refractory rejection episodes and adverse side effects in all patients. The incidence rate (x100) of rejection episodes before and after conversion was 7.98 and 2.11, respectively ($p = <0.0001$). A significant incidence of cardiac allograft vasculopathy after conversion to tacrolimus was found ($p = 0.004$). When comparing patients on tacrolimus to patients who remained on cyclosporine, there was a significant decrease in the incidence of rejection ($p = 0.001$), and infectious episodes ($p = 0.002$) in patients using tacrolimus. Patients converted to tacrolimus had lower neurological complications, hirsutism and gingival hyperplasia, but higher prevalence of anemia. There was a 25% mortality rate in patients using tacrolimus after a mean period of 60 months after conversion. Patients using tacrolimus showed greater survival rate when compared to patients taking cyclosporine. Conclusions: Tacrolimus is effective as rescue therapy for refractory rejection and is a therapeutic option for pediatric patients.

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982 – EFFECTIVENESS OF ALTERNATIVES FOR THE SECONDARY PREVENTION OF CHRONIC RENAL FAILURE IN BRAZIL

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The objective of the present study was to estimate the effectiveness of different programs to delay end stage chronic renal disease (CRD) associated with hypertension and diabetes in Brazil. The study assessed and compared the effectiveness of 5 alternative programs for diabetes-related CRD: a) traditional treatment, prevalent in the Brazilian system; b) local University (UERJ) CRD Postponement Program, an actual prospective study (program 1) c) basic Postponement Program plus statin but without antagonist receptor of angiotensin II (ARA II) (program 2), d) basic Postponement Program plus ARA II (without statin) (program 3) and e) basic Postponement Program plus statin and ARA II (program 4). For patients with hypertension-related CRD, 2 alternatives were compared: the State University program and the traditional approach. The estimates of effectiveness were based on local and international studies that have produced evidence related to the efficacy and effectiveness of postponement procedures. For diabetes-related CRD, the study showed an average increase of 5.18 life years (from stage 3 to initial dialysis), when comparing traditional care and program 1. Compared to program 1, 15.5 life years were added by program 4, mostly due to a higher rate of adherence to the program. The impact of the insertion of ARA II, by comparing programs 2 and 4, was an increase of 12.9 years; between alternatives 3 and 4 (impact of statins) there was an increase of 0.64 years. For patients with hypertension-related CRD, program 1 accrued an average increase of 3.06 life years over traditional care. The estimated gains of diabetes and hypertension-related CRD postponement programs when compared with traditional care in Brazil, and a positive impact of adding ARA II and statins to the program, point to the improvement of the adequacy of hypertension and diabetes-related CRD care in the Brazilian health system.

543 – WHAT WOULD BE THE OPTIMAL SALIVARY COLLECTION DEVICE TO SELECT SUSCEPTIBLE GROUPS FOR VACCINATION AND TO EVALUATE VACCINE-INDUCED HUMORAL RESPONSE AGAINST HEPATITIS A VIRUS (HAV)?

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Pathogenesis of HAV infection is a critical point to detect antibodies among oral fluids, since immunity induced by HAV vaccine is at least 10 times lower than resulting from natural infection. This fact is aggravated in oral fluids in which antibodies titers are 800 to 1,000 fold lower than serum. Therewith, evaluation of different collection devices will allow distinguishing immune and susceptible individuals with greater sensitivity. This study aimed to evaluate anti-HAV antibodies in oral fluids among vaccinated and naturally immune individuals using three different collection devices. For that, 90 paired serum and oral fluid samples were collected from non-reactive (n=35), vaccinated (n=25) and naturally immune volunteers (n=30). Serum was collected by venipuncture, centrifuged at 1800g/5 min, and stored at -20ºC. Oral fluid was obtained using 3 commercial devices: Salivette, OraSure and ChemBio. Samples were centrifuged at 1300g/10 min and stored at -20ºC to 4-8°C depending on collection device. Sera and oral fluids were submitted to commercial EIA (ImmunoCombHAVAb). Optimization panel demonstrated that oral samples were in agreement with all serum groups of non-reactive and naturally immune individuals. However, in vaccinated group, there were 2 false-negative samples collected with the OraSure and 4 with Salivette device. The oral fluid test for total anti-HAV was 92.7% sensitive for Salivette, 96.3% for Orasure and 100% for ChemBio. All collection devices showed 100% of specificity. A follow-up of samples collected with ChemBio device was realize to evaluate stability of oral fluid and it was observed that 210 days after oral fluid collection was possible to detect anti-HAV antibodies. These results showed that Chembio was the oral fluid collection device which better distinguishes between susceptible and immune individuals. This collector can be use to facilitate the screening of age groups to receive HAV vaccine and the implementation of a program to control disease.

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553 – SHORT TERM FOLLOW-UP OF CORONARY ARTERY STENTING PATIENTS: EXPERIENCE FROM SOUTH OF BRAZIL

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Introduction: In most published studies drug eluting stents reduce the risk of restenosis but are also more expensive when compared to bare metal stents, and there seems to be no effect on mortality and myocardial infarction. However, data from real life in developing countries are lacking. Objectives: We aimed to compare major cardiovascular events on short term follow-up of patients with bare metal and drug-eluting stents in south of Brazil. Methods: All patients having a percutaneous coronary intervention with stenting between 2008-2010 at a healthcare plan affiliated hospital from south of Brazil were included. Demographic, clinical and procedural data were obtained from chart review. Research nurses collected follow-up data by phone calls at one and six months after the procedure using a predefined collection form. Main outcomes analysed were death, myocardial infarction and restenosis. Outcomes were compared between patients with bare metal and drug-eluting stents. Results From 201 patients entering the study, four patients were lost for follow-up. Of the 197 patients with follow-up data, two thirds were male and 70% had a bare metal stent. Data of main and secondary outcomes can be seen in table 1. Table 1. Short term 6 months post-stenting follow-up data Bare metal(n=139) Drug eluting(n=58) p value Major cardio- vascular events(%) 18,52 18,18 0,96 Death(%) 5,76 3,45 0,50 AMI(%) 3,05 3,57 0,85 Revascularisation%) 14,06 13,21 0,88 Hospitalisation(%) 19,08 22,64 0,58 AAS+clopidogrel(%) 68,94 71,43 0,73 Statin use(%) 81,68 87,50 0,32 Conclusion: Contrasting to international studies we did not find significant differences in major cardiovascular outcomes between bare metal and drug-eluting stents after a short term follow-up. A greater sample size and a longer follow up are necessary before we can draw definite conclusions.

733 – ADJUVANT TREATMENT WITH TRASTUZUMAB IN PATIENTS WITH BREAST CANCER IN URUGUAY

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Introduction: Breast cancer is the most frequent and the leading cause of death from cancer in women in Uruguay. Trastuzumab is a recombinant humanized monoclonal antibody targeted against the HER2 transmembrane growth factor receptor. RCT phase III had showed its benefit in adjuvant-treatment, associated to chemotherapy, in patients with HER2-positive breast cancer. The treatment with Trastuzumab is funded, with central and universal coverage, for breast cancer patients in Uruguay. A regulatory framework for coverage and a systematic process of evaluation were established. Objective: Assess the effectiveness and tolerance of Trastuzumab associated with chemotherapy in patients with HER2-positive breast cancer in Uruguay. Methods: Cohort study of patients treated with adjuvant Trastuzumab between October 2006 and March 31st, 2009. We assessed disease-free survival, overall survival (Kaplan-Meier method), and adverse effects. Monthly information was required during the 12 month of treatment, and a phone interview was made for complete the long-term followup. Results: treatment was solicited for 215 patients and was approved for 171 (79.5%). Median of follow-up was 31.9 months, 12 (7%) patients were lost of follow-up for disease progression evaluation. 20 patients died and disease progressed in 36 patients. At 3 years, disease-free survival and overall survival were 75.6% and 85.9%, respectively. 37 (22.2%) patients developed adverse effects, mainly cardiovascular in 15 (8.8%). In 15 (7.8%) patients treatment was stoped, 12 (7%) by cardiac adverse effects (9 definitively stoped, 3 transitorily). Conclusions: Disease-free survival and overall survival were was lower than reported internationally. Adverse effects were frequent and similar to reported. Monitoring of adverse cardiac effects should be careful.

155 – COMPUTERISED CLINICAL DECISION SUPPORT SYSTEMS FOR PRIMARY PREVENTIVE CARE: A DECISION-MAKER-RESEARCHER PARTNERSHIP SYSTEMATIC REVIEW OF EFFECTS ON PROCESS OF CARE AND PATIENT OUTCOMES

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Objective: To review randomised controlled trials (RCTs) assessing the effects of computerised clinical decision support systems (CCDSSs) for primary preventive care (PPC) on process of care, patient outcomes, harms, and costs. Design: A decision-maker-researcher partnership systematic review. Data Sources: We searched MEDLINE, EMBASE, Ovid's EBM Reviews Database, Inspec and other databases, and reference lists through January 2010. We contacted authors to confirm data or provide additional information. Eligibility criteria for selecting studies: We included RCTs that assessed the effect of a CCDSS for PPC on process of care and patient outcomes compared to care provided without a CCDSS. Results: We added 17 new RCTs to our 2005 review for a total of 41 studies. RCT quality improved over time. CCDSSs improved process of care in 25 of 40 (63%) RCTs. Cumulative good evidence supports the effectiveness of CCDSSs for screening and management of dyslipidaemia in primary care. There is mixed evidence for effectiveness in screening for cancer and mental health conditions, multiple preventive care activities, vaccination and other preventive care interventions. 14 (34%) trials assessed patient outcomes, and 4 (29%) reported improvements with the CCDSS. CCDSS costs and adverse events were reported in only 6 (15%) and 2 (5%) trials, respectively. Conclusion: Evidence supports the effectiveness of CCDSSs for screening and treatment of dyslipidaemia in primary care with less consistent evidence for CCDSSs used in screening for cancer and mental health-related conditions, vaccinations, and other preventive care. CCDSS effects on patient outcomes, safety, costs of care, and provider satisfaction remain poorly supported.

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343 – ANTIOXIDANTS FOR PREVENTING PREECLAMPSIA: A SYSTEMATIC REVIEW

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Objective: To investigate the effectiveness of antioxidants for preventing preeclampsia and other maternal and fetal complications among pregnant women with low, moderate or high risk of preeclampsia. Methods: A systematic review in which a literature search was conducted in February 2010 and was then updated monthly until January 5, 2011, in Medline (via Pubmed), Embase, Cochrane Central, metaRegister of Controlled Trials (mRCT), Centre for Reviews and Dissemination, ISI Web of Science, Lilacs, Scielo and Scopus databases, without language restriction or limits on date of publication. Grey literature was investigated using the Proquest and Capes Thesis databases. Randomized controlled clinical trials evaluating the use of antioxidants versus placebo or a group without antioxidants were considered eligible. Results: A total of 1,120 articles were located, and 16 randomized clinical trials involving 20,808 women were analyzed. None of the grey literature was considered relevant. A meta-analysis did not show any statistically significant difference between women who received an antioxidant (vitamin C, vitamin E, lycopene, selenium, red palm oil) and women who received placebo, for the outcomes of preeclampsia (RR = 0.92; CI 95% 0.80, 1.06), severe preeclampsia (RR = 1.03; CI 95% 0.87, 1.22), preterm birth (RR = 1.03; CI 95% 0.95, 1.11), small-for-gestational-age infants (RR = 0.95; CI 95% 0.86, 1.05) and any baby death (RR = 1.02; CI 95% 0.87, 1.20). Side-effects occurred more frequently among the women who took antioxidants than among those who took placebo (RR = 1.58; CI 95% 1.11 a 2.24). Side-effects were abdominal pain, itching, eczema, vomiting, diarrhea, headache, constipation, malaise, decreased vision, skin rash and chest pain. Conclusion: The evidence does not support the use of antioxidants during pregnancy. Not only are its benefits unclear, but also adverse effects occurred more frequently with this intervention. Financial support: MCT/CT-Saúde and MS/SCTIE/DECIT, via CNPq (Edital 67/2009)

497 – EFFICACY OF HPV VACCINES TO PROTECT AGAINST CERVICAL CANCER: A META-ANALYSIS

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Persistent HPV infection is a necessary condition for the occurrence of cervical cancer. The oncogenic types HPV 16 and HPV 18 are responsible for approximately 70% of cervical cancer cases. Prophylactic HPV vaccines have been developed aimed at reducing the incidence of cervical cancer, with priority given to adolescent girls aged 9 to 15 years old. There are two commercially available HPV vaccines: Bivalent (HPV 16 and 18) and Quadrivalent (types 6, 11, 16, 18). This study aimed to perform a meta-analysis on commercially available HPV vaccine efficacy in women, with a focus on evaluation of vaccine efficacy stratified by age groups and outcomes. Six randomized controlled trials (41,750 subjects) were selected of the 378 studies identified in MEDLINE, LILACS and Cochrane Library. The vaccines significantly reduced the risk of occurrence of precursor lesions of cervical cancer presenting efficacy of 96.9% (95% CI, 90.2-99.0) for CIN2 and 96.2% (CI 95%, 89.0- 98.7) for CIN3 in the per protocol population analysis when compared to the control group. Only one study brought results of HPV vaccine efficacy by age subgroup. Involving 3,819 women of 24-45 years without previous history of infection with the vaccine subtypes on the baseline, enrolled in a randomized multicenter study with the Quadrivalent vaccine, placebo controlled with follow-up period about 26 months. For the age group of 24-34 years, vaccine efficacy was 91.8% (95% CI, 67.1-99.1) and age 35-45 years was 88.6% (CI 95%, 51.9-98.7). The prophylactic vaccination can prevent precursor lesions of cervical cancer in women from 15 to 45 years not previously infected with the HPV subtypes by at least 5 years, corresponding to the maximum time of follow-up studies included in this review. For evaluation of vaccine efficacy on the incidence and mortality of cervical cancer will be necessary, however, longer follow up studies.

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687 – PHYSICAL ACTIVITY INTERVENTIONS IN CHILDHOOD OBESITY: A SYSTEMATIC REVIEW WITH METANALYSIS OF RANDOMIZED CLINICAL TRIALS

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Context: While obesity has an increasing impact in childhood health all over the world, the effectivenes of physical activity interventions in pediatric obesity remains unclear. Objective: To assess the effect of physical activity interventions to prevent or treat childhood obesity by a systematic review and meta-analysis of RCTs. Data Sources: PubMed, Embase and Cochrane CENTRAL and references from studies and reviews included (from inception until March 2010) without language restriction. Study Selection: Eligible studies were randomized clinical trials (RCTs) enrolling children 6- 12 years-old which assessed the impact of physical activity interventions longer than 6 months on body mass index (BMI), blood pressure, total cholesterol (TC) and triglycerides. Data Extraction: Two reviewers independently carried out data extraction and quality assessment. Data Analysis: Calculations were performed using a random-effect model. Absolute changes in the studied variables were reported as differences between arithmetic means before and after interventions. Data Synthesis: Of 18.014 articles retrieved, 6 RCTs (3.528 patients) that reported BMI were included; of those, 3 reported also the other outcomes considered. Physical activity (6 comparisons; n 3.528 participants) altered: A) BMI by -0.07kg/m2(95%CI -0.31, 0.17; I20.0%) vs. no intervention, B) Systolic blood pressure (3 comparisons; n 1816 participants) by -1.16mmHg (95%CI -2.02, -0.31; I20.0%); C) Diastolic blood pressure

by -1.11mmHg (95% CI-2.30, 0.07; I270.5%), D) TC (3 comparisons; n 1529 participants) by 2.62mg/dL (95%CI -1.89, 7.13; I251.0%) and E) Triglycerides (3 comparisons; n 1675 participants) by -5.16mg/dL (95%CI -8.65, -1.67; I220.8%). Conclusion: Physical activity intervention programs longer than 6 months caused no significant effect on BMI and small changes in on triglycerides and blood pressure compared with control. All comparisons included low to moderate intensity physical activity. New approaches, including trials with greater exercise intensity and association of more comprehensive strategies are needed to improve these results. Financial support: MCT/CNPq/CT-Saúde/MS/SCTIE/DECIT, FAPICC

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721 – HIGH DOSES VERSUS LOW DOSES OF STATIN THERAPY

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Objective: The aim of this study is uptodate the information of morbidity and mortality with the use of statins in different doses, high dose versus low doses, using measures of absolute risk. Methods: We conducted a search of articles in the PubMed, EMBASE and Cochrane, with an end date in 31/12/10. Qualitatively evaluated by the Jadad scale, the percentage adjustment to the main CONSORT items. We extracted data from articles by a spreadsheet developed based on the model suggested by SR_CRD York. Data were tabulated comparing statins in high and low doses, by absolute risk in the control group (RAC) the reduction in the intervention group (ARR), CI95% and NNT. Results:29.202 articles were retrieved, 26.611 in english, spanish or portuguese languages, 2.997 selected with RCT[Publication Type], 2.925 excluded after title and resume evaluation and 30 after full evaluation. 42 articles were included and entirely extracted, 6 of them were comparing high doses versus low doses. 2 of this articles compared 80mg of atorvastatin (A) with 40mg of pravastatin (P), 2 compared 80mg of simvastatin (S) with 20mg, 1 study A80 versus S20 and another A80 versus A10, with a total of 40505 patients. All cause mortality, unstable angina and cardiac insufficiency hospitalization were not significant. Non fatal acute myocardial infarction RAC 0,0674; ARR 0,0051 (0,0004 – 0,0099); NNT 196, Non fatal stroke 0,0142; ARR 0,0025 (0,0009 – 0,0059); NNT 400 and CABG RAC 0,0272; ARR 0,0117 (0,0009-0,0224); NNT 85 were significant in favor of high doses. Conclusions: High doses of statins demonstrated more relevant morbidity outcomes related to non fatal AMI and CABG, however the effect size expressed in NNT are 196 and 85.

827 – SUSTAINABLE VIOLENCE PREVENTION: INTERVENTIONS ASSOCIATED WITH A LONG-TERM REDUCTION IN VIOLENT BEHAVIOUR

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Background: A sustainable society is one in which conflict is successfully managed. Violent behaviour is a type of conflict which has high public and political visibility and which can be managed through a range of interventions delivered by health and criminal justice agencies. A recent update of a systematic review conducted by the Liverpool Violence Research Group explores the evidence base for interventions to reduce violence in mental health and offender populations and provides the opportunity to examine which interventions are associated with sustained improvements in violence propensity. Objective: To examine the factors associated with long-term reductions in violent behaviour amongst mental health and offender populations. Method: A comprehensive search strategy covered the period 2002-2008 and included 19 databases. Predefined inclusion/exclusion criteria were applied to citations in a two-stage process and data were extracted into SPSS. For the purpose of this analysis a follow-up period of at least two years was required. Results: Forty-four studies met the inclusion criteria. Most of these were quasi-experimental trials (N=43%) and single-group pre-post comparisons (39%). Most (84%) were interventions for offenders, including those with a mental illness. The mode of intervention was primarily non-pharmacological (95%). Reported outcomes were mainly reassault (68.2%); either reconviction or recorded incidents of violence and 57% of studies reported a significant reduction in violence over the study period. A series of post-hoc bivariate analyses of study characteristics against a significant reduction in violence failed to show any relationship; therefore multivariate analyses were not conducted. Conclusions: Only 57% of studies showed a sustainable reduction in violence and bivariate analyses failed to show any characteristics that may increase the likelihood of an intervention working long-term. Future research should aim to measure longer-term outcomes particularly in pharmacological studies and studies including non-offenders.

267 – ECONOMIC EVALUATIONS OF HUMAN PAPILLOMAVIRUS (HPV) VACCINE IN ADOLESCENT GIRLS: A SYSTEMATIC REVIEW

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Cervical cancer is a major health problem worldwide, particularly in developing countries. Two vaccines against HPV are available for use in adolescent girls before the onset of sexual behavior: a bivalent against serotypes 16 and 18, and a quadrivalent against serotypes 6, 11, 16 and 18. These are intended to act as primary prevention of cervix cancer. The use of vaccine in population based programs depends on a complex decision making process based on a Health Technology Assessment. The economic evaluations are part of this process. These assessments were the object of this work, which evaluate the evidence coming from a systematic literature review of studies of economic evaluation of the use of human papillomavirus vaccination in adolescent girls and pre-teens. We performed a literature search in MEDLINE, LILACS and NHSEED until June 2010. Two readers independently selected full economic evaluation. After the search, 188 of these titles were identified, 39 studies met the eligibility criteria and were included in the review. As a review of economic evaluations we did not performe a synthesis of ICER. The 39 articles included 51 economic evaluations in 26 countries. Cost-utility studies predominate (51%). From the standpoint of the perspective, there were predominant view of health systems (76.4%). Most studies (94.9%) chose girls, aged between 9 and 12 years as target population (94.9%) and developed simulations considering immunity for life (84.6%). The models used were Markov in 23 analysis, transmission dynamics in 11 and hybrid models in 5. The sensitivity analysis revealed a number of critical elements that influenced ICER, a significant part of which related to vaccine: costs, duration of immunity, booster doses, vaccine efficacy and program coverage. These elements make up an area of special attention for future models that may be developed in Brazil for economic analysis of vaccination against HPV.

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280 – CLINICAL AND ECONOMIC IMPACT OF INTRODUCING THE USE OF CHLORHEXIDINE-IMPREGNATED SPONGES FOR CENTRAL VENOUS CATHETERS DRESSINGS IN AN INTENSIVE CARE UNIT

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Background: Nosocomial infections occur in 5 to 10% of hospitalised patients and can have serious consequences including patient's death. Central venous catheter (CVC) infections can be prevented by applying a disinfectant-impregnated dressing (e.g.chlorhexidine, Biopatch®), which is more expensive than usual dressings. We assessed its clinical and economic impact in our 32-bed intensive care unit in 2009 as compared with 2006. Methods: Prospective surveillance of catheter-related infections was carried out according to standard guidelines, allowing computation of infection rates / 1000 CVC-days. The number and costs of Biopatch® dressings changed every 4 days was compared with the number and costs of usual dressings changed every 2 days, and balanced against the number of CVC infections (primary and CVC-related bacteremia) observed with each methods, assuming a 10-day increase in length of stay and CHF 20'000 increase in costs for each infection, in a hospital perspective. Results: The introduction of Biopatch® dressing decreased the infection rates from 3.8/1000 CVC-days to 1.8/1000 CVC-days (40% reduction), saving 68 infectious episodes per year. The cost increase associated with the 12'041 Biopatch® dressings (CHF 84'286) was balanced by a decrease in ICU utilisation of 683 days, amounting to CHF 1'366'760. Conclusion: The new dressing increases material costs, but decreases CVC associated infectious episodes, allowing indirect savings in ICU days and costs, and reallocation of these rare resources to other patients.

524 – PRE-OPERATIVE FLUID LOADING FOR HIGH RISK PATIENTS UNDERGOING MAJOR ELECTIVE SURGERY: A COST-EFFECTIVENESS ANALYSIS

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Objective: To determine the cost-effectiveness of pre-operative fluid loading using 25ml/kg Hartmann's (Ringers) solution over the six hour period before surgery in the ward setting in patients undergoing high risk major elective surgery compared with no fluid loading. Methods: We conducted an economic evaluation alongside a pragmatic multi-centred randomised controlled trial. Costs relating to the intervention and subsequent use of health care resources were estimated over the 6 months after surgery. Patient utility estimated using the EQ-5D questionnaire administered at baseline (before surgery), 48 hours, 1, 3 and 6 months after surgery was used to calculate Quality Adjusted Life Years (QALYs). Cost and QALY differences between arms were compared using incremental cost effectiveness ratios and the probability of cost-effectiveness was estimated and presented using cost-effectiveness acceptability curves. Results: We randomised a total of 111 patients, (fluid: 57; no fluid: 54), of which 109 contributed data at the primary outcome time point (fluid: 55; no fluid: 54). The intervention cost £51. When adjusted for baseline EQ-5D and minimization variables, the fluid loading group was on average -£2,047 less costly (95% CI -£6,947 to £2,854 p= 0.254) than no fluid loading. Reduction in hospital length of stay immediately post surgery was the main driver of cost differences. Fluid loading resulted in greater quality adjusted life years (0.3527 vs. 0.3175; 95% CI -0.0171 to 0.1033) than no fluid loading and was thus the dominant treatment option. Fluid loading was associated with an 87% probability of cost-effectiveness at a willingness to pay per QALY threshold of £20,000. Sensitivity analyses did not alter the overall conclusions. Conclusion: There is a high probability of pre-operative fluid loading using 25ml/kg Hartmann's (Ringers) solution over the six hour period before surgery being less costly and more beneficial than routine (no fluid) care.

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698 – COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF RIVAROXABAN IN THE PREVENTION OF THROMBOEMBOLIC EVENTS IN PATIENTS PERFORMING HIP AND KNEE ARTHROPLASTY IN COMPARISON WITH ENOXAPARIN UNDER THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM PERSPECTIVE

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Objectives: To develop a cost-effectiveness and a budget impact analysis of Rivaroxaban in the prevention of thromboembolic events in patients performing hip and knee arthroplasty in comparison with Enoxaparin under the Brazilian private health care system perspective. Methods: A decision tree analysis was developed for the first 90 days, considering the occurrence of Deep Venous Thrombosis, Pulmonary Embolism and thromboembolic events, followed by a Markov model, for Post Thrombotic Syndrome and Thrombotic Pulmonary Hypertension. The time horizon of the analysis was 5 year. The cycle duration was 1 year and corresponding epidemiological and efficacy data were obtained from a critical appraisal of the scientific literature. The outcomes were expressed as the incremental number of all thromboembolic events. The analysis considered only direct medical costs. Unit costs for drugs, procedures, materials and daily hospital were obtained from Kairos Magazine (Maximum price consumers 18% ICMS), Hierarchical Brazilian Classification of Medical Procedures (CBHPM 5thedition), Simpro Magazine (Maximum price consumers 18%ICMS) and UNIDAS 2008, respectively. A budget impact analysis was developed considering an increase of 10% per year in market share of Rivaroxaban. Results: Total costs associated with Rivaroxaban and Enoxaparin, considering the indication for knee arthroplasty, were BRL363 (US$214) and BRL632 (US$372), respectively. Rivaroxaban reduces the number of all thromboembolic events in 0.0167. Rivaroxaban treatment is more effective and cheaper than Enoxaparin treatment (dominant). Total costs associated with Rivaroxaban and Enoxaparin, considering the indication for hip arthroplasty, were BRL332 (US$195) and BRL468 (US$275), respectively. The number of all thromboembolic events was the same. Rivaroxaban treatment is cheaper with same efficacy. The budget impact analysis estimated an economy of BRL98,810 (US$58,124) and BRL184,630 (US$108,606) for knee and hip indication, respectively, in 5 years. Conclusions: By this pharmacoeconomic analysis, the treatment with Rivaroxaban, shown to reduce treatment costs and events compared with Enoxaparin.

947 – INCREMENTAL COST-EFFECTIVENESS ANALYSIS OF USING ANTITETANUS IMMUNOGLOBULIN BY INTRATHECAL ROUTE TO THE TREATMENT OF TETANUS IN RECIFE (PE), BRAZIL

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Introduction: This is a cost-effectiveness study of a previously reported randomised controlled trial of tetanus treatment with anti-tetanus immunoglobulin administrated via intrathecal or intramuscular route in Recife, Brazil. Objective: The main objective of this study was to estimate the incremental cost-effectiveness ratio of two routes of treatment of tetanus. Methods: The study consisted of a sample of 120 patients with tetanus, aged 12 years or more, both sexes, admitted to the intensive care unit at the Oswaldo Cruz University Hospital in Recife. Patients were randomised to receive 1000 international units (IU) of human immunoglobulin either via an intrathecal (treatment group) or intramuscular route (control group). Effectiveness was assessed by comparing the two routes of treatment in terms of severity of tetanus within 10 days of admission, defined as the duration of occurrence of spasms and grade of disease (I and II, less severe; III and IV, more severe). Costs were estimated using standard methodology, where the mean (or median) use of resource is multiplied by the unit cost of the referred resource to result the estimated direct mean cost incurred by the public health system. The discounted incremental cost-effectiveness ratio was estimated in terms of cost per DALY averted, comparing the two alternatives; a 3% discount rate was used in the analysis. Results: The average cost to treat patients with a tetanus grade I was US$ 1,042, grade II, US$ 2,299, grade III, US$ 3,628, and grade IV, US$ 6,369, in the control group. In the intervention group, the costs were, US$ 1,465; US$ 2,740; US$ 4,069; and US$ 6,809, respectively, in the intervention group. The effectiveness of the intrathecal route was estimated in 44%. The discounted cost per DALY averted was US$ 111. Conclusion: Intrathecal route to treat tetanus is highly cost-effective.

171 – CLINICAL PRACTICE GUIDELINE ON CELIAC DISEASE: EXPERIENCE FROM A DEVELOPING COUNTRY

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Objectives: To develop evidence-based recommendations on Celiac Disease (CD) and thus assist both professionals and patients in making informed decisions on the most appropriate healthcare approach for this specific condition. The groups of clinical interest are: adults and children who attend the Primary Health Care System in Argentina. Methods: The guideline development group is a multidisciplinary team of all relevant specialists and includes methodologists and patients. We used the Guideline Adaptation Process defined by the AGREE Collaboration and the National Ministry of Health. The professionals defined the scope and agreed on 6 key clinical questions in PICO format. Bibliographic search for clinical practice guidelines (CPG), systematic reviews and original studies was performed in: Medline, Cochrane Library, US National Guidelines Clearinghouse, TRIP Database, Pubgle, Lilacs, from January 2000 to June 2009. The critical appraisal of the retrieved literature was done using specific instruments (AGREE, SIGN checklists and evidence tables). Recommendations were developed using SIGN's methodology and involving patient's points of view. The final clinical practice guideline is presented in different formats: complete version, short version, algorithms and patient decision aids. Findings: The CPG included 15 recommendations. The key recommendations were: 1) Screening for CD should be performed with IgA antihuman tissue transglutaminase (evidence graded A); 2) Biopsies of the small bowel are indicated in individuals with a positive celiac disease antibody test (evidence graded A); 3) If celiac disease is strongly suspected despite negative serologic test results we recommend to derivate to the specialist (evidence graded B); 4) The management of celiac disease is a gluten-free diet for life (consensus); 5) Psychological support is recommended to increase gluten-free diet compliance (evidence graded A). Conclusions: This evidence-based clinical practice guideline on celiac disease is an important tool for the decision making process of Argentinean National Healthcare System professionals and patients.

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180 – HOW FAR AWAY PRACTICE GUIDELINE ARE FROM THE EVIDENCE BASED GUIDELINE IN CHINA?

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Background Clinical guideline is the bridge from the research evidence to practice and evidence based guideline is thought as current better guideline which developed by scientific methods. With the increasingly costs, the complication and diversity of healthcare, more clinical guidelines were developed. How far away practice guidelines are from the evidence based guideline in China? Objective To explore the current status of practice guidelines and better improve the quality of healthcare in China. Methods We used words \'prevention and treatment guideline\' or \'clinical guideline\' or \'practice guideline\' or \'protocol\' or \'practice standard\' or \'practice option\' or \'evidence guide\' consensus in title by searching the Chaoxing Library on medicine & health; and used \'evidence\' and \'guideline\' searched Chinese biomedical database (CBM), CNKI and VIP, reference, etc. Exclude that non primary guideline, eg. News, translation, comments. Search date till April 1, 2010. Findings 1. 315 guidelines included, which published in books and in papers from 1956 to 2010. Guidelines mainly related to disease prevention and treatment, the pages from 4 to 1686. 2. Most of guidelines were developed by an inter-disciplinary group and the recommendations were based on experts\' consensus. Only 4.76% (15/315) guidelines based on evidence and with grade of evidence and relevant recommendations. These guidelines were issued after 2000 and developed by Chinese medical association, which mainly related to stroke, critical care, diabetes and chronic hepatitis, etc. 3. We identified few guidelines which patients had opportunity involved in development process. Only a few guidelines stated the target population, relevant harm, costs, and with external review and seldom cited reference. Conclusions Currently there are small proportions of evidence based guidelines in China. More activities on translating current evidence into guidelines should be promoted. It is necessary to develop a national guideline for development of evidence based guideline to facilitate the guideline

250 – EVIDENCE-BASED USE OF HUMAN ALBUMIN SOLUTIONS IN PEDIATRIC INPATIENTS. ANALYSIS OF THE ECONOMIC IMPACT OF A CLINICAL PRACTICE GUIDELINE IN A PUBLIC HOSPITAL

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Background: In 2000 albumin ranked fourth in our pharmacy drug expense list. This fact, together with the controversial publication of a Cochrane systematic review on albumin use, triggered our first technology assessment and marked the beginning of our hospital-based HTA program. This study analyzes the economic impact of sequential interventions aimed at the evidence-based use of albumin in our hospital, a national pediatric referral center with 500 beds and a self-managed budget. Methods: A systematic review of available evidence followed by expert consensus was used to generate and periodically update a clinical practice guideline on pediatric indications for albumin solutions. Different implementation methods were tested during sequential interventions. Data on albumin consumption were continuously monitored over 10 years as a time series. Associated costs in argentine pesos are presented for each pre and post-intervention periods. Results: During the pre-intervention phase in 2000, 5911 vials of albumin were consumed resulting in a $115.265 pharmacy expense. In 2002, after the first intervention (guideline diffusion at a local scientific meeting in 2001), albumin utilization and expenses were reduced by 50%. In 2003 albumin consumption raised again, mandating our second intervention (publication of a brief version of the guideline as a printed pharmacy bulletin). Sequential monitoring revealed a stabilization period (2004-2006) followed by a substantial increase in expenses in 2007-2008 (vials consumed raised and price tripled). Following our last intervention (an updated web-based full guideline) albumin use decreased by 37% in 2009, resulting in annual savings of $201.264. Conclusions: Albumin is one of the main tracing drugs in our HTA program. Multi-modal guideline implementation strategies can be effective in changing prescription patterns, but they should be tailored to local needs and habits. Continuous monitoring is mandatory to detect non-random variability and enable timely reinterventions aimed at improving healthcare quality and reducing unnecessary expenses.

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623 – PRODUCTION AND DIFFUSION OF CLINICAL PRACTICE GUIDELINES (CPGS) IN IBEROAMERICAN COUNTRIES: A CROSS SECTIONAL STUDY

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Aim: to map, catalogue and compare the quantity and characteristics of published CPGs produced in different Iberoamerican countries. Secondarily, valuable CPGs and CPG producers will be identified in order to test the feasibility of a Latin-American Guidelines Clearinghouse. Methods: Published guidelines (GLs) produced in Iberoamerican countries in a 10-year-period (January 1996 -December 2005) were identified through electronic database searching. We included documents that were produced in an Iberoamerican country; published during the 1996-2005 period and provided a full abstract. Electronic databases searching (EDS) were executed through a validated strategy. It was performed in MEDLINE under PubMed platform and EMBASE. The strategy was adapted to regional databases (LILACS). Results were registered in a single database and duplicated articles were eliminated. Results: A total amount of 5,512 documents were identified; 1,559 (28%) were finally considered eligible. Percentage of eligible documents was similar in Medline (553/1160; 48%) and Embase (375/750; 50%) databases and lower in Lilacs (631/3602; 18%). 65% of Iberoamerican guidelines were produced by two countries: Spain and Brazil. 42% of the 311 finally considered guidelines were produced by Spanish organizations, followed by Brazil (23%), Colombia (9%), Chile (9%), Mexico (7%), Argentina (5%) and Portugal (4%). Three countries (Cuba, Puerto Rico and Venezuela) published only one guideline indexed in databases, representing less than 1%. There were marked differences in the guideline diffusion pattern when comparing European and Latin-American countries. Conclusion: With the exception of Spain, guideline development and diffusion in Iberoamerican countries are in their initial stages. Although some Latin-American countries have already made some progress in this area, most of these initiatives have not been systematized, reducing the number of guidelines indexed in biomedical journals. Efforts have been especially made in Brazil and Mexico to increase the CPG production, those efforts should contrasted with the production identified in this research.

883 – EVALUATION OF THROMBOPROPHYLAXIS IN A TERTIARY CARE HOSPITAL IN BRAZIL BY ELECTRONIC EVIDENCE-BASED TOOL

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Venous thromboembolism (VTE) is the leading preventable cause of inpatient death. Worldwide researches have shown that most hospitalized patients are at risk for VTE, but many do not receive the appropriate interventions. Despite many trials demonstrating benefits, low adherece to evidence-based thromboprophylaxis compromises the optimal benefits of therapy. Objective: To evaluate the compliance with the 8th Edition of the ACCP VTE guidelines in a tertiary care teaching hospital using the convenience of the local electronic health records (EHR). Methods: Hospital Nossa Senhora da Conceição is a 750-bed tertiary care teaching hospital located in Porto Alegre, Brazil. We developed a specific template integrated to our EHR to facilitate data collection and minimize errors. Between October 2008 and January 2009 we randomly selected 262 inpatients for evaluation. Previously trained physicians interviewed patients and reviewed charts of all patient sample. All data was collected and analyzed using the new tools built in the local EHR. Findings: Most patients were at high risk for VTE(54,6%)or were at moderate risk(44,7%). Despite the elevated risks, only 46.2% of the study population was receiving adequate prophylaxis. There was no difference between medical or surgical patients, 44,2% vs 53,6%, respectively (OR 0,69 IC95% 0,38-1,24). Risk factors more commonly found were immobilization (70,6%), infection (44,3%) and cancer (27,5%). The lowest evidence based care was related to patients with 3 or more risk factors (25%) or cancer (18,1%), both at high risk of events. Conclusions: In agreement with previous published studies, we found low adherence to best practices. The findings related to patients at high risk for events were especially worrisome. Actions targeted to both groups are being undertaken. The use of an electronic template integrated in the EHR made large data collection feasible. This resource will be crucial, allowing for systematic evaluations and quality improvement initiatives.

162 – STORAGE AND DISPOSAL OF MEDICINES IN HOMES OF RESIDENTS OF A POOR NEIGHBORHOOD IN THE CITY OF XANGRI-LÁ, RS

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Objective - To have drugs at home may seem a matter of security. Poor storage and proper disposal is not easily accessible to children can become a big problem. This research proposed to determine the presence of pharmacy home, documenting the sites for storage and, if the population would have the knowledge of how to make your disposal. Methods - A cross sectional study was conducted among 70 families from the neighborhood Figueirinha located in the central city of Xangri-Lá, RS, registered in the Basic Health Unit of the Family Health Strategy Figueirinha. Information was gathered through interviews conducted in homes using a semi-structured questionnaire with closed questions in a period of 12 months. Results: The age of residents ranged from: 45.75% 6-12 years, 10.85% 13-18 years, 35.85% 19-60 years and 7.54% over 60 years . All 70 families had different types of drugs stored at home, with a predominance of drugs acting on central nervous system emphasizing analgesics followed by those working in the cardiovascular system due to the high prevalence of hypertension in this population. 55.7% in the kitchen store the medicines out to be a convenient place for easy viewing and 34.8% in the quarter. 98.7% of households had expired products and was discarded in the trash. In the neighborhood does not have basic sanitation which made us find packages of drugs around the streets and in the backyard of the houses. The knowledge on the subject is lacking, preventing the population to an appropriate storage and disposal of medicamentos. Showed the important role of health professionals to guide how to direct the expired products to the right place, aiming to avoid public exposure the risks of drug poisoning and environmental pollution.

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177 – PATIENTS' ATTITUDES AND VALUE TO ORAL ANTICOAGULATION THERAPY TESTING AT OUTPATIENTS SERVICES: A SURVEY

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Background: Oral anticoagulation therapy is prescribed for long-term in several medical conditions such as the deep vein thrombosis and stroke. A large number of patients frequently visit outpatient clinical services for regular monitoring of the OAT through testing of the prothrombin time (PT) and the international normalised ratio (INR) to avoid complications because of higher or lower coagulation of the blood. Objectives: To determine latent dimensions and predictors of outpatients' experiences with anticoagulation services. Study Design: Cross-sectional questionnaire survey of patients at an acute NHS trust hospital in London. Results: Response rate was 35.7% (n=125). The majority of patients were male (64%), aged ≥71 years (60%) and white British (84%). Thirty-five percent patients attended the outpatient anticoagulation clinic every month for PT/INR testing and 97% of patients received the test results by a letter from the clinic. Seventy-eight percent patients were very satisfied with the current method of getting test results and kept a personal record of their PT/INR test results, which was rated very useful by 76% of those patients who kept the record. Fifty-two percent patients discussed their PT/INR level with anticoagulation clinic doctors or nurses and 73% of them were very satisfied with the discussions. Two latent dimensions representing the 'attitude' and 'value' of patients' experience with outpatient anticoagulation services were identified through exploratory and confirmatory factor analyses. The 'attitude' dimension was statistically significantly predicted by 'how long the patient will continue to have PT/INR checked' while the 'value' dimension was statistically significantly predicted by the 'satisfaction with the way the patient gets PT/INR test results' and 'usefulness of keeping a personal record of results of PT/INR tests at the hospital clinic'. Conclusions: Patients taking OAT recognise PT/INR testing at outpatient anticoagulation clinic as valuable and they have positive attitudes towards the service. Keywords: PT/INR testing, patient

317 – DOES INR POINT-OF-CARE TESTING BY HOMECARE NURSES IMPROVES CLINICAL OUTCOMES FOR PATIENTS ON LONG-TERM ORAL ANTICOAGULATION THERAPY?

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Objective: To evaluate the effectiveness of INR point-of-care (POC) testing in management of long-term oral anticoagulation therapy (OAT) by homecare nurses. METHODS: Literature search was performed in multiple databases (PubMed, Embase, Cinhal) and grey literature to identify systematic reviews (SRs) and randomized controlled trials (RCTs). INR monitoring by POC testing was compared to standard laboratory method. Primary outcomes were time in therapeutic range (TTR), major thromboembolic and haemorrhagic events, and deaths. Two independent reviewers performed article selection, quality assessment, and data extraction. Synthesis review and appraisal were shared with a medical experts group. RESULTS: Data extraction was performed in eight SRs (n=25 RCTs) and three RCTs (updated search). No data about INR POC testing by homecare nurses were found. Results suggest that clinical effectiveness of POC devices in OAT management depends on the type of care delivery model. Patient self-testing (PST) and self-management (PSM) were the most evaluated models and account for 83% of RCTs. Higher percent TTR of INR values, fewer major thromboembolic and haemorrhagic events were associated with these models but results varied depending on the comparison group. Similar outcomes were observed with INR results by laboratory testing in OAT clinics but not in general practice. The effect of POC testing on all-causes mortality remains unclear. Methodological flaws in RCTs were seen including OAT indications, study duration, and outcome definitions. Moreover, other factors (higher frequency of INR testing, training performance bias) than the POC testing could have contributed to the results in the intervention group. Low participation rate and high level of lost to follow-up in most studies limit also the generalizability of the results to the population under OAT. CONCLUSION: Clinical effectiveness of POC devices does not appear detrimental in a highly selected population (PST and PSM) taking OAT whereas it is undetermined in other settings.

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498 – COMPLIANCE OF CHRONIC ELDERLY PATIENTS AND PRIMARY HEALTHCARE PROFESSIONALS WITH A HOME TELEMONITORING SYSTEM

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Introduction: The issues of follow-up and compliance with the emerging telemonitoring systems have not been thoroughly evaluated but could be critical for the adoption of these technologies. Objectives: To assess the compliance of chronic elderly patients and healthcare professionals with a novel primary care-based telemonitoring system. Methods: In-home patients with heart failure and chronic lung disease aged 81.0±7.5 years were enrolled at 23 primary healthcare centres and randomised to either a home telemonitoring intervention (intervention group n=28) or usual care (control group n=30). For the intervention group telemonitoring consisted of daily transmissions of self-measured respiratory/heart-rate, blood-pressure, oxygen-saturation, weight, temperature, and a brief clinical questionnaire. The telemonitoring system comprised personalised alerts set for each patient, triggered when measurements were out of the established limits. Preliminary telemonitoring compliance outcomes were assessed at three-month follow-up. Results: Patients' compliance with the telemonitoring system was high. During a cumulative monitoring period of 2,373 days, there were 1,994 data transfer sessions, a mean of 71.2 (SD 16.8) per patient. 75.3% of the patients conducted the pre-established daily data transmission. There were 2,311 accesses to the telemonitoring Web-platform by healthcare professionals. General practitioners accessed the platform more frequently than nurses, 57.4% over 42.7%, respectively. An average of 51.5 alerts was generated per patient. The alerts were triggered by oxygen-saturation (25.4%), blood-pressure (25.1%), respiratory-rate (18.6%), responses to the clinical questionnaire (16.5%) and high body-temperature (6.3%). Conclusions: Compliance with telemonitoring was high and well documented both for patients and healthcare professionals. Our results indicate that the use of ICTs for healthcare applications is feasible for elderly patients with limited computer literacy. Despite the compliance of nurses has been fairly high, strategies should be put in place to enhance the roll of nurses in future telemonitoring interventions. Compliance variations over time will be analysed after one year of follow-up.

625 – HEALTH TECHNOLOGY ASSESSMENT FOR PATIENT DECISION AIDS SOFTWARE IN BREAST CANCER

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Objectives: To develop a health technology assessment (HTA) focused on Patient Decision Aids (PDA) for breast cancer and to build up a PDA tool in software format for this context. Our aim is to improve the quality of decisions for therapeutic options and to promote shared decision making. Methods: A systematic review (SR) of Decision Aids in breast cancer was performed. Search includes main databases as well as websites of institutions working with PDAs. Additionally, qualitative research (QR) techniques were conducted: semi-structured interviews and a focus group with stakeholders (patients, family members and health professionals). Through this HTA process we developed a PDA for breast cancer. Results: The SR shows that PDAs in breast cancer increase patient knowledge on the illness and generates more realistic expectations. PDAs also reduce passivity in the decision-making process to find the option that best suits their preferences. Analysis of QR reflects that both patients and professionals agree that surgery, adjuvant treatments and breast reconstruction are most important decisions to face. Patients' experience of the illness is related to anxiety but also to optimism and confidence in professionals. The PDA software offers an interrelated treatment sequence and includes general information, treatment descriptions, benefits and risks (with visual aids explaining probability of risk), information regarding body image, a glossarys, the experiences of other people who've lived similar situations, and decisional balance sheets with which to reflect on the pros and cons of each option, with statistical and animated graphics and resources. Conclusions: This PDA for breast cancer, based in a SR and QR, allows patients to access information and to share decisions regarding treatment. It also provides patients and professionals the opportunity to acquire knowledge and to exchange experiences. PDA software through patient involvement in HTA is crucial to afford the challenge of sustainability in healthcare.

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630 – EFFECT OF WRITTEN EMOTIONAL DISCLOSURE INTERVENTIONS IN PERSONS WITH PSORIASIS UNDERGOING NARROW BAND ULTRAVIOLET B PHOTOTHERAPY

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Objectives: A beneficial health effects of emotional writing disclosure (ED) on several chronic diseases has been described. The aim of this staudy was to investigate the effects of two different ED techniques on disease severity and quality of life (QoL) in psoriatic patients treated with UVB therapy. METHODS Forty patients with psoriasis (mean age 45± 18 years) were randomly assigned to two different ED treatments (according to Pennebaker [PW] writing about stressful events, or according to King [KW], writing about major life goals), or to a control group (CG). Disease severity and QoL were assessed at baseline, halfway through and at the end of UVB treatment, and again 4 months after ED. Outcome measures were the PASI and SAPASI scores, to assess disease severity; the Skindex-29, to evaluate health-related QoL; and the GHQ-12, to assess psychological wellbeing. Findings: Statistically significant differences in SAPASI scores were recorded between end of therapy and the final assessment in KW and CG individuals, whereas no differences were found in PW patients. Differences between baseline and final Skindex-29 scores were not statistically significant in any group; nonetheless consistently lower 4-month scores in PW patients indicated a better health status. Also, all but the PW patients showed significant increases between end of UVB therapy and final scores on all three scales (emotional, functioning and symptoms). Although all groups had similar GHQ scores, KW patients had the worst GHQ values, especially at the final assessment. Conclusions: In our pilot study, we observed that patients with psoriasis allocated to the writing exercise on traumatic and distressing experiences (PW protocol) have a longer period of remission after phototherapy. This provides preliminary evidence that such a simple and inexpensive tool may play a role in enhancing treatment efficacy and QoL, so that further research in this area may be warranted.

264 – EVALUATION OF EFFICACY OF ENDOSCOPIC SCREENING FOR GASTRIC CANCER

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Although gastric cancer mortality has decreased in Japan, there were 50,017 deaths from gastric cancer in 2009, which accounted for 14.5% of all cancer deaths. Gastric cancer screening using radiography has been conducted for the last three decades as public policy and is still expected to prevent premature deaths. It is anticipated that endoscopy will be used as a new screening method. A case-control study was conducted to evaluate the efficacy of endoscopic screening for gastric cancer in Tottori prefecture, Japan. Case subjects were defined as persons who had died of gastric cancer between 2001 and 2006 in Tottori prefecture. Those who died of gastric cancer were identified using death certificates. Up to six control subjects were matched by sex, birth year (plus and minus 3 years), and residence of each corresponding case from population lists in the study areas; thus, 270 cases and 1496 controls were selected. Compared with those who had never participated in screening before the date of diagnosis of gastric cancer in cases, the odds ratios (ORs) within 12 months from diagnosis were 0.643 for endoscopic screening and 0.726 for radiographic screening, but these were not significant. When the screening period was expanded to 24 months, the OR of endoscopic screening was significant (0.511, 95%CI: 0.282-0.926), but it was not significant for radiographic screening (0.671, 95%CI: 0.400-1.125). Although our result suggests the efficacy of endoscopic screening for gastric cancer, there were several limitations, including self-selection bias. Further study is needed before introducing endoscopic screening in communities.

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564 – DETECTION OF NERVE FIBRES IN AN ENDOMETRIAL BIOPSY AS A NEW DIAGNOSTIC TEST FOR ENDOMETRIOSIS

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Background: Laparoscopy is a surgical procedure considered the gold standard method for the diagnosis of endometriosis. Recent studies have showed that there is a high density of small nerve fibres in the functional layer of the endometrium in women with endometriosis. Objective: To study the efficacy of endometrial biopsy in detecting small nerve fibres in the endometrium as a less invasive diagnostic test in women with endometriosis. Method: Early assessment of this technology identified and prioritized by the early warning system “SINTESIS-new technologies” of AETS-ISCIII. Databases searched were Medline (Pubmed), Embase, the Cochrane Library and CRD. Studies published in any language until December 2010 were retrieved. We calculated from each study Sensitivity (S) Specificity (Sp) Positive Predictive Value (PPV), and Negative Predictive Value (NPV) (95% Confidence Interval) of the test. Results: Only three retrieved studies analysed endometrial nerve fibres using immunohistochemical techniques by neurotransmitters on an endometrial biopsy as a diagnostic test of endometriosis. Selected studies included women of reproductive age undergoing laparoscopy for pelvic pain and/or infertility and not receiving hormonal treatment. Studies compared endometrial biopsies in women with and without endometriosis using laparoscopy as a gold standard. Two studies were case-control studies and the third study was a double blind prospective study. Sample size was 27, 40 and 99 cases, respectively. Measures of S were: 100%, 90% (66.9-98.2%), and 98% (90-99%); Sp: 80% (51.4-94.7%), 60% (36.4-80%) and 83% (66–93%); PPV: 80% (51.4-94.7%), 69% (48.1-84.9%) and 91% (81–96%), NPV: 100%, 85% (56.1-97.5%) and 96% (81–99%). The area under the curve was calculated to be 0.96 in the only study providing this data. Conclusions: Detection of endometrial nerve fibres in an endometrial biopsy can be an accurate method for diagnosis of endometriosis and it is less invasive than laparoscopy. Additional studies are necessary to confirm these results.

768 – POSITRON EMISSION TOMOGRAPHY WITH 2-[18F]-FLUORO-2-DESOXY-D-GLUCOSE AFTER TWO CYCLES OF R-CHOP PREDICTS EVENT FREE SURVIVAL IN DIFFUSE LARGE B-CELL LYMPHOMA IN BRAZIL

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Objectives: To assess the prognostic value of interim FDG-PET after two cycles of chemotherapy using R-CHOP in overall patients with diffuse large B-cell lymphoma (DLBCL). Methods: A total of 46 patients with newly diagnosed DLBCL were prospectively included in this multicenter study including patients from Brazil and Chile. All submitted to standard R-CHOP therapy followed by consolidation radiotherapy in case of bulky disease. After two cycles of R-CHOP patients were evaluated with interim PET (PET2). Prognostic analysis compared three-year event free survival (EFS) rate to PET2 results, clinical data and R-International Prognostic index (RIPI). Results: Of the 46 evaluated patients, 40 achieved complete remission after first-line therapy. In a median follow-up of 8.0 (±4) months, death, relapse or disease progression was seen in 12 patients. Treatment failure was seen in five of the 13 PET2-positve patients and in only seven of the 33 PET2-negative patients. PET2 had hazard ratio of 2.3. One year EFS for PET2-positive patients was 41.0% and 77.3% for PET2-negative ones. Conclusion: PET2 is an accurate and independent predictor of EFS in DLBC. A negative interim FDG-PET is highly predictive of treatment success in overall DLBC patients independent of RIPI risk.

178 – RAPID TESTS AS NEW METHODOLOGIES FOR HEPATITIS B AND C DIAGNOSIS

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Health authorities in several countries recently recommended the expansion of Hepatitis B and C virus (HBV and HCV) testing, including the use of rapid tests. Several HBV and HCV rapid tests are now licensed in Brazil but their sensitivity and specificity on total blood and/or serum samples is not known. The objective of this study was to evaluate four different rapid tests, two of them to detect HBV surface antigen (HBsAg) and two of them to detect antibodies against HCV (anti-HCV) among serum samples. One hundred and thirty four healthy adults and 39 HBsAg seropositive volunteers were recruited to give serum samples to evaluate HBV assays. For HCV assays evaluation, 125 healthy subjects and 77 seropositive individuals were included. HCV infection was confirmed by RIBA positivity (Ortho-Clinical Diagnostics) and HBV infection was confirmed by neutralization assay (Diasorin). The two HBV rapid tests were Imuno-Rápido HBsAg (Wama Diagnostica) and Vikia HBsAg (Biomérieux) while HCV rapid tests were Imuno-Rápido HCV (Wama Diagnostica) and Bioeasy anti-HCV. All assays were performed according manufacturer´s instructions. Sensitivities of HBV rapid tests were 89.7% for Vikia and 92.3% for Imuno-Rápido HBsAg, while specificities were 100% for Vikia and 96.2% for Imuno-Rápido HBsAg. Vikia presented higher concordance (97.7%, k = 0.931) than Imuno-Rápido HBsAg (95.3%, k =0.87) to detect HBsAg among serum samples. The overall sensitivity and specificity for anti-HCV detection using Bioeasy assay were 98.7 and 100%, while using Imuno-Rápido HCV 92.2% of sensitivity and 100% of specificity were found. Bioeasy assay presented higher concordance (99.5%, k =0.989) than Imuno-Rápido HCV (87%, k=0.936). Since all assays presented high kappa values, we recommended all assays for HBV and HCV detection in small laboratories where facilities to conduct automated enzyme-linked immunosorbent assays are not available.

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251 – SCREENING STRATEGIES FOR DETECTION GROUP B STREPTOCOCCUS DURING PRENATAL CARE FOR PREVENTION OF EARLY-ONSET NEONATAL INFECTION: SYSTEMATIC REVIEW AND META-ANALYSIS

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Context: Group B Streptococcus (GBS) is an important public health concern. It is a cause of early neonatal death and has been associated with septic abortion, chorioamnionitis, perinatal sepsis, meningitis and pneumonia. There is no national consensus on the best antenatal screening strategy for the prevention of early neonatal infection.Objective: To determine the best GBS screening strategy in pregnant women. Methods: Systematic review with meta-analysis. Setting: Nursing Department, São Paulo Federal University and Brazilian Cochrane Center. Search strategies: EMBASE, Medline, LILACS and the Cochrane library databases were searched as well as bibliographic references lists and personal communications. Selection criteria for the studies: Studies that presented any GBS screening strategy in pregnant women. Results: Eight studies were included: four compared universal screening versus no screening and four compared universal screening versus screening based on risk factors.Regardless of the comparison, analyses indicate that universal screening for GBS is more effective in reducing early-onset neonatal sepsis. Conclusions: According to the available evidence, universal screening strategy for pregnant women, along with the use of prophylactic antibiotics, is safe and effective.

314 – CAN SERUM CONCENTRATION OF C-REACTIVE PROTEIN BE USED AS A RISK MARKER FOR PREECLAMPSIA? RESULTS FROM A SYSTEMATIC LITERATURE REVIEW

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Background: Hypertensive disorders during pregnancy affects 5-7% of the obstetric population and contributes significantly to morbidity, stillbirth and neonatal mortality. Several studies have shown that women with preeclampsia (PE) had high serum concentrations of inflammatory markers such as C-reactive protein (CRP). Objective: To evaluate if serum concentrations of CRP in the first and second trimesters of pregnancy are associated with the occurrence of PE and thus the potentiality of this inflammatory marker to be used as a health technology in the routine of health services for prenatal care. Methods: The study design comprised a systematic literature review (SLR). The identification of references was made through MEDLINE search using the following keywords: (C-reactive protein OR CRP) AND (preeclampsia OR gestational Hypertension). Only studies in which CRP levels were measured before the diagnosis of PE were included. Findings: Twelve studies were selected. Seven studies found a positive association between higher CRP serum concentration at the beginning and middle of pregnancy and the subsequent occurrence of PE. Of the seven studies that evaluated the PCR in the first trimester, only four found a positive association between serum levels of this inflammatory marker with the occurrence of PE. Among the five studies that evaluated CRP levels in the second trimester, three found a positive association. However, there is great heterogeneity in relation to some important methodological issues of the reviewed studies, as the moment of the serum CRP evaluation and variety in sample size that must be taken into account when interpreting these results. Conclusions: The evidence on the relationship between serum concentration of CRP in pregnancy and the occurrence of PE are still scarce and insufficient. So there is no scientific support to justify its use as a technology in health care routine prenatal care to identify women at risk of developing PE.

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837 – DIAGNOSTIC ACCURACY OF IN-HOUSE POLYMERASE CHAIN REACTION FOR MYCOBACTERIUM TUBERCULOSIS IN PLEURAL EFFUSION

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Background: Pleural tuberculosis is the most frequent extrapulmonary form of the disease, and is associated with high morbimortality and elevated consumption of health system resources. The diagnosis is dependent on isolation of mycobacteria from pleural fluid by time-consuming low-sensitivity techniques. In this scenario, identification of Mycobacterium tuberculosis (MTB) by polymerase chain reaction (PCR) appears as a promising tool. As an alternative to the costly commercial kits available, some institutions have been developing in house MTB PCR assays. Notwithstanding, this in house techniques require clinical validation. Objetive: Evaluate the accuracy of an in-house MTB PCR for diagnosis of pleural tuberculosis. Methods: Patients with suspected pleural tuberculosis, attending our institution (Hospital de Clinicas de Porto Alegre, Brazil) from January/2004 to December/2009, were considered for inclusion in this study. The medical records were reviewed, and all patients for whom MTB PCR and culture were ordered in the same pleural fluid sample, were selected for analysis. Diagnostic test accuracy was evaluated against a gold standard composed by microbiological methods (direct stain, culture and biopsy). Agreement was measured with Kappa statistics. Findings: A total of 85 patients were included: 62 (73%) man, 50 ± 20 years-old, 70 (82,7%) white and 27 (31,8%) HIV positive. The prevalence of pleural tuberculosis was 26%. MTB PCR sensitivity, specificity, positive and negative likelihood ratios were, respectively, 0.41 (CI95% 0.21-0.93), 0.97 (CI95% 0.88-0.99), 12.89 (CI95% 3.01-55.12) and 0.61 (CI95% 0.43-0.86). The MTB PCR accuracy and calculated Kappa were, respectively 0.82 and 0.45 (CI95% 0.20-0.70). Time length for PCR and culture results were 3 and 50 days, respectively ($p<0.001$). Conclusions: Our results demonstrate that our in house MTB PCR is a useful diagnostic tool for pleural tuberculosis. Additionally, when positive, MTB PCR shortens time to diagnosis and initiation of specific therapy.

382 – ANALYSIS OF CER INVESTMENTS UNDER THE AMERICAN RECOVERY AND REINVESTMENT ACT OF 2009

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Background: Under the American Recovery and Reinvestment Act (ARRA) of 2009, the federal government allocated an unprecedented $1.1 billion for comparative effectiveness research (CER) to the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), and the Department of Health and Human Services (HHS). As of September 2010, all related funds had been awarded to universities, hospitals, and other private and public entities. Aim & Methods: Using a proprietary tool derived from publicly available sources, we characterized how the funding is being used, describing the resources, analyses, and tools that these investments will yield. We further conducted an analysis of the goals of the awards, as well as the therapeutic areas and interventions involved. Results: We accounted for 97.5% ($1.07B) of the $1.1B allocated to CER under ARRA. In total, 422 grants and contracts were awarded: 219 through NIH, 82 through AHRQ, and 101 through HHS. Nearly half (46%) of awards are dedicated to the creation of more sophisticated research infrastructures and methodologies. For example, one infrastructure award supports the Registry of Patient Registries, linking elements for a more robust data source ($5 million). Another award will help adapt existing electronic health networks for the conduct of prospective CER ($25 million). The remaining (non-infrastructure) awards comprise funding for new evidence development and synthesis (38%), and evidence dissemination and translation (16%). The highest-funded therapeutic areas are cardiovascular ($121 million) and oncology ($124 million). Overall, just 10% of awards focus on generating new evidence on pharmaceuticals. Conclusions: Much of the new US investment in CER supports the creation of a sustainable research infrastructure. Although there are fewer awards generating new evidence for payer and clinical use in the near term, establishing a sound long-term architecture will likely facilitate greater integration of comparative clinical evidence going forward.

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589 – SHOULD COSTS OF INTERVENTIONS BE REIMBURSED WHEN EFFECTS MAY BE LARGELY NON-SPECIFIC? THE CASE OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) IN THE TREATMENT OF CHRONIC PAIN

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Background: The clinical and cost-effectiveness of TENS in the treatment of chronic pain is uncertain. Methods: A systematic review and random effects meta analysis, covering 7 databases. Selection and data abstraction were carried out by two researchers independently. Findings: After exclusion of duplicate records, 1181 records were retrieved, 34 of which met predefined inclusion criteria, covering data from 1519 patients. The Standardized Mean Difference of TENS vs placebo was 1.14 (0.52 – 1.48), indicative of a clinically relevant and statistically significant treatment effect. However, there was substantial heterogeneity, as well as indications for publication bias (Egger test, p = 0.04). Methodologically weak studies produced larger treatment effects than methodologically strong studies (SMDs of 1.44 and 0.75, resp.). Also, trials with parallel groups showed lower effect sizes than trials with crossover design (SMDs of 0.64 and 1.88, resp.). The two largest, high-quality RCTs did not show a significant difference in pain relief after TENS as compared to placebo. Interpretation: There is no consistent evidence of the superiority of TENS over placebo in the treatment of chronic pain. Although its effects may be largely non-specific, TENS can provide significant relief in otherwise intractable pain. It creates a sense of control and is not known to produce adverse effects. Health care agencies are confronted with the fundamental decision whether the costs of interventions should be covered, when the beneficial effects may be largely non-specific.

790 – ADVERSE EFFECTS OF BIOLOGICS: A NETWORK META-ANALYSIS AND COCHRANE OVERVIEW

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Objective: We assessed the adverse effects of nine biologics: abatacept, adalimumab, anakinra, certolizumab, etanercept, golimumab, infliximab, rituximab and tocilizumab, across different indications for use. Methods: This network meta-analysis used evidence from randomized controlled trials (RCTs), controlled clinical trials (CCTs) and open-label extension studies (OLEs) in any condition (with the exception of HIV/AIDS). Major Outcomes: number of adverse events (AEs); number of serious adverse events (SAEs); number of serious infections; tuberculosis reactivation; lymphoproliferative cancers (included leukemia and lymphoma); congestive heart failure; withdrawals due to adverse events. The data were extracted independently and in duplicate. For the network meta-analysis, we performed mixed-effects logistic regression using an arm-based, random-effects model within an empirical Bayes framework. Main results: 163 RCTs with 50,010 participants and 46 OLEs with 11,954 participants were included. The median length for RCTs and OLEs was six and 13 months respectively. Data were limited for tuberculosis reactivation, lymphoma, and congestive heart failure. Adjusted for dose, biologics as a group were associated with a statistically significant higher rate of total adverse events (OR of 1.19, 95%CI, 1.09 to 1.30; NNTH=30, 95% CI 21 to 60), withdrawals due to adverse events (OR 1.32, 95% CI 1.06 to 1.64; NNTH=37, 95% CI 19 to 190) and an increased risk of TB reactivation (OR of 4.68, 95% CI 1.18 to 18.60; NNTH=681, 95% CI 143 to 14706), compared to control. The rate of serious adverse events, serious infections, lymphoma, and congestive heart failure were not statistically significantly different between biologics and control treatment. Indirect comparisons revealed that abatacept and anakinra were associated with significantly lower risk of serious adverse events compared to most other biologics. Conclusions: Overall, in the short-term, biologics were associated with significantly higher rates of adverse events, withdrawals due to adverse events and TB reactivation.

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839 – INAPPROPRIATE USE OF TUMOR MARKERS AND IMAGING STUDIES ORDERED OSTENSIBLY FOR EARLY CANCER DETECTION

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Background: HTA tends to focus on the introduction and diffusion of novel health technologies, but its methods can also be applied to study how existing technologies are used in clinical practice. HTA of cancer screening programs usually focuses on cost-effectiveness and impact on cancer mortality. Objectives: Identify examples of inappropriate use of tumor markers and imaging technology – ordered ostensibly for cancer screening - and quantify the magnitude of such misuse. Methods: Utilization data were extracted from population databases in Brazil and British Columbia (BC), Canada for 2007-2009. The number of tests performed, testing rates, and the proportion of the populations tested at least once over a two year period were determined. Results: In a population of 280,000 Brazilian beneficiaries, 32,129 tests of eight tumor markers (CEA, AFP, CA-125, CA-19.9, CA-15.3, CA-72.4, CA-50, CA-242) were performed in 2007 and 2008. Tumor marker use in the Brazilian cohort was three-fold greater than in BC. Among 56,727 Brazilian women age 30 to 59, 59.4% had undergone pelvic ultrasound at least once in 24 months. Among 21,069 women age 40 to 49, the rate was 65.6%. These rates were two to six-fold rates greater than in BC. Although some ultrasounds were performed to investigate symptoms or accompany pathologies, thousands of asymptomatic women underwent imaging to screen for ovarian cancer, contrary to evidence-based recommendations. Conclusions: We identified inappropriate use of costly tumor markers and imaging technologies, ordered to screen normal risk individuals, a wasteful misapplication of resources. False positive results (not quantified) likely trigger further diagnostic investigation and associated morbidity. Reducing unnecessary testing would save money and could improve access to screening for those for whom there is evidence of benefit. Primary care physicians, especially gynecologists, need to be educated regarding the appropriate use of tumor markers and consensus guidelines about ovarian cancer screening.

841 – QUALITY ASSESSMENT OF TRIALS INCLUDED ON THE SYSTEMATIC REVIEW

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The purpose of this study was to evaluate the quality of trials included in a systematic review for the immunosuppression therapy efficacy and effectiveness in renal recipients. Study quality was assessed by Cochrane Collaboration “Checklist’’ and modified Jaddah scale for Clinical Trials; and Newcastle-Ottawa scale for Cohort Trials. Two investigators independently rated study quality. Discrepancies were solved by another independent reviewer and interrater agreement was calculated by the kappa coefficient (kappa= 0,63 indicating good agreement). In the efficacy revision 49 trials were included. We identified 44 randomized controlled trials that obtained medium Jaddah score of 2,68 points. Although reported randomization, 25 studies did not describe the method of randomization; 19described adequate sequence of allocation; only 8reported adequate allocation concealment; 36 were open label; 34 adequately addressed incomplete outcome data. For the effectiveness revision, we identified 25 longitudinal studies, in which 10 was prospective cohorts. None of them scored 9 stars in the Newcastle-Ottawa scale. The majority (22) scored 5 stars or more, and three scored 3 stars or less. The median was 6 stars. In the selection criteria, 19 studies scored 4 stars; 3 scored 3 stars; and 3 scored 1 star. In the comparability criteria 15 studies scored 1 or 2 stars. In the outcome criteria only one study scored 3 stars; 18 scored 2 stars; and 6 scored 1 star. This study revealed the occurrence of inadequacies in the quality standards of the studies evaluated, which introduces important limitations to the findings. To obtain strong evidence studies are needed.

Poster Sessions

Monday Session – 27th June

Tuesday Session, 28th June

Monday Session – 27th June

M-001

194 – TRANSLATION OF THE AGREE II (APRAISAL OF GUIDELINES FOR RESEARCH & EVALUATION II) INSTRUMENT TO PORTUGUESE

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Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. In addition, guidelines can play an important role in health policy formation and have evolved to cover topics across the health care continuum. The objective of the present research is to translate and apply the AGREE II instrument to the portuguese language. We will also evaluate the quality of the following guideline: Dementia in elderly: diagnosis in primary health care, in which apply the instrument AGREE II. We have used the translation protocol developed by the AGREE Trust, which outlines recommended steps. The Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument was developed to address the issue of variability in guideline quality. The AGREE instrument is a tool that assesses the methodological rigour and transparency in which a guideline is developed. The AGREE II consists of 23 key items organized within 6 domains (Scope and Purpose, Stakeholder Involvement, Rigour of Development, Clarity of Presentation, Applicability, Editorial Independence) followed by 2 global rating items (Overall Assessment). The guideline that will be evaluated has been developed by the Brazilian Society of Family and Comunity Medicine and Brazilian Association of Neurology and has been available on the Brazilian Medical Association site. The AGREE instrument has been used internationally and it is an important tool to evaluate quality of the Brazilian guidelines.

M-002

227 – ANKLE BRACHIAL INDEX TO PREDICT CARDIOVASCULAR EVENTS IN PRIMARY HEALTH CARE

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It is essential to develop an accurate identification of those at risk of Cardiovascular Disease in asymptomatic patients who seek care at Primary Health Care level. The prevention of such events remains a serious public health challenge. There are several instruments to evaluate cardiovascular risk, such as Framingham Risk Score, Carotid Wall Thickness, Abdominal Circumference and Reactive C Protein. A low ankle brachial index (ABI) is an indicator of atherosclerosis and has the potential to improve prediction. We have designed a health technology assessment to determine whether the ABI provides information on the risk of cardiovascular events and mortality. We will also evaluate the risk prediction at primary health care level. The ABI is the ratio of systolic pressure at the ankle to that in the arm, which is a quick and easy instrument to measure. A search of MEDLINE, Scielo, Cochrane Library, LILACS and EMBASE has been conducted using common text words for the term ankle brachial index combined with primary health care and cardiovascular risk. We have identified the articles published about this topic and have been doing a critical appraisal of the articles selected. Further evaluation is now required of the potential of incorporating ABI measurement into cardiovascular prevention programmes. We will evaluate whether the measurement of the ABI may improve the accuracy of cardiovascular risk prediction at primary health care level.

M-003

958 – QALY – A MODEL TO PREDICT QUALITY-ADJUSTED LIFE YEARS IN CANCER PATIENTS NEEDING INTENSIVE CARE: STUDY DESIGN

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Background: Quality-adjusted life years (QALY) measures length and quality of life simultaneously. QALY might be useful to inform clinical management of critically ill cancer patients. However, a model to predict QALY for critically ill patients is not available. Objectives: To develop a prognostic model having QALY as outcome for critically ill cancer patients being considered for intensive care unit (ICU) admission and another model for cancer patients on the fifth ICU day. Methods: Prospective cohort study, conducted in two cancer-specialized intensive care units. Participants are adult patients with cancer admitted to intensive care units. We will collect the following potential prognostic factors: Demographic data; socio-economic data; relevant prior health variables; pre-ICU in-hospital characteristics; reason for admission to ICU; clinical, physiological and laboratory variables within one hour of ICU admission and between 96 and 120 hours of ICU admission. Follow-up will be carried out by telephone, at 15 days, and in 3, 6, 12, 18 and 24 months, to determine vital status and health-related quality of life using EQ-5D. Main outcome is QALY, which is a product of each individual patient life span times the EQ-5D summary index (from 0 to 1). EQ-5D value set from a time trade-off UK study study will be used to calculate the summary indexes. Sample size and statistical analysis: 500 patients will be included for developing the model, the aim of this proposal. After its development, we intend to carry out second study enrolling 250 patients to validate it. Weibull regression will be used to model QALY. Findings: Up to January 14th, 2011, 412 had been included. Recruitment should be finished by March, 2011, and the 24-month follow up of the last patient available in March 2013.

M-004

984 – HEALTH-RELATED QUALITY OF LIFE AND MORTALITY OF CANCER PATIENTS ADMITTED TO INTENSIVE CARE UNITS: PRELIMINARY RESULTS OF THE QALY STUDY

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Background: Very limited data is available regarding health-related quality of life of cancer patients who are admitted to intensive care units (ICU). Objectives: To describe survival and health-related quality of life in an unselected population of cancer patients admitted to ICU. Design: Prospective cohort study. Setting: Two cancer-specialized intensive care units. Patients: Adult patients with cancer admitted to intensive care units. Variables and follow-up: We have collected data on health-related quality of life before the onset of the acute illness using the EQ-5D. Follow-up has been carried out at 15 days, and in 3, 6, 12, 18 and 24 months, to determine vital status and health-related quality of life using EQ-5D. Sample size and statistical analysis: We will include 500 patients. Results: Up to January 14th, 2011, 412 had been included in our study and 3-month follow-up data is available for 124 patients. Mean age was 60.5±15.3 and 53.3% were male. 50.9% were admitted due to clinical reasons, 45.6% after elective surgery and 3.5% after emergency surgery. In-hospital mortality was 30.2%. Prevalence of moderate or severe problems before the acute-illness onset and 3-month after ICU admission, respectively, were as follows: mobility problems, 42.7% and 46.5%; self-care problems, 32.5% and 28.7%; usual activities problems, 45.8% and 49.5%; pain or discomfort, 62.1% and 61.4%; anxiety or depression, 58.6% and 50.5%. Conclusions: Health-related quality of life problems were similar before the onset of acute illness and in 3-month after ICU admission survivors, although about one-third of the patients had died before 3 months.

M-005

788 – EFFICACY OF TWO PAP SMEAR SAMPLING METHODS: A RANDOMIZED CONTROLLED TRIAL

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Background: Cervical cancer is the third cause of cancer mortality in women in the world and 80% of the cases occur in developing countries. Cervical screening (Pap smear) has proven to be effective in decreasing the incidence of invasive disease by detecting pre-cancerous abnormalities of the cervix. Effectiveness of the test can be affected by the design of the sampling device. Inadequate samples can produce incorrect results, causing stress and inconvenience to women having to undergo repeated screening. In Uruguay, pap smears samples in many public health settings are obtained using a thin wooden stick instead of using a cytobrush which is the standard of use in privet health services. The general purpose of this study is to produce scientific knowledge that contributes to health equity and to the development of evidence-based health policy in Uruguay. Objective: The specific objective of the study is to assess the efficacy of wooden stick vs. cytobrush as Pap smear sampling devices. Methodology: This is a simple blind randomized controlled trial with allocation concealment that evaluates presence of endocervical cells in Pap smears (using wooden stick or cytobrush) as a measure of quality of sampling. Results: 511 women were randomized to cytobrush or wooden stick sampling method for their pap smear. Socio demographic characteristics and sexual and obstetric background was comparables in both groups. The results show that endocervical cells were more likely to be present in samples obtained with cytobrush than with wooden stick (RR 1.55 IC95% 1.075-2.25). The type of technician who obtained the sample was an effect modifier for quality of sampling. Conclusion: Cytobrush should be considered as the adequate method for Pap smear sampling in all public setting of Uruguay in order to avoid inequity in quality of care, inconvenience for the women and costs for the health system.

M-006

738 – TECHNICAL PERFORMANCE OF PORTABLE COAGULOMETERS FOR THE FOLLOW-UP OF LONG-TERM ANTICOAGULANT THERAPY

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Background: Long-term use of oral anticoagulants exposes patients to hemorrhagic or thrombotic complications. A close monitoring by measuring the international normalized ratio (INR) is required in this population involving healthcare system resources and inconveniences for patients. Portable coagulometers are available for INR testing outside regulated laboratories. Objectives: To compare the diagnostic performance of portable coagulometers approved by Health Canada (CoaguChek, ProTime, INRatio) with the standard laboratory method. Methods: A systematic review was performed including a literature search in Medline (PubMed), The Cochrane Library and EMBASE until October 2010, without language restrictions. Quality assessment of selected articles and data extraction were performed by two independent reviewers. The evaluated parameters were precision (coefficient of variation – CV), and clinical (%) and technical agreement (Bland-Altman method) between portable coagulometers vs. laboratory test results. Results: Eighteen primary studies meeting the inclusion criteria were selected. Eleven had been included in three HTA reports on the topic, and seven were published after the search closure dates of these reports. CV estimate was from 2% to 8% (2% to 4% for the latest model, CoaguChek XS), which is generally under the acceptable limit of 5%. The agreement between laboratory and portable coagulometer INR results ranged from 50% to 97% and was underperforming for INR values > 3. The overall mean difference (−0.70¬ to 0.35) increased when the INR results were ≥ 3. Between 82% and 100% of the INR results obtained with the portable coagulometers were within ± 0.5 INR units compared to standard laboratory results. Conclusions: Studies results on diagnostic performance of portable coagulometers showed good precision and agreement with laboratory results. However, they may overestimate or underestimate INR values. Health professionals should be aware about the possibility of underperformance of portable coagulometers for results above 3 before to implement point of care INR testing.

M-007

796 – ACCURACY OF DUAL – SOURCE COMPUTED TOMOGRAPHY IN THE CORONARY ARTERY DISEASE DIAGNOSIS: A META-ANALYSIS

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Dual–source computed tomography (DSCT) is an imaging technology that enables the visualization of coronary artery stenosis in a non-invasive way. Earlier studies showed high accuracy compared to invasive coronary angiography (CA). The aims of this study were to evaluate the evidence of this technology using a meta-analytic process and its accuracy in different subgroups such as patients with high heart rates, arrhythmia, increased calcium score and high body mass index. A search of the literature published between January/2000 and October/2009 in MEDLINE, LILACS and Cochrane Library was performed. Studies in English, Spanish and Portuguese that compared DSCT with invasive CA performed for all patients and included sufficient data for compilation of 2 X 2 tables were included. Three investigators independently extracted the characteristics of the studies and differences were settled by consensus. Twenty studies were included in the meta-analysis, using three units of analysis: patient, vessels and segment. Analysis of patients, vessels and segments yielded a sensitivity of 0.98 (95%CI, 0.96-0.99), 0.94 (95%CI, 0.89-0.97) and 0.93 (95%CI, 0.89-0.95) and a specificity of 0.84 (95%CI, 0.76-0.89), 0.92 (95%CI, 0.87-0.95) and 0.96 (95%CI, 0.91-0.98), respectively. Sensitivity and specificity remained high in patients with high heart rates — 0.93 (95%CI, 0.90-0.95) and 0.98 (CI95%, 0.95-0.99), and also in patients with increased calcium score (> 400 Agatston units) — 0.95 (95%CI, 0.92-0.97) and 0.91 (95%CI, 0.82-0.96), respectively. The available evidence points to a high accuracy of DSCT for the detection of coronary artery stenosis. However, the population who might benefit from this technology — individuals with chest pain and intermediate risk of coronary artery disease (CAD) — has not been included in the retrieved studies since the studies were conducted in reference centers where patients have an indication for invasive CA, and consequently a high pretest probability of CAD.

M-008

336 — SYNTHESIS OF THE EVIDENCE REGARDING NEGATIVE PRESSURE WOUND THERAPY (NPWT)

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Introduction: Wounds have diverse etiologies and the technology proposed for this study presents a broad range of indications, therefore it is difficult to find epidemiological data for all types of wounds. Many wounds are difficult to heal, despite adequate medical and nursing care. They may result from complications from diabetes, or from surgery, constant pressure, trauma or burns. Acute and chronic wounds affect at least 1% of the population. V.A.C. therapy (Vacuum Assisted Closure) consists of Negative Pressure Wound Therapy (NPWT) (measured in mmHg) to accelerate wound healing, thus making it an aid in healing of wounds. Methods: In order to produce a synthesis using the best evidence currently available on the efficacy and safety of V.A.C. in the closure of chronic and acute wounds, an extensive search was conducted using Medline (via Pubmed), The Cochrane Library, Tripdatabase, The Centre for Reviews and Dissemination (CRD), and The National Institute for Clinical Excellence (NICE). The aim was to find systematic reviews or, failing such, randomized controlled trials, which are considered the highest quality of scientific evidence. Results: Two systematic reviews were located and the methodological quality of these studies, in spite of their limitations (small sample size, inadequate methods of randomization, large confidence intervals, mostly unproven patient eligibility criteria and characteristics), was adequate. Conclusion: A promising aid in the treatment of chronic wounds using NPWT does exist, but due to the poor quality of the publications available, more randomized clinical trials should be conducted to confirm such potential. Additionally, there are few studies on its clinical efficacy when treating acute wounds. An implementation of a Brazilian cost-effectiveness study on the different types of wounds is also recommended to compare NPWT with a specific standard therapy, be it conventional or modern, in order to define its role in the treatment of wounds.

M-009

552 – ARE WE USING DRUG-ELUTING STENTS APPROPRIATELY? A COHORT STUDY FROM SOUTH OF BRAZIL

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Introduction: Coronary drug-eluting stents lower the risk of restenosis, but are more expensive compared to bare metal stents. Patients at higher risk of restenosis may have the greatest benefit. Objectives: We aimed to compare risk factors for restenosis in a cohort of patients with bare metal and drug-eluting stents to assess appropriateness of coronary stents use in a healthcare plan. Methods: All patients having a percutaneous coronary intervention with stenting between 2008-2010 at a healthcare plan affiliated hospital were included. Demographic, clinical and procedural data were obtained from chart review. Research nurses collected follow-up data by phone calls at one and six months after the procedure. Diabetes, multiple vessels affected and prior angioplasty or cardiac surgery were considered the main risk factors for restenosis. Results: Two hundred and one patients with coronary stenting between 2008 and 2010 at a single centre were included, 70.65% with bare metal and 29.35% with drug-eluting stents. Patients and procedure characteristics can be seen on table 1. Table 1. Demographic and clinical characteristics of patients with coronary stenting at Centro Hospitalar Unimed Joinville between 2008-2010 Bare metal(n=142) Drug eluting(n=59) p value Men(%) 68,31 64,41 0,59 Age(years-median-SD) 63,9 62,3 0,31 ≥ 65 years(%) 46,48 44,07 0,75 Diabetes(%) 27,41 66,10 <0,001 Ever smoker 57,68 46,30 0,15 Two or more vessels(%) 55,72 52,83 0,93 Previous angioplasty(%) 44,62 61,82 0,03 Cardiac surgery(%) 22,48 35,19 0,07 Right CA(%) 34,29 40,68 0,39 Circumflex CA(%) 32,86 32,20 0,93 Left CA(%) 5,71 10,17 0,26 Conclusion: At our centre less than 30% of patients got a drug eluting stent. Patients with diabetes and previous angioplasty had significantly more drug eluting stents. Albeit a small sample it seems that drug eluting stents are being used appropriately.

M-010

885 — STROKE AND ACUTE MYOCARDIAL INFARCTION (AMI) DIAGNOSIS AND TREATMENT AFTER A CASE MANAGEMENT PROTOCOL IMPLEMENTATION. OUR ONE-YEAR EXPERIENCE WITH A HEART AND BRAIN ALERT PROTOCOL

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Introduction: Time elapsed from first stroke and AMI symptoms until effective treatment is a crucial prognosis variable. Objective: To describe the implementation process and partial results of a stroke and AMI managed protocol in the emergency room of a 195-bed general hospital in south of Brazil. Methodology: During 2010 a stroke and AMI protocol were implemented in the emergency room which consisted of training of nursing and medical staff and receptionists about warning stroke and AMI signs and symptoms and introduction of a registry form which contains diagnostic and treatment guidance and process variables to be filled during the emergency room care. A nurse refers symptomatic patients immediately to physician evaluation, and electrocardiogram or CT scan. A before-after analysis was undertaken and the main outcomes measured are door-to-electrocardiogram (ECG) and door-to-balloon in AMI with ST-elevation suspected patients and door-to-imaging time in stroke suspected patients. Results: Main outcomes were measured at baseline and at the end of the first, second, third and fourth trimester 2010 and can be seen at table 1. Table 1. Process measures of a stroke and AMI management protocol Baseline 1.Trim 2.Trim 3.Trim 4. Trim Mean door-ECG time(min) 54 24 5.3 10.7 7 Mean door-ballon time(min) 203 125 69 107 111 Mean door-image time(min) 123 63 25 25 21 Conclusion: The implementation of a managed protocol for patients with chest pain and sudden neurologic deficit in the emergency room associated with all staff training seems effective to achieve diagnostic and therapeutic established goals. Patient-oriented outcomes have to be measured.

M-011

892 — AN ELECTRONIC EARLY WARNING SYSTEM (EWS) SHORTENS DETECTION TIME OF PATIENTS AT RISK OF SEPSIS

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Introduction: In a general private 195-bed hospital we introduced in 2005 the Surviving Sepsis Campaign with a nurse triggered screening protocol for patients at risk of sepsis, based on changes of vital signs that were registered in a paper form in each ward. The sepsis detection time decreased significantly but many patients at risk were not identified. A screening alternative linked to electronic medical records was developed. Objective: To test the hypothesis that an EWS can shorten the time interval between the first signs and the definite diagnosis of inhospital septic patients. Methodology: In 2010 we introduced an EWS which sends an automatic electronic mail and phone call to the ward nurse whenever a patient has two or more abnormal vital signs, altered consciousness or need of supplemental oxygen. The sepsis protocol nurse is then called and sepsis workup is done by the hospitalist if needed. Main outcomes measured are time interval from first signs until sepsis detection, mortality and need of intensive care for the treatment of the septic episode. Results: After one year of the EWS implementation the sepsis detection time decreased from 13:50 hours after applying the paper form to 3:27 hours after EWS ($p < 0.001$). Mortality related to severe sepsis or septic shock did not change (32% with the paper form and 37.1% with EWS). The proportion of septic patients who needed intensive care decreased from 61.7% to 48% ($p = 0.09$) Conclusion: electronic detection associated with case management by nurses appears to improve the efficiency of detecting patients at risk of severe sepsis and septic shock.

M-012

153— PROFILE OF THE PHARMACOTHERAPY IN ELDERLY PATIENTS USERS OF PUBLIC HEALTH SYSTEM

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Objective: to study the profile and prevalence of use inappropriate drugs, polypharmacy, drug interactions and adverse reactions in elderly patients users of Public Health System (SUS) method: To collect the data, a form standardized and approved by Ethics Committee in Research of Health School Center of the College of Medicine of Ribeirão Preto, University of São Paulo (CEP-CSE-FMRP-USP) was used. With this instrument, 1000 elderly was interviewed in the period of November 2008 to May 2009, the data of these patients were inserted in statistic program, Epi Info ® version 3.4.3. Beers´ Criteria was utilized to classification of inappropriate drugs, and drug interactions were analyzed according the Model Formulary of World Health Organization. Results: The average age was 69.8 years, 66.1% were female, the average income per capita was R$ 581.00, with predominance of whites (56.2%), married (51%), with elementary school incomplete (65%). Regarding the pharmacoepidemiological profile, a range of one to twenty-one drugs used was found per patient, with an average of seven drugs/patient, the greater prevalence was cardiovascular drugs (83.4%) 30.9% perform self-medication; polypharmacy (use of six or more drugs) was present in 60.1% of the elderly, and 74% are women, 80.2% use OTC's (over-the- counter), 46.2% reported at least one ADR, 44.2% used drugs considered inappropriate for the elderly, and we found 282 drug interactions. The variables most strongly correlated with the use of six drugs are: female gender, use of inappropriate drugs by elderly, self-medication, increased amount of health problems, number of medical visits scheduled, the presence of ADR, use of OTC's. Conclusion: Facing these evidences and high prevalence of problems related to drugs, it is perceptible the need to adopt strategies to improve pharmacotherapy and health assistance offered to the elderly patient.

M-013

866 — PALLIATIVE CARE PROGRAM ADOPTION IN A BRAZILIAN GENERAL HOSPITAL

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Objective: Experience report of Palliative Care (PC) program adoption in brazilian private general hospital. Methods: Patients in semi-intensive and ICU were triaged using Palliative Performace Scale (PPS) with cutoff in 20 points and the criteria: chronic and progressive disease; lifetime supposedly restricted to months or years; unresponsive to disease-modifying treatment; emotional impact related to possibility of death. With this group, were realized family conferences to discuss clinical status, change of therapeutic focus and ingress in program. After, the most important needs and symptoms were periodically evaluated through interviews and Edmontom Symptom Assessment System (ESAS-r). Other interventions were related to interdisciplinary discussions, symptom control, comfort measures, decisions support and restrictive measures. After death, was sent letter of condolence or realized finishing visits. Findings: In 710 patients, the prevalence of PPS ≤ 20 was 9.43%, in which 3.09% hospitalized and 6.33% in home care. Of these, 50.74% is related to severe neurological sequelae, 46.26% functional degradation and dementia and 2.98% cancer. In 10 followed ICU patients, there was 20.9 points reduction ($p<0,05$) in Therapeutic Intervention Scoring System (TISS-28), that represents about 3 hours and 40 minutes in 8 working hours, while the control group (7 patients) reduction was only 4 points (42 minutes). Conclusions: Is important get hospital managers support and availability of interdisciplinary team to permanent activity with patients/families. The palliative physician must participate the initial approach to attending physician. Since resources are scarce at first, it must prioritize patients with lower functional level. The most important training to teams should be interpersonal communication. Detailed medical records are essential to communication flow and for legal support. Both professionals and patients/families are unaware of practices of PC and usually associate with fear and euthanasia. By understanding the purpose of PC, in general, families accept the restrictive measures.

M-014

976 — USE OF PAPAIN AS TECHNOLOGY IN THE PROCESS OF WOUND HEALING: AN INTEGRATIVE REVIEW

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The intention of this essay is to analyze the evidences in the literature about the use of papain in the process of wound healing, having as specific objectives: characterize the scientific studies that have used papain to wound healing, emphasizing the indications and contraindications, identify the presentations of papain used for wound treatment in scientific studies and describe the evidences reported in these studies on the effectiveness of papain for wound healing. As a method, we used an integrative review, carried out a manual and electronic bibliographic research, in the following databases LILACS, MEDLINE via PubMed, CINAHL, MINERVA and DEDALUS. Results: of the 218 articles found with papain as a subject, only 13 were included by treating the issue and the entire access, published between 1987 and 2009, and 11 of those being Brazilian. The types of studies that predominated were descriptive, exploratory, case studies, case reports and only one randomized controlled clinical trial, which means prevalence of studies with low scientific evidence. There was no specificity in the indications, so it can be used in various types of wounds. Weren't found any contraindications on the analyzed studies, although, currently there are reports that people who are allergic to latex may have crossed allergic reaction with papain. The presentation forms found were: powder, diluted in saline solution or distilled water; gel; papaya pulp; cream and spray, both associated with urea. It is concluded that papain is used in some countries for the care of tissue damage, indicated because of the low cost, easy to apply, but there is no consensus on the indications for the use of papain, the presentation forms, effectiveness and stability. That indicates the need for studies with greater methodology and evidence-based.

M-015

229 – ROBOTIC ASSISTED LAPAROSCOPIC RADICAL PROSTATECTOMY VERSUS RETROPUBIC RADICAL PROSTATECTOMY: METHODOLOGICAL ISSUES OF A CONTROLLED RANDOMIZED CLINICAL TRIAL

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Introduction: Prostatic cancer (PC) is the second most common cancer among men, in Brazil. It is the 8th cause of death among men older than 59 years. In early stages of disease, surgery is a very efficient treatment and retropubic radical prostatectomy (RRP) is the gold standard technique. Since 2000, when FDA approved the da Vinci® surgical system, robotic assisted laparoscopic radical prostatectomy (RALRP) is growing in several countries, especially in United States and Europe. Nowadays, there are three hospitals using da Vinci® surgical systems in Brazil. Several prospective studies have been carried out comparing both surgical techniques, and many of them suggest that RALRP causes less bleeding, less pain, and also improving early continence and erectile function. However, almost all data is based on case series and observational studies, without appropriated control of bias and confounding factors. Objective: To present methodological issues of a controlled randomized clinical trial (RCT) designed in order to compare return of urinary continence between men undergoing RRP or RALRP. Methods: A RCT is been carried out at Hospital Alemão Oswaldo Cruz and Hospital das Clinicas da Faculdade de Medicina de São Paulo. Patients with early stages PC (T1c, T2a, T2b) were randomized for one of two treatments. Clinical data and biochemical status (PSA level), urinary continence, erectile function and quality of life will be obtained before the surgery and 1, 3, 6 and 12 months after, using standardized instruments. The sample size was calculated to test the hypothesis that the probability which a patient treated with RALRP will recover his urinary continence faster than a patient treated with RRP will be 60% (n = 100 patients in each group). Results: All surgeries were performed between March and December 2010 and patients have been evaluated to assess the outcomes.

M-016

354 – HIFU ABLATION FOR LOCALISED PROSTATE CANCER: AN ITALIAN HTA

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Agenas are carrying out an HTA aimed to: Assess the effectiveness and safety data from the scientific literature on the HIFU treatment of localised prostate cancer compared to standard treatments; Describe the level of adoption and utilisation of the technology within the Italian NHS; Perform an economic analysis on the utilisation of the technology within the national clinical practice. We intend to perform a systematic review to find evidence of effectiveness and safety for the HIFU treatment compared with alternatives in the target population, i.e. males with localised prostate cancer (T1-T2), with low or intermediate risk disease who are being treated with curative intent. We will consider primary as well as secondary literature documents published from 2002 in English or Italian. Primary studies will be searched on three databases: EMBASE, Cochrane Library and Medline. Secondary literature will be searched on the Cochrane Database of Systematic Review and on the CRD database. A context analysis will be carried out by a national survey to describe the level of use and dissemination of the HIFU technology in Italy. Our study will allow us: To produce a systematic review of evidence supporting the use of HIFU technology in the treatment of localised prostate cancer; To get a comprehensive overview of the distribution and use of the technology within the healthcare providers of the Italian NHS; To assess the costs associated to the HIFU treatment of prostate cancer as compared to standard treatments; To create an economic model able to describe the economic and organizational impact of the technology compared to standard treatments. As implications for practice and research, our HTA report will be an useful decisional tool at all the levels of the NHS, and will highlight the evidence gaps that may be the main targets for the further studies.

M-017

204 – PHOTODYNAMIC THERAPY FOR BARRETT`S ESOPHAGUS AND ESOPHAGUS CANCER: A SYSTEMATIC REVIEW

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Background: Worldwide, esophagus cancer (EC) is the eigth malign neoplasm in frequency. Barrett´s esophagus (BE) can progress to adenocarcinoma. Treatments utilized are surgery, endoscopic ablation and mixed modalities. Photodynamic therapy (PT) is an emerging endoscopic technique. Objectives: To evaluate the effectiveness of PT for the treatment of early and late EC and BE. Methods: We performed a systematic literature search in main electronic databases, Cochrane Collaboration, CRD York and other relevant sites, like cancer and gastroenterology societies. We defined a set of inclusion criteria and selected those studies fulfilling it. Results: We identified 7 RCTs, 2 non-randomized controlled studies, 2 retrospective cohorts, and 14 case-series. In a RCT including 208 EB patients, in 77% (CI95% 70-84%) of those treated with PT a complete ablation of the high-grade dysplasia (HGD) was possible, versus 39% (CI95% 27-50%) in the group treated with pump-inhibitor drugs. No RCT comparing PT with Radiofrequency Ablation were identified. Another RCT randomized 218 patients with obstructive EC to PT or thermo-ablation (TA). At one month follow up, endoscopic successful outcomes were observed in 32% vs. 20% ($p<0,05$) of PT or TA respectively, although differences in dysphagia were non-significant. Conclusions: In patients with BE and HGD PT seemed to be superior to placebo and to some alternatives for which an evaluation was found. For early EC no RCTs comparing PT with other techniques were identified. In late EC, PT seemed to be equally efficacious than laser ablation and better than stent placing.

M-018

930 – IMPACT OF FDG-PET IN PREOPERATIVE STAGING AND CLINICAL MANAGEMENT OF PATIENTS WITH ESOPHAGEAL CANCER – EXPERIENCE OF A SINGLE CENTER IN BRAZIL

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Introduction: Esophageal cancer is among the most common neoplasms in Brazil, and presents with high mortality rates, especially in late stages. Recent studies have shown FDG-PET as the imaging method with higher accuracy in preoperative staging of this kind of tumor, with significant impact on its therapeutic management. This study aims to evaluate the role of FDG-PET in preoperative staging and in management of patients with esophageal cancer in a single center in Brazil. Methods: 98 patients (mean age of 58,8±9,7 years, 85% male) with biopsy proven oesophageal cancer were included. All patients were prospectively evaluated between September 2006 and March 2008 and underwent FDG-PET whole body scans in addition to conventional staging methods (computed tomography – CT, and gastro-esophageal endoscopy). After evaluating the findings of both methods, therapy was defined. Results: FDG-PET was positive at the primary sites in 92% of the cases. Only 8 patients didn´t have positive PET findings at the primary site, 3 of which were limited to the submucosa and 2 were in situ adenocarcinomas. There was no statistically significant differences in the degree of metabolism measured by SUV between adenocarcinomas and spinocellular carcinomas. PET showed no difference in initial staging in only 37,6% of the patients, with 25,8% of the patients being upstaged and 36,6% downstaged. This translated into a change in management decision for 26% of the patients. Conclusion: FDG-PET showed high sensitivity in the detection of esophageal cancer and proved to be effective in preoperative staging of the disease, changing management in 26% of the patients.

M-019

929 – EPIDEMIOLOGICAL PROFILE OF PATIENTS WITH LEG ULCERS CARED IN THE AMBULATORY OF A UNIVERSITY HOSPITAL, BRAZIL

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Introduction: the aim of this paper is to present the epidemiological profile of patients cared with leg ulcers in the Wound Repair Ambulatory at the University Hospital. Methods: it is an exploratory study performed from January 2009 to December 2010 in the city of Niterói, Rio de Janeiro /Brazil. It presents demographic, social and pathological data as well as description and wound treatment. Approved by the Research Ethics Committee. Results: There were 186 patients researched in 2 years with a total number of 2500 appointments. 54% female, 55 % aging from 57 to 82 years old; 53 % with incomplete middle school, being 54% married and living in Niteroi/Brazil. All of them present cardiovascular diseases and/or mellitus diabetes. Among them, 65% have chronic venous ulcers, 25% diabetic ulcers and 2% arterial ulcers. The ulcers are 15 cm in average, located in the lower part of the leg, with little exudate, no fetid smell and being treated for over five years. The evolution of the wound was of at least 2 months and maximum of 20 years, having initiated the treatment with the minimum of 1 week and maximum of 4 years. Macerated borders; periwound skin with moisture or redness. The products used for dressing were essential fatty acid, alginate, hydrogel, and Unna´s boot. Conclusions: Most patients are adults or elders, with leg ulcer, base disease such as diabetes or heart disease, being necessary the systematic and periodical care of the nursing and medical team. The Repair Wound Ambulatory, coordinated by nursing professors is a regional reference center which offers high quality care to patients and train professionals and students to wound treatment.

M-020

619 – BRAIN INJURY REHABILITATION – A HEALTH TECHNOLOGY ASSESSMENT

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Objective: to critically assess the evidence for the effect of a broad range of physical, mental and social rehabilitation interventions for persons with acquired brain injury. Furthermore, to investigate the total costs associated with rehabilitating people with acquired brain injury and to identify possible economic benefits. Methods: a systematic literature review and registry based economic analyses. Results: The assessment found strong evidence for many interventions targeting physical dysfunctioning, and moderate to strong evidence for some mental interventions. Among social interventions, strong evidence supports various interventions targeting relatives, and moderate to strong evidence supports other interventions, such as those targeting labour market. The assessment found evidence supporting numerous positive effects for the hospital-based rehabilitation of people with stroke organised in multidisciplinary teams. Evidence also support positive effects of hospital-based multidisciplinary rehabilitation on return to labour market. The total cost of treatment and rehabilitation for a person with acquired brain injury were 36,200 euro based on 2008 figures. Conclusion: In the light of the broad range of positive effects of rehabilitation interventions a process in which the specific interventions with documented moderate or great effects are implemented should be initiated. Furthermore, the extent to which the positive results from hospital based, multidisciplinary intervention can be transferred to other administrative levels, such as municipalities should be systematically clarified. The economic analysis concludes cautiously that the treatment and rehabilitation of people with brain injury is costly, with the municipalities paying for a large but variable proportion of the costs. Further, positive clinical effects and economic benefits are expected in the form of increased return to the labour market and less dependence on municipal transfer payments and services.

M-021

313 – THE USE OF ADALIMUMAB AS FIRST OR SECOND LINE OPTION IN THE TREATMENT OF RHEUMATOID ARTHRITIS: A SYSTEMATIC REVIEW

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Objectives: To conduct a systematic review of randomized controlled trials (RCTs) related to adalimumab and verify its effectiveness by measuring the absolute risk. Methods: A search was conducted in PubMed, EMBASE and Cochrane to recover all articles on rheumatoid arthritis treated with adalimumab with end date 01/05/2010. Critical appraisal was done by the Jadad scale, the percentage of adequacy to the CONSORT items and the level of evidence of the Oxford Center of Evidence-based Medicine. Data extraction from the selected articles was performed using a spreadsheet based on the model suggested by the CRD-York. Results: We found 18 RCTs. Half of the articles (9) were excluded for not reaching the eligibility criteria. Included studies had Jadad scores ranging from 2 to 5 and percentage of CONSORT adequacy from 66 to 84. Two of the articles included, found that the participants had never received any previous treatment, with disease duration ranging from 0.4 to 0.7 years, while other articles from 6 to 12 years. Participants age ranged from 46.3 to 57 years and the percentage of women 54 to 84%. The total number of patients in the treatment group was 1162 and in the control group was 1129. The benefits measured by ACR20 were NNT = 5, ARR = 0.19, CI95% 0.15-0.23, ACR50 NNT = 6, ARR = 0.18, CI95% 0.14-0.22, ACR70 NNT = 9, ARR = 0.11, CI95% 0.07-0.14. Conclusion: The most important clinical endpoints ACR50 and ACR70 showed that one patient will have the benefit if 6 or 9 patients are treated with adalimumab for 16 to 52 weeks, especially when combined with methotrexate. The performance of adalimumab as a first-line option was also favorable.

M-022

137 – STUDY ON MORTALITY OF THE DIABETES AT THE NATIONAL CENTRAL HOSPITAL OF MONGOLIA

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Objective: to determine causes of the death in patients with diabetes, and to identify strategies for preventing deaths due to diabetes and prolonging the life of diabetes patients. Methodology: From 2825 cases, we have selected 48 patient records from the last 5 years (2005-2009) of the National Central Hospital of Mongolia. We extracted information on age, sex, type of work and cause of death. Conclusion: 1. The high rate male mortality indicates that male diabetes patients have poor self-control, and excessive alcohol and tobacco usage. 2. 95.5% of the newly diagnosed patients were over 30 years of age showing that type 2 diabetes is soaring. 3. High rates of mortality within 5 years of diagnosis indicates high rates of late diagnosis, and inadequate and inconsistent treatment of the disease. 4. Data from the five year period prior to 2005 indicates that the main cause of the death was kidney failure (42.1%), however from 2005-2009 a smaller proportion of patients died from kidney disease, which is possibly the result of improvements in hemodialysis and the introduction of kidney transplant treatments in Mongolia. 5. The increased number of septic coma deaths during the past 5 years indicates that bacterial resistance to antibiotics has grown due to inadequate usage of antibiotics by patients. Also, the high percentage of deaths due to multi-organ failure indicates that more attention should be paid to how this is diagnosed. 6. The increased number of ketoacidosys coma deaths indicates that patients come too late to tertiary health organizations and already have multiple organ failure upon admission.

M-023

394 – UTILITY MEASURES FOR ADHD: A SYSTEMATIC REVIEW

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Objective: Attention deficit/hyperactivity disorder (ADHD) is one of the most prevalent psychiatric disorders among children and adolescents. It causes direct and indirect impairment to families and patients, reducing quality of life and representing a public health concern. Due to the paucity of instruments to measure outcomes in ADHD, decision-makers face some difficulties to allocate resources to health care system. International agencies of Health Technology Assessment have recommended the use of Quality Adjusted Life Years (QALYs) as outcome measure to compare different interventions in health. QALYs is a concept that encompasses morbidity and mortality into one measure and it is based on people preferences, or utilities, for health states. The aim of this study is to perform a systematic review of studies that defined utility measures for different health states of children and adolescents diagnosed with ADHD, treated with stimulants and non-stimulants. Method: The search terms used for EMBASE and Pubmed databases were “utility index”, “health utility index”, “utility scores”, “utility values”, “health state utility”, “attention deficit hyperactivity disorder”, without time limit. Also, references from systematic reviews were analyzed. Results: From 107 papers identified, it was detected the predominance of the standard gamble method, and a scarcity on utility measures for ADHD health states based on direct reports from young patients, and the absence of such studies in developing countries. Also, there is no study based on the direct perception of the patient. Conclusion: The authors highlight the importance to perform clinical trials and utility measures with different instruments, in a heterogeneous ADHD sample. Also, there is a scarcity of studies in this area on developing countries.

M-024

445 – MIDDLE EAR IMPLANT FOR HEARING LOSS– WHAT IS THE EVIDENCE?

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Objective: Middle ear implants (MEI) are surgically implanted electronic devices which stimulate the ossicular chain or middle ear in order to correct hearing loss. The objectives were to assess the safety and efficacy of the MEI in patients with hearing loss through a systematic review of the literature. The comparators were the cochlear implant (CI) and the bone-anchored hearing aid (BAHA). Methods: Literature was identified through PubMed, EMBASE, the Cochrane Library and Current Contents to August 2009. Systematic reviews and clinical studies that reported the use and clinical outcomes of MEI in patients with hearing loss were included for review. Case reports were included for the evaluation of safety. The TRIP database was searched in August 2009 for available guidelines. Findings No comparative evidence was available to inform on safety of the MEI compared with either the BAHA or CI. Overall, absolute evidence from case series studies suggests that MEI appears to be as safe as CI and BAHA. Only one comparative study assessed the effectiveness of MEI versus the CI, and no comparative studies assessed the effectiveness of MEI versus the BAHA. The remaining studies included to assess effectiveness were all case series, and subject to bias. Generally, MEI implantation and/or activation led to improvements in patients with mild, moderate and severe sensorineural hearing loss (SNHL); SNHL of undefined severity; mild, moderate and severe mixed hearing loss (MHL); MHL of undefined severity; and CHL. The MEI appears to be at least as effective as an external hearing aid. However, these conclusions are limited by the paucity of high-level evidence. Conclusions: There is a paucity of high level evidence upon which to draw conclusions on the relative safety and effectiveness of MEI. This may be related to the relative youth of the MEI procedure.

M-025

421 – DOES INDUCTION OF LABOUR INCREASE THE RISK OF CAESAREAN SECTION? A REVIEW OF COCHRANE REVIEWS

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Background: Induction of labour is the process of initiation of uterine activity and cervical ripening to achieve vaginal delivery. It is a relatively common procedure and a wide variety of methods are used. Caesarean section is considered one of the major complications of induction of labour. This review investigates whether Caesarean section rates are higher following induction compared to spontaneous labour. Methods: The Cochrane database of systematic reviews was searched from inception to November 2010. Included were any Cochrane reviews with studies with pregnant women in their third trimester of pregnancy carrying a viable foetus. Interventions (mechanical methods: amniotomy, membrane sweeping, Foley catheter insertion with/without extra-amniotic saline infusion; pharmacological agents: prostaglandins, oxytocin, corticosteroids, hyaluronidase, mifepristome, oestrogens, relaxin, misoprostol, isosorbide mononitrate; and other means: acupuncture, breast stimulation, sexual intercourse, homeopathic preparations, castor oil, bath and/or enema) were compared to spontaneous labour/placebo/expectant management where Caesarean section rates were reported. Primary studies in the Cochrane reviews were obtained and Caesarean section rates cross-checked with those in the Cochrane reviews. Quality assessment of primary studies was taken from the Cochrane reviews and crosschecked. Meta-analysis of primary study results was in StatsDirect version 2.7.8. Results: Initial searches found 56 Cochrane reviews of which 26 provided 180 relevant primary studies, some being reported in more than one Cochrane review. Twenty-seven references were not retrievable. The combined meta-analysis results were 0.92 (95%CI 0.87-0.96 fixed and random effects), suggesting that Induction was less likely to lead to Caesarean section than spontaneous labour. There was considerable statistical heterogeneity and meta-analysis results for individual comparisons varied considerably. Conclusions: The Cochrane library provides a rich source of data for quick reviews. A full systematic review may be warranted because of heterogeneity of interventions, missing references and because the results were contrary to those expected.

M-026

764 – THE IMPORTANCE OF HEALTH TECHNOLOGY ASSESSMENT FOR THE RECOGNITION OF THE VALUE OF NEW PRODUCTS: THE CASE OF RHEUMATOID ARTHRITIS

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Background: Rheumatoid Arthritis (RA) is a chronic inflammatory disease treated with non-biologic disease-modifying anti-rheumatic drugs (nbDMARDs) as first-line agents. Patients with inadequate response to nbDMARDs are managed with biologic agents, used in combination with nbDMARDs. Anyway, several biologics are nowadays available; new ones, such as tocilizumab, a humanised monoclonal antibody interacting with IL-6 receptor, should be thoroughly evaluated in order to understand their potential advantages. Methods: The Health Technology Assessment (HTA) approach was chosen to study the clinical, economic and organisational impacts of tocilizumab in the Italian epidemiological and socio-economic context. Literature reviews were carried out to evaluate epidemiological, clinical and organisational aspects and a mathematical modelisation allowed the economic and budget impact analysis from the National Health Service viewpoint. Results: Literature review showed that RA is not a frequent disease with a prevalence in Italy under 1%. Anyway, RA sequelae are really harmful: 80% of patients develop disability and it is estimated a reduction of 3-18 years in survival. The mathematical modelisation demonstrated that

tocilizumab, together with a nbDMARD, dominates on other biologics when used as first choice in the second-line therapeutic approach, whichever the biologic drug used as comparator was. Thus, there would be a gain in terms of Quality Adjusted Life Years and a reduction in costs, with a saving of 3.1% in a five years horizon. A timely and multidisciplinary therapeutical intervention, together with a personalised assistance, were shown to be the key elements in the management of RA and in care organisation. The equity in the access to drugs would be anyway pursued through the promotion of consultation processes and procedures to regulate and homogenise the formularies update. Conclusions: This HTA may support decision-makers in the informed evaluation of impacts deriving from the employment of new drugs, such as tocilizumab, for the treatment of RA.

M-027

807 – THREE NEW FRAMEWORKS OF ORTHOPEDIC CLINIC IMPROVING ACCESSIBILITY WHILE INCREASING PROPORTION OF SUITABLE PATIENT'S CASES FOR ORTHOPEDIC SURGEONS

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Objective: To describe clinical framework and assess accessibility, effectiveness and costs associated with the first clinical visit of three new orthopedic clinics based on interdisciplinary teamwork. Method: Focus groups with administrators, physicians and clinical professionals were done to establish clinical frameworks and patient's pathway of each clinic. Accessibility, effectiveness and costs of the first clinical visit were assessed using a retrospective review of clinical and administrative data. Findings: These clinics are supported by a nurse coordinator for triage and a formal interdisciplinary committee that involves the nurse coordinator and health care professionals, including orthopedic surgeons only when necessary. The main contribution is in the service organization of these clinics where patients are first examined by a health care professional instead of an orthopedic surgeon, while in a standard clinic patients are systematically examined by the orthopedic surgeon. Our results showed a significant improvement in accessibility by a waiting time reduction of about 50%. Those clinics show a near 50% increase in the number of patients suited to be examined by an orthopedic surgeon. The expected annual number of hip and knee replacement surgeries was reached even with a reduced number of available surgeons. The cost associated with the first clinical visit is slightly more expensive [78.29 CAD] than that of a standard clinic [74.32 CAD]. However, we expect an important decrease in cost as these clinics become more mature. Conclusion: The aim of these clinics is to provide a high quality service with increased accessibility in which patients who don't require the expertise of an orthopedic surgeon are taken care by another qualified professional. Our results lead us to recognize the benefits of pursuing the development of interdisciplinary orthopedic clinics. These clinics become an innovative solution to the shortage of orthopedic surgeons while increasing patient's accessibility to orthopedic care.

M-028

722 – REREADING THE MULTIMEDIA PROGRAM "INTEGRATING SPEECH-LANGUAGE THERAPY AND SCHOOL": A SUGGESTION FOR READING AND WRITTING DISABILITIES PREVENTION

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This study objectified comparing the multimedia program "Integrando Fonoaudiologia e Escola" developed and applied among fundamental class teachers, between 2002 and 2004, prompting the stimulation of reading and writing abilities, the early detection of children with difficulties in these areas and their refering to specialized professionals, to new software used for similar purposes. A transversal-quantitative research was developed in three steps, in which 39 fundamental class teachers from 4 pre-selected primary schools participated. Before the software use, 57,90% (22) of the teachers considered educational phonoaudiology actions at school as preventive and therapeutic; 82,05% (32) told they had students with some kind of reading and writing disability; 66,67% (26) judged themselves disqualified to deal with these students and 53,85% (21) were not trained for this task. After the training program, 92,31% (36) of the teachers classified it as great; 38,46% (15) considered their knowledge about educational phonoaudiology as very good and 46,15% (18) as enough. Another point to consider was the knowledge increasing about the educational phonoaudiologist functions, once 84,20% (32) classified it as preventive and 94,87% (37) intend to refer their students with problems to this professional. After six years, it is possible to conclude that the training program with this software application still reaches completely its purposes, because there are not many similar programs available to sensitize teachers about the educational phonoaudiologist functions at school, besides alerting and offering subsidies to understanding the importance of the reading and writing stimulation, the identification of children with reading and writing disabilities and their refering to the speech-language therapist. Nowadays, there are many new technological resources for speech-language therapy of reading and writing disabilities; but not for the speech-language therapists train school teachers to identify children with these problems.

M-029

426 – TOTAL HIP ARTHROPLASTY COMPARED TO HEMIARTHROPLASTY FOR DISPLACED INTRACAPSULAR FRACTURE OF THE HIP: A SYSTEMATIC REVIEW

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Background: Hip fracture is a common problem in people aged 60 years or more. Half of all hip fractures are displaced intracapsular fractures, i.e. unstable fractures in which the blood supply to the femoral head may be impaired. There is currently no consensus regarding the optimal treatment for individuals with high pre-facture mobility who experience such fractures: the two options are total hip arthroplasty (THA) and hemiarthoplasty (HA). Methods: A systematic review of randomised controlled trials to assess the effectiveness of THA compared to HA in terms of dislocations, revisions, pain and function, and quality of life. Eleven databases of published and unpublished studies were searched. All citations retrieved were double-screened for inclusion. Meta-analysis and independent sub-group analyses were performed. Findings: The literature search identified 531 unique citations, fourteen of which satisfied the inclusion criteria. This represented eight separate trials with almost 1000 participants. Meta-analysis of seven trials found a statistically significant increased risk of dislocation for patients treated with THA compared to HA (p=0.01) but a statistically significant 69% reduced risk of revision (p=0.0003). There were no differences in terms of mortality. In all eight studies individuals treated with THA reported better function and mobility and less pain than those treated with HA. In four studies this difference was reported to be statistically significant. Four trials reporting utility data found similar trends. Sensitivity analyses indicated that there was no statistically significant difference in outcomes based on the duration of follow-up, study quality, the surgical approach taken (lateral or posterior), type of head (unipolar versus bipolar), or the use of cement. Conclusions: THA may require greater surgical expertise and operating time than HA, but outperforms HA on all outcomes except dislocations. The quality of the evidence is good and the direction of effect consistent across trials, both individually and combined.

M-030

583 – POSITRON EMISSION TOMOGRAPHY (PET) IN COLORECTAL CANCER: RESULTS OF A RAPID REVIEW

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Cancers of the colon and rectum (CCR) occupy fifth place in terms of incidence in Brazil. Its more accurate staging and early detection of recurrence may avoid unnecessary surgery, with potential impact on survival and quality of life of patients. The use of Positron Emission Tomography (PET) can help diagnosis in these processes. This study evaluated the evidence on the accuracy and clinical value of PET in CCR in the following clinical indications: (1) diagnosis; (2) staging; (3) assessment of treatment response; and (4) detection of recurrent disease. It also examined its influence on the decisions of clinical and therapeutic management and its impact on health outcomes. The methodology used was a rapid review of HTA. We conducted: (1) research on reviews produced by HTA agencies belonging to the INAHTA network; (2) survey of clinical practice protocols relating to the use of PET in CCR in the National Guideline Clearinghouse and National Library of Guidelines bases; and (3) literature search for systematic reviews and meta-analysis in MEDLINE, COCHRANE, LILACS and SciELO. The results show a good diagnostic accuracy of PET in: (i) the recurrence evaluation, particularly in the detection of hepatic and extra-hepatic metastases; (ii) cases of suspected recurrence from the increase of serum carcino-embryonic antigen, with negative or doubtful anatomical imaging techniques; and (iii) staging of patients with liver metastases suitable for surgical treatment. The main impact of the clinical use of PET seems to be to avoid unnecessary surgery, especially after the detection of additional lesions not identified by the more usual diagnostic techniques. It is recommended that the possible incorporation of PET on the Brazilian medical procedures reimbursement rates preferentially consider those situations in which technology is accurate and shows potential to change clinical management therapy, to ensure their rational and cost effective use.

M-031

966 – PRESCRIBED THERAPEUTIC SCHEMES FOR ADOLESCENTS WITH ASTHMA: PRELIMINARY RESULTS OF CASE STUDY IN SCHOOLING HOSPITAL

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Pharmacological approach requires quite attention for the chronic use and the possibility of unsatisfactory outcomes, such as adverse events and ending of treatment and the high costs associated. This study analyzed pharmacological treatment regimens for adolescents presenting different degrees of asthma. This is an exploratory and descriptive case study. Patients have been treated in the Instituto Fernandes Figueira (IFF/FIOCRUZ) for the July 2000 - October 2010. The data source were the patients' charts. The collection was performed to characterize the specific population, the treatment regimen, identify compliance and clinical outcomes. Characteristics such as quotidian life habits were observed since changes over the years observed may occur. The study noted the diversity and frequency of drugs used for treatment of asthma by grade and aimed to compare findings with characteristics of the population, treatment adherence and clinical outcomes. 152 records have been observed. The average attendance was 8.3 patients for 10 years. Most patients were from male sex (54.1%), were 13 to 15 years (43.1%) at the time of initial approach, and were diagnosed with mild persistent asthma (72.6%). The respiratory function test was performed in about 18% of cases while 32.3% of patients presented wheezing at the time. On the other hand, we have identified a low exposure to secondhand smoke (39%) and presence of pets in home (37%). We observed 20 different treatment regimens for intermittent asthma, 89 for persistent mild degree, 36 persistent moderate to severe, 12 severe. Budesonide was present in all the commonly prescribed regimens, despite of the degree of asthma. It was estimated that the diversity of treatment is higher than recommended. Besides, pharmacological approach included drugs out of Brazilian Guidelines for asthma treatment (2006). We conclude that our preliminary results ought to have to be confronted with clinical outcomes and also to be discussed with physicians and government authorities.

M-032

21 – LEARNING ASSESSMENT OF HEALTHCARE PROFESSIONALS ENROLLED IN THE TELECONFERENCED EVIDENCE-BASED HEALTHCARE COURSE

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Background: In December 2009, the third edition of the distance refresher course was initiated with about 2,900 enrollments. The 150-hour course, developed along a whole year, was given by members of Brazil Cochrane Center in the Syrian-Lebanese Hospital's Education & Research Institute, supported by Brazil Health Ministry. Students actively participated in the course through an Internet platform, which presented ancillary materials and tutored discussion forums for doubts solving and aids to develop research projects. Objective: Assessing the course effects on concept learnings and competency developments in Evidence-Based Practice; featuring the enrolled students' social-academic profile, as well as their satisfaction level with the course. Methods: Learning was measured by two evaluations taken at the beginning and ending of the Internet-plataform course. Students first filled in a questionnaire about their profession, age, computer skills, etc. Afterwards, they answered to a 20-multiple-choice question evaluation about the contents exposed during the course. Question structure was based on existing concepts of knowledge and skills assessment in Evidence-Based Medicine, such as question formulation, available evidence search, evidence critical evaluation, among others. The research projects carried out and an interview on the students' satisfaction with the course were also assessed. Results: Of the one thousand and forty students who answered the socio-academic profile questionnaire, most were female (79,3%) and mean age 40,13 (±10,41). We concluded that 299 students answered both evaluations. The mean grade for the students (number of questions answered correctly out of 20) in the pre-course test was 8.12 (± 3.36); in the post-course test the mean was 13.64 (± 2.87) with $p < 0.01$. The results of the teleconferenced EBH course showed a mean 68% improvement in learning and skills on EBM. Seven hundred and ninety-two students completed the research project assignment acceptably. Satisfaction level with the course was around 97%.

M-033

754 – TUBERCULOSIS AND DIABETES MELLITUS IN PATIENTS WITH RESPIRATORY SYMPTOMS IN SALVADOR/BAHIA – BRAZIL

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Introduction: Tuberculosis and Diabetes Mellitus (DM) are underdiagnosed conditions in the developing world and increasingly associated as DM is an immunosuppressive disease. Patients with DM have 3 times more chance of developing tuberculosis as compared with the general population. During TB treatment the morbi-mortality of DM patients is also increased. This paper aims to determine the prevalence of DM in patients with respiratory symptoms (PRS), including tuberculosis in the Brazilian National Health System (SUS). Methods: From May to December 2010, all PRS (cough for 2 or more weeks plus another symptom: fever, weight loss, night sweats or loss of appetite; including 20% of tuberculosis patients) at 2 public health care centers at Salvador-Bahia/Brazil were evaluated for DM (Oral Glucose Tolerance Test – OGTT, fasting plasma glucose test (FPG) and HbA1C) and TB (AFB, LJ culture) and had the medical history reviewed. Results. 470 PRS were included. 80 (17%) patients had DM; 32/80 (40%) PRS did not know they had DM. Of those who with DM status known, 60.4% did not have DM well controlled (HbA1C >7%). Fever (PR [prevalence ratio]=2.1; 95%CI 1.3-3.6), weight-loss (4.5; 2.1-9.6), night-sweats (1.8; 1.2-2.9), loss of appetite (2.4; 1.4-4.1), chronic alcohol ingestion (2.2; 1.2-3.9) were associated with TB but not with DM. Tuberculosis patients were younger (44.8+14.5 X 48.8+15.2 years; p=0.04), thinner (BMI 20.5+3.0 X 23.5+4.7 kg/m2; p=0.001) than non-Tuberculosis. DM was associated with age (58.6+12.2 X 46.0+14.8 years; p=0.001). Tuberculosis was associated with DM status, being the prevalence: Controlled-DM 5.3%; Non-DM 12.8%; Glucose Intolerance 15.6%, UNK-DM 18.8%, Uncontrolled-DM 44.8%; p=0.001. Conclusions: A high proportion (40%) of PRS with DM presenting at SUS in Salvador were unknown of their glucose status. Most of DM patients (60.4%) had very poor glucose control. Glucose level control was strongly associated with TB prevalence. CNPQ 559276/09-5

M-034

755 – DIABETES MELLITUS SCREENING IN PATIENTS WITH RESPIRATORY SYMPTOMS

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Introduction: Diabetes Mellitus (DM) prevalence is increasing dramatically. In 2030, it is estimated that 366 million individuals will have DM and as a high morbi-mortality condition it implies in important costs to the health system in all societies. In the developing world, it is a highly under diagnosed disease. On the other hand, it is associated with immunosuppression and infectious diseases. Looking for care to treat respiratory symptoms at the emergency rooms is one of the most frequent reasons for an individual to be visible to the health system. This study aims to evaluate the efficacy of fasting plasma glucose (FPG), capillary blood glucose (CBG), HbA1C in the screening of DM in patients with respiratory symptoms (PRS). Methods: From May to December 2010, all PRS (cough for 2 or more weeks plus another symptom: fever, weight loss, night sweats or loss of appetite; including 20% of tuberculosis patients) at 2 public health care centers at Salvador Bahia/Brazil were evaluated for DM (Oral Glucose Tolerance Test - OGTT). All patients performed FPG (cutoff= 99mg/dl), CBG (90), HbA1C (5.7%), besides having the medical history reviewed. Results: 470 PRS were included, mean age was 48.2+15.2yrs and 54.5% were female. 72 individuals were infected with TB (15.3%) and 80 (17.0%) had DM, of these 32 patients did not know (40%) their status. The highest sensitivity to screen DM was the HbA1C (81.3%) followed by CBG (62.5%) and FPG (46.9%). The negative predictive value was respectively: 97.2%, 96.2% and 95.2%. The ROC (IC95%) for predicting DM in PSR for FBG, CBG and HbA1C were similar, respectively: 0.80 (0.72-0.87); 0.79 (0.70-0.88) and 0.79 (0.69-0.89). Conclusion: Although HbA1C had a better sensitivity, all tests had similar negative predictive value so capillary glucose test had the best cost-efficacy to screen as being fast, easier and cheaper. CNPQ 559276/09

M-035

361 – HEALTH TECHNOLOGY ASSESSMENT STUDY ON DRUG USE IN PATIENTS UNDERGOING BARIATRIC SURGERY

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Introduction: the rapidly growing epidemics of obesity has been a major concern for health systems, once the increasing BMI is associated to an increase in comorbidities, and consequent wider use of therapeutic services and resources, such as drugs. The bariatric surgery has shown to be effective in keeping weight loss and improving life quality in adults morbidly obese. Objective: to assess changes in drug use in patients undergoing bariatric surgery. Method: this is a case series study; 27 morbidly obese patients were interviewed before and after undergoing a surgical procedure between October 2009 and October 2010. Results: A significant reduction in the number of health problems (32.1 % $p<0.01$) was observed; the ones most often reported by patients were: hypertension, dyslipidemia, diabetes and arthicular pain. Dyslipidemia (87.50%) and hypertension (80%) were the ones that had a greater reduction. Gastritis and circulatory problems have been reported only after the surgery. In the pre-surgical phase, 96.3% have used drugs, in which, 84.6% had used after the surgery. Nevertheless, there was a change in the consumption profile due to the need of vitamin and mineral supplementation, as well as the use of proton pump inhibitors. There was a reduction in the consumption of anti-hypertensive, hypoglycemic, anti-inflammatory and anti-depressant drugs; however there was no statistically difference between the number of drugs used before and after the surgery. With regards to non-prescribed drugs, the most significant reduction occurred with the use of analgesics. A reduction in the daily doses of drugs that remained in use was also observed. Conclusion: the surgery was effective to solve health problems, although a bigger sample size would have a higher power to identify the reduction of number of drugs used. There is a possibility that this result is due to the need of including other drugs.

M-036

1002 – ELLABORATION AND VALIDATION A TOOL FOR THE DETECTION OF THE FRAIL ELDERL WITH INCREASED RISK OF HOSPIAL ADMISSIONS IN THE COMMUNITY

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AIM: The purpose of this project was to elaborate and validate a tool for the detection of the frail elderly at high risk for hospitali admission among the community dwelling elderly people and verify if the use of this tool with adequate intervention could reduce the incidence of hospital admissions in the community. Methods: A Questionaire for the Prediction for Repeated Admissions in the Hospital (PRA) was ellaborated based on the literature and applied for a sample of the community dwelling elderly through an existing Primay Health Care System (called Family Health Program, PSF). Those elderly people detected as being at high risk for hospital admission received a healt care intervention to avoid the health problem. The rate of hospital admissions in this sample was compared to the same rate in another sample of the elderly with the same characteristics and the results were compared, using a log-ranking statistical method having the hospital admission as the endpont. Results: 7% of the sampl population was classified as having high risk for hospital admissions. These high risk elderly people have 6.5 time more risk of being hospitalized than those classified at basal risk. The intervention in this high risk group did not decrease the risk for hospitalization, however, decreased the rate of incapacities (functionality) compared to the control group. Conclusion: The use of a tool to idetify frail elderly in the community together with an adequate intervention, may decrease the dependency ratio in the community and improve the functionality of the community dwlling elderly people.

M-037

499 – DIAGNOSTIC RELIABILITY OF A STORE-AND-FORWARD TELEDERMATOLOGY CONSULT SYSTEM FOR GENERAL PRACTITIONERS

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Objective: The aim of this study was to evaluate the diagnostic agreement between a store-and-forward teledermatology consult system and the conventional dermatology consultation. Methods: A prospective non-randomised pilot study was conducted from March 2009 to May 2010 at the dermatology department of a tertiary hospital and a primary healthcare centre in the Basque Country. A total of 225 consecutive patients with 228 skin lesions were diagnosed by means of a teledermatology consult system and conventional dermatological examination. The clinical history, demographic data and digital photographs were obtained by the GPs and sent for teleconsultation via the teledermatology system. The patients were then seen in person by a dermatologist and a final diagnosis was made. Agreement between the diagnoses was assessed. Results: The diagnosed skin lesion categories showed the following distribution: 46 (20.2%) nevus, 37 (16.2%) seborrheic keratosis, 34 (14.9%) eczema, 18 (7.9%) extensive inflammatory dermatitis, 8 (3.5%) skin cancer, 5 (2.2%) pre-malignant skin lesions, 3 (1.3%) benign skin tumours and 77 (33.8%) miscellaneous skin lesions. A reasonably good agreement, 73.6% (CI 95%: 67.5%-78.9%), was achieved between direct observation and teleconsultation. The overall kappa index for all diagnosed lesions was $\kappa = 0.731$ (IC 95%: 0.664-0.798). The kappa index for the seven pre-established skin lesion categories was $\kappa = 0.844$ (IC 95%: 0.775-0.913). Conclusions: Our results show that teledermatology is a highly reliable diagnostic tool with kappa values reflecting an excellent diagnostic agreement between conventional examination and teleconsultation. Store-and-forward teledermatology could be a useful tool for a rapid diagnosis of low complexity skin lesions from primary healthcare units. However, in addition to the reliability assessment, other important aspects such as, patient satisfaction and the acceptance of the new technology by general practitioners and dermatologists should be taken into consideration prior to the large scale diffusion of teledermatology in the healthcare system.

M-038

694 – TOBRAMYCIN AND ALPHA-DORNASE TREATMENT FOR CYSTIC FIBROSIS (CF) IN URUGUAY

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Background: CF is an inherited disease in which exocrine glands produce abnormally viscous mucus, causing chronic respiratory and digestive dysfunctions. Recurrent infections by Ps. aeruginose and others are associated with a faster deterioration in lung function and increase morbidity and mortality. Inhaled Tobramycin and mucolytic therapy with Alpha-Dornase have improved lung function and decreased hospitalization days. Access to these drugs was restricted because it wasn´t covered until December 2007. A system of universal coverage, under a policy framework based in the best evidence and supported by a strong monitoring program was implemented. A systematic process of evaluation was established since the beginning of the coverage. Objective: describe the population, evaluate the impact of treatment (lung functionality, nutritional assessment) and adherence. Methods: Cohort study who began treatment with Tobramycin and/or Alfa-Dornase from December 2007 to July 2010. Adherence to Tobramycine was measured by an index that relates the number of cycles received/optimal number of cycles, values > 0.8 were considered optimal. Changes in forced expiratory volume in 1st second (FEV1) and body mass index (BMI) were assessed. Results: 34 patients (median age 18 years) were included (9 Tobramycin, 7 Alfa-Dornase and 18 both). 21% were Oxygen dependent, 63% had pancreatic dysfunction, 24% diabetes and 11% liver dysfunction. Median age at diagnosis was 2.8 years. Indications of Tobramycine treatment were chronic colonization (70%) and chronic infection (19%). Adherence to Tobramycine was optimal in 81%. Between start and year of treatment there was an increase in FEV1 (43% to 54%, $p<0.05$) but BMI didn't change (19 and 20 Kg/m2). Conclusions: A delay in the diagnostic was observed comparing with international literature (acceptable during the first year of life). Adherence was good, and lung function improved after one year of treatment, but BMI didn't change.

M-039

649 – RISK FACTORS AND INTERVENTIONS FOR DECREASED MATERNAL INFANTILE MORBIDITY AND MORTALITY IN PREGNANT TEENS

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It is a systematic literature review (SLR) whose objectives were to assess risk factors for materno infantile morbidity and mortality in pregnant adolescents and to evaluate the effectiveness of interventions used to reduce materno infantile morbidity and mortality in pregnant adolescents. We consulted the following databases: MEDLINE via PubMed, Scientific Electronic Library Online (SciELO) and Latin American and Caribbean Center on Health Sciences (LILACS). We identified studies published between 2000 to 2010 with the descriptors: risk factors, teenage pregnancy, maternal mortality, adolescent, infant mortality, neonatal mortality. Seven studies presented relevant aspects and were included. Social, cultural, educational and economic indicators became evident as preponderants risk factors to materno infantile morbidity and mortality in pregnant adolescents. The dystocia were seen as an important risk factor for maternal mortality. Prematurity and low birthweight as the main risk factors for early mortality in children ofadolescents. As the interventions towards this serious public health problem monitoring during pre-natal, childbirth and puerperium showed itself as the strongest evidenc. The reduction in length of stay (reduction of exposure in the hospital), increasing the number of services providing care to pregnant women were also evident in the studies. The paternal support was seen as a protective effect. The need for further actions aimed at sex education among adolescents has been shown to be effective intervention also quite intense. Given these data, we suggest the most straightforward implementation of sectoral public policies aimed at groups of adolescents, both within the basic health andeducation (schools, youth groups and others), with the prospect of reducing teenage pregnancy and recurrence, whereas the existence of large personal, existential conflicts, and vulnerability to which they are exposed.

M-040

668 – PREGNANCY IN ADOLESCENCE AS A RISK FACTOR FOR NEONATAL AND POSNEONATAL MORTALITY

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It is a systematic literature review (SLR) with meta-analysis aimed to show teenage pregnancy as a risk factor for neonatal and posneonatal mortality. We consulted the databases of MEDLINE via PubMed, Scientific Electronic Library Online (SciELO) and Latin American and Caribbean Center on Health Sciences (LILACS). We identified studies published between 2000 to 2010 with the descriptors: risk factors, teenage pregnancy, maternal mortality, adolescent, infant mortality, neonatal mortality. Five studies were included because they had relevant aspects. For data analysis we used Stata software version 11.0 where the forest plot type charts were constructed from the odds ratios and their confidence intervals. Q test was used to evaluate the hetorogeneity between studies and in the case face facts it was used the random model. We conducted a meta-analysis of association of teenage pregnancy with neonatal mortality. Q test (16.28) confirms the heterogeneity of the studies and points to the need to use a random model, taking as the combined effect of 1.28 (95% CI 1.13 to 1,44, p<0.001). These results confirm the association between teenage pregnancy and neonatal mortality. In meta-analysis of association of teenage pregnancy with posneonatal mortality also showed the heterogeneity (Q test of 45.34). The meta-analysis also confirms the association between teenage pregnancy and posneonatal mortality in children of adolescents 18 to 19 years as the combined effect of 1,64 (95% CI 1.08 to 2.50, p<0.001). Thus, we suggest the most straightforward implementation of sectoral public policies aimed at groups of adolescents in order to reduce teenage pregnancies and relapses, considering the existence of large personal, existencial conflicts, and vulnerability to which they are exposed.

M-041

1001 – CLINICAL EFFECTIVENESS OF DEEP VEIN THROMBOSIS PROPHYLAXIS IN ORTHOPEDIC SURGERY

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Venous thromboembolism (VTE) is a serious and frequent complication of orthopedic surgery. Despite prophylaxis, subclinical deep-vein thrombosis develops in 15 to 20% of patients, and symptomatic VTE develops in 2 to 4% during the first 3 months after surgery. Current prophylactic treatments include low-molecular- weight heparins, subcutaneous heparin, warfarin and fondaparinux. Low-molecular-weight heparins require subcutaneous injection and Warfarin has a delayed onset of action. Practical limitations of current prophylactic techniques have stimulated a search for simpler methods. The development of new oral anticoagulant agents has raised hopes that they will combine convenience, efficacy and safety profiles similar to or even better than current methods. The use of rivaroxaban, a factor Xa inhibitor, and dabigatran etexilate, a direct thrombin inhibitor, has already been evaluated for safety and efficacy in several phase 3 clinical trials for the prevention of VTE in hip and knee surgery. The Instituto Nacional de Traumatologia e Ortopedia (INTO) is the main public orthopedic Brazilian hospital and also a health technology (HT) advisor for Brazilian government. INTO has recently created it's Health Technology Assessment (HTA) Unit. For the first time, a multidisciplinary team has been working on a HT subject. The pilot project of the unit is to evaluate clinical effectiveness of the new oral anticoagulants for DVT prophylaxis. This is the first part of this project – a one year hip and knee arthroplasty registry. From September 2009 to September 2010, 849 patients were submitted to knee and hip artroplasty and received DVT prophylaxis with enoxaparin according to the institution protocol. The effectiveness and safety endpoints were symptomatic DVT and bleeding. Deep vein thrombosis and major bleeding occurred in 22 (2,6%) and 80 (9,4%) patients respectively. The second part of this project will be a registry comparing the new oral anticoagulants to enoxaparin in a real world

M-042

396 – HOW DO CLINICIANS ASSESS THE VALIDITY OF SCIENTIFIC PUBLICATIONS IN DAILY CLINICAL PRACTICE?

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Objectives: Clinicians are trained to apply the methods of Evidence-Based Practice (EBP) to assess the validity of publications but may only partially apply it in daily clinical practice. We investigated in a first study which of 11 evidence-based criteria were considered important to assess the validity and in a second study if evidence-based criteria were considered more important than “traditional” criteria. Methods: First, we asked 40 medical students, 95 residents, 109 consultants and 31 non-medical staff at Ulm University hospital (total = 275) to rate the importance of 9 evidence-based criteria (e.g. baseline risks were similar) and 2 unrelated validity criteria (e.g. patients recruited in time) on a scale 5 to 1 point (very to not important). Second, we asked 190 physicians, 44 Germans, 22 Italians and 124 Brazilians to rank the importance of 8 evidence-based criteria and 8 “traditional” criteria (e.g. study was supported by a known grant agency). Findings: The evidence based criteria were rated between 4.62 – 3.93 points on a scale of 5 to 1 (very important to not important at all). The two unrelated criteria were rated 3.29 and 3.87. In the second experiment 75% of German, 64% of Italian, and 51% of Brazilian physicians filled in the questionnaires. Unexpectedly, 7 of 8 “traditional” criteria were rated less important than evidence-based criteria. Conclusions: Physicians will agree on the validity of scientific publications if most or none of the validity criteria are met but will likely disagree when some of the criteria are not met. The compliance to fill in questionnaires seems to be different in physicians from different cultures. Physicians of all cultures claim to use preferably evidence-based instead of “traditional” criteria to assess the validity of scientific publications. As these results may reflect true or socially desired answers we should and will continue this

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M-043

569 – SUSTAINABLE VIOLENCE PREVENTION: USING A SYSTEMATIC REVIEW TO INFORM THE DEVELOPMENT OF EVIDENCE-BASED GUIDELINES FOR THE PREVENTION OF VIOLENCE IN MENTAL HEALTH SETTINGS

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Introduction: The successful management of conflict contributes to a sustainable society. Violent behaviour is a type of conflict with high public and political visibility, and can be managed through a range of interventions delivered by health and criminal justice agencies. The extensive evidence base in this area needs to be synthesised to make it accessible to practitioners when making clinical decisions. A recent update of a systematic review conducted by the Liverpool Violence Research Group (LiVio) aims to underpin a decision-making guideline for frontline staff. Issues in converting ‘science’ into ‘practice’ identified by this task will be discussed here. Objective: To examine the issues in translating aggregated quantitative systematic review data into useable guidance for practice. Methods: (1) a systematic review of violence risk assessment and intervention studies published between 2002 -2008; (2) focus groups involving mental health staff and service users about violence management and evidence; (3) synthesis of this evidence to produce a comprehensive guideline for mental health practitioners. Results: The review yielded 990 risk assessment studies and 195 intervention studies. Meta analysis provided some support for medication in the management of violence, supplemented by non-pharmacological interventions for long term management. This was echoed in the focus groups’ main themes, with emphasis on collaboration and ‘breaking down barriers’ between staff and service users. This evidence formed the basis of the guideline, whose structure was based on a policy document developed by the LiVio team. Various data-reduction strategies were examined to ensure effective communication. The final version, presenting structured information on 16 aspects of 35 risk assessment tools and 21 aspects of 127 intervention studies, was evaluated by further focus groups. Conclusion: The detailed findings of systematic reviews require substantial translation and contextualisation in order to be useful to practitioners working with individual patients.

M-044

398– SERUM CONCENTRATION OF C-REACTIVE PROTEIN MAY BE A RISK MARKER FOR THE DEVELOPMENT OF GESTATIONAL DIABETES MELLITUS. RESULTS FROM A SYSTEMATIC LITERATURE REVIEW

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Background: Gestational Diabetes Mellitus (GDM) complicates approximately 7% of all pregnancies and increases risk of maternal and neonatal morbidity and mortality. The recommendation of serum-screening for diagnosis of GDM begins late in pregnancy and leaves not much time to intervention. Limited available data suggest that pro-inflammatory cytokines may be predictive of GDM. Objective: Assess whether serum levels of C- Reactive Protein (CRP) during pregnancy are associated with later diagnosis of gestational diabetes mellitus and the potentiality of this marker to be used as a routine technology in prenatal care services. Methods: The literature search included articles published in English, indexed in the Medline database, using the key words: (C-reactive protein OR inflammatory markers) AND (pregnancy OR gestation) AND (gestational diabetes mellitus). Only studies with prospective design, with healthy pregnant women were included. Findings: Five articles met the criteria and were included. Four out of five showed positive association between levels of CRP in early and middle pregnancy and later development of GDM, three of them found association even after adjustment for maternal body mass index. The risk (assessed by odds ratio in the four nested case-control studies and by relative risk in the cohort) of developing GDM among women in the highest CRP tertile, compared to the lowest, ranged from 2.7 to 3.7. The study with the greater sample size (n=632) revealed the higher risk (RR=3.7). Even though the gestational age at the moment of the analysis varied considerably (11th to 28th week), in four of the studies the CRP assessment was performed before 16 weeks of gestation. Conclusions: The inflammatory status assessed by serum CRP levels seems to be a good parameter to predict the development of GDM. However, further studies are needed to assess what is the correct time for screening.

M-045

686 – EPIDEMIOLOGICAL AND EVOLUTIONARY FEATURES OF OBESE PATIENTS UNDERGOING BARIATRIC SURGERY IN A VITÓRIA-ES HEALTH MAINTENANCE ORGANIZATION

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Objective: To describe the epidemiological profile of patients undergoing bariatric surgery between September 2008 and August 2010 and to assess the weight loss. Method: A retrospective, descriptive and quantitative approach undertaken in the records of a private health maintenance organization from Vitória-ES, in 180 obese patients operated. Weight change was assessed by BMI in pre-and postoperatively. Results: Seventy-four percent of the operated patients were women and 28.6% were men. The most frequent age ranged from 29 to 33 years (18.9%) and less frequent below 18 years (0.6%). Most patients (58.9%) had a BMI above 40, and a minority (0.6%) BMI below 30. 96.2% of men had a waist circumference greater than 102 cm, and 90.6% of women had waist circumference greater than 88 cm. Most of these patients had comorbidities. The most frequent, in decreasing order, were hypertension, hepatic steatosis, dyslipidemia, abdominal obesity, diabetes mellitus, gastroesophageal reflux disease, arthropathy, sleep apnea, and glucose intolerance. Open surgery was performed in 23.5% of the patients, and the laparoscopic approach in 76.7%. The three most commonly used techniques were: Fobi-Capella (73.3%), gastroplasty (14.4%), and duodenal switch (8.3%). During a mean follow-up of 14 months, 86.7% of patients showed weight reduction from 20 to 50%, and 23.3% reduced the weight below the criteria for obesity, therefore there was fall in BMI in both surgery, open and laparoscopic ($p < 0.0001$). Conclusions: Patients undergoing bariatric surgery were mostly women, youth, with a BMI above 40, with waist circumference beyond 88 cm (women) and 102 cm (men) and had the most commom comorbidities being liver steatosis and hypertension. There was a significant reduction of weight regardless of the approach used.

M-046

210 – OXYBUTYNIN VERSUS TOLTERODINE IN THE TREATMENT OF NEUROGENIC BLADDER: A SYSTEMATIC REVIEW OF RANDOMIZED AND NON-RANDOMIZED STUDIES

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Introduction: Oral antimuscarinics such as oxybutynin and tolterodine, in both formulations immediate (IR) and extended release (ER), are the main pharmacological options to manage conservatively neurogenic detrusor overactivity (NDO). Objective: To review the effects of these antimuscarinics on 2 urodynamic parameters clinically meaningful (cystometric capacity and detrusor pressure) as well as its tolerability in pediatric and adult patients. Methods: PubMed, Cochrane Library, Cinahl, Embase, Medline, Web of Science, Evidence-NHS, CRD York, Inahta, Lilacs, Scielo, Ibecs were searched and also the references in key articles were hand searched. Four independent reviewers performed the search; two reviewers independently assessed study quality and extracted data. Results: Twenty-two publications were included, but one of them used 2 research designs which ended-up a total of 23 studies (6 randomized and 17 observational). In the group of pediatric patients, 286 children were treated with oxybutynin IR; 91 with oxybutynin ER; 147 with tolterodine IR and 43 with tolterodine ER. Comparing two times of observation, before and after antimuscarinic therapy, the children who took oxybutynin IR had a percentual mean change of 44.84% in increasing cystometric capacity and 33.53% of reduction in the detrusor pressure to a level less than 40cmH2O. In the group of adult patients, 220 patients were treated with oxybutynin IR; 39 with oxybutynin ER; 99 with tolterodine IR and 11 with tolterodine ER. The adults who took tolterodine IR had a percentual mean change of 146.03% in the bladder capacity increase and 44.57% of reduction in the detrusor pressure for those who took oxybutynin IR. Concerning the presence of side effects, oxybutynin ER and oxybutynin IR had the highest incidence among children and adult patients, respectively. Conclusion: Oxybutynin and tolterodine IR increased cystometric capacity and decreased detrusor pressure at clinically significant levels in the neurogenic population; however with oxybutynin presenting noticeable side effects.

M-047

467 – SCHOOL – BASED INTERVENTIONS FOR OBESITY REDUCTION IN CHILDREN AND ADOLESCENTS: A SYSTEMATIC REVIEW

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Objective: To describe the current literature evidence on school-based interventions to prevent or reduce overweight/obesity in children and adolescents. Methodology: Systematic review. PubMed electronic database was searched up to August 2010. Inclusion criteria: school-based nutrition interventions aiming to reduce overweight/obesity, promote healthy nutrition consumption and/or nutrition knowledge, with ≥4 weeks of intervention and ≥6 months of follow-up for outcome assessment; studies published in English, Portuguese or Spanish and focusing on individuals aged 0-19 years. Exclusion criteria: studies including specific groups (i.e. only girls or boys; only overweight children); interventions not involving children directly. Results: Search strategy using selected keywords founded 4637 studies, and after evaluation for two independent reviewers only 109 studies remained for data extraction, which included 295 different analyses. 44% of the studies were published in the last 10 years; 40% of the interventions were educational, 11% environmental, 46% combined both and only 4% were regulatory. More than a half (57%) of the interventions lasted 6-24 months, and most of them were conducted in North America (55%) ore Europe (30%). Only 45% of 118 analyses for overweight/obesity reduction (or evaluating other similar outcomes: BMI, abdominal obesity, skinfolds thickness, body fatness) showed an improvement in the intervention group, and in 4% the results were worse than in the controls. For healthy nutrition attitudes (increase of fruit, vegetable and/or water intake, and reduction of snacks, soft drinks, candies and/or fat intake), 56% of the 151 analyses showed a significant positive effect in the intervention group and only in 3% the results were worst than in controls. Knowledge about healthy nutrition showed better results, and 89% of the 26 analyses showed a positive effect in the intervention group (11% without effect). Conclusion: interventions showed modest effectiveness to reduce obesity/overweight or modifying nutrition behavior, although improvement in nutrition knowledge was found.

M-048
949 – QUALITY OF LIFE IN A SAMPLE OF PATIENTS WITH CHRONIC HEPATITIS B INFECTION

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Introduction: About 350 million people worldwide live with chronic infection by hepatitis B virus (HBV). An estimated 600 000 persons die each year due cirrhosis and/or hepatocellular carcinoma due hepatitis B. The aim of this study is to determine the quality of life (QOL) of patients with chronic HBV infection comparing QOL of patients with and without clinically significant viremia. Methods: We conducted a cross-sectional survey in patients with chronic hepatitis B infection treated in primary care setting in Bento Gonçalves, Rio Grande do Sul, Brazil. Quality of life was using the validated Portuguese version of the Medical Outcomes Study 36-Item Short Form Health Survey Version 2.0 (SF-36v2®). Anxiety and depression prevalence was assessed using Hospital Anxiety and Depression Scale (HADS). Viral DNA samples were extracted from the plasma of patients and amplified by polymerase chain reaction (PCR) in real time to quantify CV. Results: The mean age of 97 participants was 44.5 years. SF-36v2 scores for the physical component summary (PCS) was 48.4 for women and 46.2 for men (P=NS) and the mental component summary (MCS) was 49.7 for women and 51.6 for men (P=NS). Anxiety was present in 37.8% of women and 30.8% of men. Depression was present in 22.2% of women and 17.3% of men. No differences of PCS, MCS score or anxiety or depression prevalences were found between patients with and without HBV significant viremia. Conclusion: HBV carriers had good physical and mental health and QOL did not differ according viremia status. The prevalences of anxiety and depression were lower than the prevalences found in a similar study conducted among functional dyspeptic patients by our group. Financial support: Edital Rebrats-SCTIE/MS/CNPq.

M-049
900 – HYDROGEL DRESSINGS FOR VENOUS LEG ULCERS

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Background: Venous leg ulceration (VLU) is a condition that causes functional, psychological and financial impact on the affected patients and ultimately impacts quality of life. Treatment based on hydrogel dressing has been prescribed to help ulcer healing. Methods: In this systematic review searches were conducted on major databases to select randomized controlled trials (RCTs) that have evaluated the effects and safety of hydrogel on venous leg ulcer healing. Results: Eight studies met the inclusion criteria. Common exclusion criteria were the comparison to larval therapy and studies evaluating patients with mixed ulcers, without reporting individual outcomes for VLU. From the included studies, the majority of them lacks a clear description of randomization methods and exclusion criteria and do not always have a clear description of side effects. Overall, patients treated with hydrogel dressings had significant reduction in the wound area or volume. The percentage of completed healed ulcers at end points of 8 and 12 weeks ranged from 10% to 33%. In comparison, hydrogel was as efficient as Manuka Honey in deslough. Prostacyclin hydrogel was comparable to hydrogel placebo in wound healing efficiency. Comparing two other types of hydrogel Flaminal demonstrates better effects on wound area and volume reduction compared to Intrasite. Also, Cadexomer Iodine had superior effects on area reduction compared to Hydrocolloid at 12 weeks. Conclusions: There is insufficient data to allow us to drawn strong conclusions. There is a lack of studies comparing hydrogel to standard low-adherent dressings. We have found evidence, although not strong, that hydrogel is beneficial to venous ulcer healing. Financial support: MCT/CT-Saúde and Decit/SCTIE/MS (CNPq – process 559416/2009-1), Brazil

M-050

792 – MEASURES OF ABSOLUTE RISK OF ETANERCEPT IN THE TREATMENT OF RHEUMATOID ARTHRITIS

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Objectives: Despite the high cost of etanercept, is of interest management of the health system studies on its effectiveness, in which usually the knowledge of the subject makes use of relative measures. This paper aims to update knowledge on the effectiveness of etanercept using measures of absolute risk. Methods: We conducted a systematic review of randomized clinical trials in the PubMed, EMBASE and Cochrane, with final date on 01/05/2010. The papers were critically appraised by the Jadad scale, the percentage adjustment to the main CONSORT items and the level evidence of the Oxford-EBMC. The articles were read by titles and summary for initial exclusion and then the full texts remaining. We extracted data from articles through a spreadsheet developed based on the model suggested by SR_CRD York. Results: We retrieved 65 articles. Of these, nine papers met eligibility criteria and study design. We analyzed the ACR20, 50 and 70 through the Absolute Risk in the Control Group (ARC), Absolute Risk Reduction (ARR), CI95% and NNT. Statistical differences were observed in the group with etanercept and methotrexate, ACR20 ARC=0.41, ARR=0.12, CI95% 0.08 to 0.20, NNT=8; ACR50 ARC=0.60, ARR=0.10, CI95% 0.04 to 0.14, NNT=11; no statistical difference for ACR70. Two of three studies that assessed etanercept monotherapy showed no statistical differences in the ACR 20 and none of the three for ACR 50 and 70. Conclusion: Etanercept as monotherapy showed no benefit with clinically relevant measures and when combined with methotrexate was necessary to treat 11 patients to produce one benefit. The approximate cost of SUS (Health Public System), estimated between 2006 and 2009, was US$ 40,567.51 person/year, 36% more than the alternatives of TNF.

M-051

507 – COMPARATIVE EFFICACY OF GUANFACINE EXTENDED RELEASE AND ATOMOXETINE FOR THE TREATMENT OF OPPOSITIONAL SYMPTOMS IN CHILDREN WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND CO-MORBID OPPOSITIONAL DEFIANT DISORDER (ODD)

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Objectives: To compare the efficacy of guanfacine extended release (GXR) vs. atomoxetine (ATX) for the treatment of oppositional symptoms in children with ADHD and co-morbid ODD. METHODS: A systematic literature review identified three placebo-controlled trials of children with ADHD+ODD (GXR: 6-12 years; ATX: 7-13 years) with GXR or ATX. One trial for GXR and two for ATX were identified. In all trials, dose was titrated based on therapeutic response and tolerability; for GXR up to 4 mg/day and for ATX up to 2 mg/kg/day or 90 mg/day, whichever was lower. A matching-adjusted indirect comparison was conducted by weighting individual patients from the GXR trial to match the mean baseline characteristics reported for the pooled ATX trials, including age, proportion female, height, weight, ADHD-RS IV total and subscale scores, and oppositional subscale score from the Conners' Parent Rating Scale-Revised Short form (CPRS-R:S). After matching, changes in the CPRS-R:S oppositional subscale score from baseline to endpoint were compared for GXR- vs. ATX-treated patients. Placebo-arm outcomes were compared in parallel to assess balance between the matched GXR and ATX trial populations. RESULTS: Before matching, patients with ADHD+ODD in the GXR trial (n=143) were significantly younger, had lower mean body weight and a higher baseline mean CPRS-R:S oppositional subscale score than those in the ATX trials (n=98). After matching, all matched-upon baseline characteristics were well-balanced across trials (GXR: n=36; ATX: n=47). Placebo-arm reductions in the mean CPRS-R:S oppositional subscale score were well-balanced at -1.8 in both trial populations. Comparing active arms between these matched trial populations, GXR was associated with a significantly greater reduction in the mean CPRS-R:S oppositional subscale score from baseline to endpoint compared to ATX (-5.0±4.6 vs. -2.4±4.5, p=0.013, effect size=0.58). CONCLUSIONS: GXR was associated with significantly greater improvement in oppositional symptoms than ATX in children with ADHD and co-morbid ODD.

M-052

331– EVALUATING THE PATIENT AND HEALTHCARE PROVIDER SATISFACTION AND CLINICAL OUTCOMES OF THE REMOTE MONITORING OF CARDIAC PACEMAKERS IN CANADIAN HEALTHCARE SETTING

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Introduction: The number of Canadians with Cardiac Pacemakers (CP) continues to grow at 5%/year with substantial increase on the burden of resource-constrained cardiac services. Patients with CP have biannual in-clinic follow-ups. New technologies have enabled clinicians to assess the device and some physiologic parameters using a home monitoring system through telephone lines, secured servers and the Internet. The purpose of this study was to evaluate the potential clinical outcomes and perceived benefits of using the CareLink Remote Monitoring system (CLRM) as a substitute for in-clinic follow-up. Methods: In an observational, multicenter prospective study, CLRM was substituted for traditional in-clinic follow-up. Patients had scheduled transmissions but could also transmit outside this schedule or come to clinic for unscheduled follow-up if necessary. Results: 120 patients with CP (58% male), mean age 73.8 (SD=11.2) years were enrolled in 3 provinces. Majority of the patients travelled between 1-3 hours, average of 121 km (range:1-1492 km) and on average spent $40.10 (range:$6.10-$154) per visit. Data from 79 scheduled batch review sessions with 325 transmissions were analyzed. 13 transmissions identified need for: device reprogramming (5), medication change (6), device change (1), and hospital admission (1). >95% clinicians/nurses were satisfied with CLRM data and felt it was equivalent to data collected during a clinic visit. >97% of patients preferred CLRM to in-clinic visit due to the convenience. Mean in-clinic device evaluation time by the allied professionals (AP) was 14.1 min. (range:2-45 min.). Average time was 8 min./patient using CLRM (range:1-27 min). This study demonstrated that one AP can evaluate 20 more patients/day with CLRM. Conclusions: Patients preferred remote monitoring of their pacemaker using CareLink and clinicians perceived the device remote evaluation information equal to in-clinic visit. When used routinely, remote device monitoring significantly increases clinic efficiency. Furthermore, earlier identification of abnormal device function or developing cardiac conditions may improve long-term patient

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M-053

730 – SUNITINIB AND SORAFENIB IN PATIENTS WITH METASTATIC RENAL CELL CANCER: ACCESS AND PERFORMANCE IN URUGUAY

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Introduction: In Uruguay, renal cell cancer (RCC) is the nineth and eleventh in frequency in men and woman, respectively. Sunitinib and Sorafenib inhibits receptor of vascular endothelial and platelet-derived, growth factor. Both are funded, with centrally and universal coverage, for metastatic RCC patients. The coverage include first-line treatment in patients without significant chance of benefit of treatment with IL-2 or I-α, and, second-line in patients without response to IL-2 or I-α. A regulatory framework for coverage and a systematic process of evaluation were established. Objective: Assess the access, effectiveness and tolerance of Sunitinib and Sorafenib in metastatic RCC. Methods: Cohort study of patients treated between January and December 2008. We assessed progression-free survival (PFS), overall survival (OS) (Kaplan-Meier method), response rates, and adverse effects. Results: treatment was solicited for 110 patients, was approved for 104 (94.5%). Rate of solicitude was 0.42/10000 inhabitants over 14 years, it was significantly lower for patients assisted at the public facilities compared with private (0.25 vs 0.64/10000 inhabitants, $p<0.001$), and for patients of the departments of rest of the country compared with de capital department (0.35 vs 0.52/10000 inhabitants, $p=0.038$). 84 patients (male 66.7%, 58 years) began the treatment before 1st October 2008 and were followed-up for 8.5 months. Clinical response was documented in 33% of patients, the duration of treatment was 6 months. Death occurred in 28 pacients and progress in 11. PFS and OS at one year were 51.6% and 56.1%, respectively. Treatment was stoped in 34.5% of patients, because disease progression in 13.1% and adverse effects in 10.7%. Adverse effects were reported in 64.5% and in 41.7% were grade III or IV. Conclusions: Response rate, and OS PFS were similar to internationally reported. Adverse effects were frequent and moderated to severe, and motivated stopping treatment. Nevertheless universal coverage, inequality in access probably persists.

M-054

731 – CLINICAL EFFECTIVENESS OF DRUG ELUTING STENT IN URUGUAY

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Introduction: Percutaneous coronary interventions (PCI) with stent implantation are funded, centrally and universal, since 1993 in Uruguay. A regulatory framework, systematic evaluation and national registry were established. Coverage of drug eluting stent (DES) was incorporated in 2005. Objective: Assess long-term results of DES and bare-metal stent (BMS) in patients with PCI. Methods: Historic-cohort study of patients undergoing PCI between January 1st 2003 and December 31st 2007. At vessel-treated level we assessed free-survival of target-vessel revascvularization (TVR). We assessed overall survival (OS), and free-survival of a composite event (CE) (death or TVR) in patients. Propensity-score (PS) was used for risk adjustment (stratification and matched-cohort). Results: 11067 patients (16166 vessels) were treated (BMS in 8650, DES in 1458 and both in 959 patients). 2846 vessels treated with DES were matched (stratified for vessel) with 2846 treated with BMS. DES was associated with greater free-survival of TVR (HR 0.69, CI 95% 0.6-0.9), effect exclusively determined for results of left anterior descending artery (LAD). 1458 patients treated with DES were matched with 1458 with BMS. OS was greater with DES (HR 0.69, CI 95% 0.5-0.90), effect mainly determined for patients in quintile 5 of PS. The CE free-survival was greater in patients with DES (HR 0.7, CI 95% 0.6-0.8), this effect was similar for patients in quintiles 3 to 5. Basal risk was not completely controlled, at day 5 there was 0.55% of absolute difference (RR=0.5) of mortality in favor of DES cohort. Correcting for this bias, OS was lower in patients with DES (HR 1.29, CI 95% 1.1-1.5). Conclusions: DES were effective in LAD artery but not for other vessels. DES were associated with greater OS and CE free-survival in patients with indication strongly adjusted to the clinical practice conducted in Uruguay. This potential benefit wasn't confirmed once the bias was corrected.

M-055

732 – BEVACIZUMB IN PATIENTS WITH METASTATIC COLORECTAL CANCER: ACCESS AND PERFORMANCE IN URUGUAY

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Introduction: Colorectal cancer is the third in frequency and the second leading cause of death from cancer in Uruguay. Bevacizumab is a recombinant humanized monoclonal antibody to vascular endothelial growth factor. It is funded, with centralized and universal coverage, for metastatic colorectal cancer patients in Uruguay. A regulatory framework for coverage and a systematic process of evaluation were established. Objective: Assess the access, effectiveness and tolerance of Bevacizumab associated with chemotherapy in patients with metastatic colorectal cancer in first or subsequent line of treatment. Methods: Cohort study of patients that began treatment with Bevacizumab between November 2008 and December 31st, 2009. We assessed adverse effects, response rates, progression-free survival and overall survival (Kaplan-Meier method). Results: treatment was solicited for 254 patients, was approved for 222 (87.4%). The rate of solicitude was 1/10 000 inhabitants over 14 years, it was significantly lower for patients assisted at the public facilities compared with private (0.52 vs 1.49/10000 inhabitants, $p<0.001$). 204 patients received the treatment and were followed-up for 15.5 months. The clinical response occurred in 40% and its duration was 12 months. Median progression-free survival was 13.7 months (CI 95%, 12-16 months). In first line was 12.5 months (CI 95%, 11-14), in relapsed was 14.2 months (CI 95%, 8-21) and in progression was 8.9 months (CI 95%, 7-11). Overall survival was 16.3 months, without difference according to clinical situation or line of treatment. Adverse effects were reported in 30% of the patients and forced the dose adjustment or suspension in 1.5%. Conclusions: Response rate and overall survival were similar to internationally reported and progression-free survival was longer than expected. Adverse effects rate was lower than reported, probably linked to underreporting. Nevertheless universal coverage inequality in access probably persists.

M-056

219 – WEB2.0 EVIDENCE-BASED MEDICINE – THE ERA OF WEB2.0 IN EBM FOR HEALTH PRACTICE

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Background and Purpose: Evidence-based medicine (EBM) activities are usually limited to academic activities. In order to actually implement the concept of EBM in clinical problems, it is necessary to enhance the convenience of EBM clinical issue discussion among medical personnels. We aim to construct “evidence-based medicine platform” through Web2.0 technology for the purpose of discussing the case of clinical problems on Internet, and provide the Internet forum for medical professionals to reach a consensus in clinical diagnosis and management. Method: We searched for related studies in English publication, and held an expert conference. The platform systems were devised according to the information requirement, the equipments specifications, and EBM specialist’s suggestions Results: The medical personnel may express the EBM cases easily, establish a PICO information, and participate in the discussion of the case via the convenient interface. The system also provides complete web admin maintenance functions to manage all information. Conclusion: The EBM platform equips with Web 2.0 technology, and the content revolves mainly around evidence-based medicine. We hope the process of innovation and EBM education with more creative and effective way may evolve from the traditional EBM teaching to a convenient paradigm for EBM practicing in Taiwan.

M-057

556 – A SYSTEMATIC LITERATURE REVIEW: ENZYME REPLACEMENT THERAPY IN FABRY DISEASE

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Fabry disease (FD) is characterized by a deficiency of the enzyme α-galactosidase A, causing the accumulation of globotriaosylceramide (GL-3) in tissues. Treatment with enzyme replacement therapy (ERT) was introduced less than 10 years ago with agalsidase alfa (biweekly dose of 0.2mg/kg) or agalsidase beta (biweekly dose of 1mg/kg). Some aspects related to ERT in FD are still being evaluated/discussed. Methodology: In order to examine the efficacy and safety of ERT, a systematic literature review was conducted searching for prospective studies comparing alpha or betagalsidase to other interventions until July 2010 in the following databases: Clinical Trials, Cochrane Library, MEDLINE, EMBASE and LILACS. Results: Ten randomized controlled trials (RCTs) comparing the biweekly dose of 0.2mg/kg or 1mg/kg (alpha or betagalsidase, respectively) to placebo were included (5 for each one). One RCT (1mg/kg biweekly) showed no difference in the incidence or rate of progression of renal, cardiac, or cerebrovascular events. Neuropathic pain was assessed in 2 RCTs; improvement was reported in one (0.2mg/kg biweekly) but not in the other (1mg/kg biweekly). One RCT with the dose of 1mg/kg biweekly showed that kidney function did not change between baseline and the final assessment. GL-3 deposits in the kidney, skin and heart normalized after the biweekly dose of 1mg/kg and partially decreased with 0.2mg/kg biweekly. Conclusion: The majority of outcomes measured in the RCTs were surrogate endpoints with clinical heterogeneity and few patients; this limits conclusions about the effect of ERT on FD. Support: MCT/CNPq/MS-SCTIE-DECIT 033/2007

M-058

558 – HAEMATOPOIETIC STEM CELL TRANSPLANTATION IN MUCOPOLYSACCHARIDOSIS TYPE II: A SYSTEMATIC LITERATURE REVIEW

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Hematopoietic stem cell transplantation (HSCT) is a therapeutic option in early life for Mucopolysaccharidosis (MPS) type II (Hunter syndrome). Methodology: to evaluate the effect of HSCT in MPS II, a systematic literature review was conducted on Clinical Trials, Cochrane Library, MEDLINE, EMBASE and LILACS until October 30, 2010. Inclusion criteria were blinded randomized controlled trials (RCTs); if <5 studies were identified, the following would be included: open label trials, non-randomized controlled trials, or prospective case series ≥5 patients. Results: RCTs were not found; clearly retrospective studies were excluded. Three case series were included; they did not specify if they were retro or prospective studies. One of the three studies evaluated eight boys that received HSCT at the age of 3-16 years and followed them for 7-17 years; this study showed that cardiovascular abnormalities and perceptual hearing defects stabilized; hepatosplenomegaly resolved; and joint stiffness improved. The neuropsychological outcome was variable and appeared to be related to the severity of the syndrome. Enzyme level improved but never achieved normal values. One patient died from an unrelated cause seven years after HSCT. The objective of the second study was to investigate Mongolian spots in seven MPS II patients after HSCT; this study concluded that there was no resolution between 7 and 26 months; none of the patient died. The third study followed five boys for 35 days to investigate papules with a 'pebbly' appearance; this study showed that it disappeared after a mean time of 18 days after HSCT. Conclusion: BMT had a potential benefit, but its use in MPS II remains controversial due to the paucity of available data. Studies comparing BMT to long-term enzyme replacement therapy are needed. A meta-analysis was planned; however, the data were heterogeneous and did not allow for it to be conducted. Support: MCT/CNPq/MS-SCTIE-DECIT 037/2008

M-059

238 – BRACING FOR RADIAL NERVE INJURY: CHEAPER, LIGHTER AND MORE PRACTICAL – MORE FUNCTIONAL

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Bracing for Radial Nerve Injury: Cheaper, lighter and more practical - More functional The hand function is extremely impaired when there is a peripheral nerve injury. In this work, we focused on the lesion type neuropraxia radial nerve, the consequences, the functional deficits caused by injury, treatments, both medical and occupational therapy, results, conclusions, finally, we will bring this work, the observation of cases were followed in a public health unit in Rio de Janeiro from 2002 to 2010. Neuropraxis is a temporary injury and functional peripheral nerve, where there is no discontinuity in it (Lianza, 82, p.319). If there is no discontinuity of nerve injury and is a temporary, is can be treated, thus avoiding later sequels that can lead to a greater commitment of the affected limb. An early approach can accelerate the recovery of this patient, providing you with a shorter treatment and recovery that can reach a whole. We verified the importance of an early approach in specific cases of neuropraxis Radial Nerve, detect as soon as the injury for which the approach can be immediate; Among the objectives: Manufacture of orthoses (dynamic) Promoting independence. The methodology consists of a standardized interview; Anamnesis; Measurement Variation Active Movement (VAM) through the periodic use of goniometry, muscle strength measurement using a dynamometer; Measurement of the difficulties in carrying out Activities of Daily Living (ADLs) and Activity Life Practice (AVP); Had resulted in the total functional recovery in cases where the approach was an early and partial recovery of hand function in cases where the approach was given later, where we concluded the importance of an early approach to the functional recovery of hand.

M-060
489 – HEALTH TECHNOLOGIES ASSESMENT AS A TOOL FOR THE RATIONAL USE OF MEDICINES

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The technological assessment in health matters aiming at effectiveness and safety recognizes the benefit of antidepressants and benzodiazepines combined therapy only in the beginning of the treatment for major depression (up to 4 weeks). Prolonged or non-monitored use of combined therapy may result in damages such as dependence, tolerance, propensity to accidents, and falls. Objetives: characterize the type of antidepressants therapy (either or not combined with benzodiazepines), which is being applied to major depression patients attended by the public health care system – SUS – of Porto Feliz City – SP, and establish a relation with antidepressants rational use indices (indication, dosage, frequency, and correct usage time). Methods: this is an observational, transversal, retrospective and analytical study developed in the public health care system of Porto Feliz City, in the State of São Paulo, Brazil. The sample comprised patients under treatment, diagnosed with major depression, attended from January 2008 to December 2009. Findings: 86.4% of users were women, 56.6% married, 70.6% aged between 21 and 59, 52.8% patients with comorbidities, 50.6% used other medicaments concomitantly and chronically with antidepressants therapy. Nearly 53.7% used combined therapy and 42.3% used monotherapy. In general, fluoxetine (52.8%) and diazepam (40.9%) were the most prescribed drugs. Approximately 65% of patients underwent combined therapy for over 360 days. Polipharmacy was found in 91% of prescriptions and major drug interactions were found in 11.3% of cases. Over 77% of prescriptions did not comply with the rational use criteria, apply misconceived dosage and frequency, besides exceeding safe usage time for combined treatment. Conclusions: the most patients attended by SUS – Porto Feliz, SP are treated with benzodiazepines-combined therapy, neither reflecting the best scientific evidence nor relating to the rational usage criteria. Education and information devoid of commercial interest could contribute to the rational use of medicines. Key words: antidepressants, benzodiazepines, depression

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M-061
349 – STEM CELL THERAPY FOR NEUROLOGICAL DISEASES

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Objective: To determine the safety, efficacy and cost implication of stem cells transplantation for neurological diseases namely, cerebral palsy, motor neuron disease, stroke, multiple sclerosis, muscular dystrophy, femoral head necrosis, diabetic foot, lower limb ischaemia, spinal cord injury and optic nerve hyperplasia. Methods: A systematic review was conducted. Literature were searched through electronic databases which included Medline, Cochrane Library, Science Direct and general databases such as Google and Yahoo. Quality of the studies was assessed using Critical Appraisal Checklist Project (CASP) checklists and the data was extracted and summarised in evidence table. Findings: There was insufficient and inconclusive evidence on the efficacy and safety of stem cell therapy for neurologic diseases in adult. The evidence on stem cells therapy for multiple sclerosis showed that it is still at experimental stage. Similarly, the evidence on stem cell therapy for stroke and spinal cord injury was insufficient and showed that it was still in the developmental stage. There was also no evidence retrieved on motor neuron disease, femoral head necrosis, diabetic foot, lower limb ischaemia, and optic nerve hyperplasia As for paediatric neurological disorders such as cerebral palsy, autism and spinal muscular atrophy, no evidence could be retrieved from the published literature to date on the use of stem cell therapy with regards to its efficacy, safety and cost-effectiveness. Adverse events are common with stem cells therapy and range from minor to severe adverse events. There was no evidence retrieved on cost effectiveness of stem cells therapy for neurologic diseases. Conclusion: Stem cell therapy for the neurological diseases is still at developmental stage. More evidence is required before it can be recommended as standard practice.

M-062

638 – CONTINUOUS INFUSION OF LOCAL ANAESTHETIC AGENTS FOR POSTOPERATIVE ANALGESIA – A SYSTEMATIC REVIEW

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Objective: Multimodal analgesia for the treatment of postoperative pain by combining different analgesics with local anaesthetic techniques is believed to improve pain relief and reduce adverse effects. The use of local anaesthetic infusions into the surgical wound area has increased during the last decade, when single-use elastomeric infusion pumps and multi-holed wound infusion catheters have become available, allowing a continuous infusion into the wound area for several days. Placing the wound catheter is technically easy and considered to be a safe procedure. The direct cost is approximately €80-220 per patient, including the pump and the catheter, a syringe for filling the pump, and the local anaesthetic solution. Methods: A systematic literature review with no language or time restrictions. Randomized, double blinded placebo controlled studies of all surgical sites and age groups with at least 25 surgical patients per group were included. The quality of original studies was assessed. Findings: The inclusion criteria were met by 16 studies including seven studies of orthopaedic surgery (shoulder, knee, iliac crest bone-graft), eight of abdominal or pelvic region operations, and one of paediatric surgery. The evidence for the efficacy of continuous local anaesthetic infusion into the wound was inconsistent. Catheter infusion did not have an unambiguous effect on postoperative nausea and vomiting or hospital stay. Complications were uncommon, and there was no evidence for increased risk of infection. Conclusions: The present evidence on the efficacy of continuous local anaesthetic infusion into the wound area does not support the routine use of wound catheters in the treatment of postoperative pain. Further research is needed to define whether some special groups, such as those with contraindications for epidural analgesia, opioids or anti-inflammatory agents, benefit from local analgesia, and to clarify the role of a single local anaesthetic infiltration of the wound in comparison to continuous infusion.

M-063

676 – SYSTEMATIC REVIEW OF THE EFFECTIVENESS OF NALTREXONE VS ACAMPROSATE IN THE TREATMENT OF ALCOHOL DEPENDENT PATIENTS WHO ADDITIONALLY UNDERGO PSYCHOTHERAPY

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Objectives: The aim of this systematic review was to compare the clinical effectiveness and safety of naltrexone (NTX) and psychotherapy (PSY) versus acamprosate (ACA) and psychotherapy (PSY) in the treatment of alcohol dependence. Methods: We searched CENTRAL, MEDLINE and EMBASE for relevant randomized controlled trials published up to 2010 according to the guidelines of the Cochrane Collaboration and the HTA Agency in Poland (AOTM). Selection criteria: adults aged ≥ 18 who are dependent on alcohol receiving at least 12 weeks of naltrexone (50 mg per day administered in oral form) with psychotherapy were compared to those receiving acamprosate also with psychotherapy; outcome: abstinence, relapse, craving, safety. Results: Following the systematic search process of publications, 3 primary, randomised clinical trials (12 weeks: Kiefer 2003, Morley 2006 and 12 months: Rubio 2001) were found (subtype II A), satisfying the analysis inclusion criteria. The analysis of clinical efficacy referring to NTX/PSY vs. ACA/PSY comparison at 12 weeks, did not show any statistically significant differences regarding: absolute abstinence, relapse, withdrawals from the treatment and adverse events (apart from diarrhea - result to the benefit of NTX/PSY). Based on results obtained for the NTX/PSY vs. ACA/PSY analysis in 12 months period, it may be assumed that treatment of naltrexone along with psychotherapy is a more effective therapy. All results were statistically significant in favour of NTX/PSY: abstinence [RR (95% CI) = 1.94 (1.30; 2.95)] relapse [RR (95% CI) = 0.71 (0.56; 0.87)] and alcohol craving intensity assessment [StMD (95% CI) = -0.36 (-0.67; -0.04)]. Naltrexone taken for 12 months turned out to be a drug well tolerated and safe. Safety profile of interventions assessed may be recognised as similar. Conclusions: Naltrexone plus psychotherapy for alcohol-dependent patients shows higher clinical effectiveness and comparable safety profile in comparison with acamprosate in long term observation period.

M-064
516 – IMPACT OF THE USE OF PALIVIZUMABE IN PREMATURE KANGAROO METHOD

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Introduction: The palivizumabe is a specific monoclonal antibody to respiratory syncytial virus, taking its use released for newborns and infants up 2 years old risk group.The purpose of its administration is to prvent pulmonary infection in a risk group, particularly in autumn/winter season.Objective: Verify the action os palivizumabe ant tobacco on the number of hospitalizations for respiratory failure en infants from the study. Method:study retrospective case-control type,consisting of 45 newbornswho have not received palivizumabe in inpatient birth(control group) and 29 neoates who received the drug(group P).Conducted phone interviews with parents os patients, questioning them about smoking in the home and lung pathologies/ hospitalizations. Effect measure used was the odds ratio and relative risk.Results:control group with average of gestacional age of 33 6/7s,birth weigth1655g,smoking home53,3% and hospitalization15,6% and Group P with gestaciobal age of 30s, birth weigth1175g, smoking 17,2% and hospitalization 6,9%.The possibility of hospitalization of group P was virtually 2,5 times samller than the control group and non smoking house presents itself as an adjunct reduction factor of hospitalization.Conclusion:use of palivizumabe produced a strong impact on the population studied, is a protective medication.

M-065
628 – SYSTEMATIC REVIEW AND META-ANALYSIS OF PHOTOSELECTIVE VAPORIZATION FOR BENIGN PROSTATIC HYPERPLASIA

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Introduction Benign prostatic hyperplasia (BPH) is a non-cancerous growth of the prostate gland, which lower urinary tract symptoms. It is a prevalent disease that rises with age, it is estimated that 25% over 40 years men suffer from BPH. Treatment of BPH should be chosen depending on the severity of symptoms, when surgery is indicated, for many years the best option has been transurethral resection of prostate (TURP). In last years, there have appeared some treatments that claim to be as effective as TURP, but with lower morbidity and mortality associated. One of the most promising is photoselective vaporization of the prostate. Our objective is to determine if photoselective vaporization is safe and effective for the treatment of BPH. Methods Systematic review of the literature was performed to establish comparative safety and efficacy of photoselective vaporization of the prostate.Electronic search of randomized controlled trials was conducted trough Medline, Embase and Cochrane Central Register of Controlled trials databases until June of 2010. Operative and postoperative measures, reoperation rates and other clinical symptoms were extracted and pooled using weighted mean difference or odds ratio meta-analysis. Results A total of 10 publications of 7 randomized controlled trials were included in our revision. Photoselective vaporization is compared with TURP in five trials, open prostatectomy in one trial and Holmium resection in another trial. Compared with TURP, photoselective vaporization is less efficacy in terms of flow rate (-3.35 ml/s), postvoid urine volume (27.6 ml) and reintervention rate (odds ratio 4.99) and not statistically different in symptom score and quality of life. Conclusions Photoselective vaporization of prostate reduces hospital stay and complications compared to TURP. In long term is not different in symptom scores despite worse clinical outcome measures. It would be considered an option of BPH treatment.

M-066

631 – SYSTEMATIC REVIEW AND META-ANALYSIS OF THE EFFECTIVENESS OF THE STEREOSCOPIC VISION SYSTEMS FOR MINIMALLY INVASIVE SURGERY

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Objective: Evaluate the effectiveness and safety of the stereoscopic vision systems compared with conventional vision for minimally invasive surgery. Methods: EMBASE, MEDLINE and CINHAL data bases were consulted. We included studies that used a system of stereoscopic vision for laparoscopic surgery or laparoscopic simulation exercises with a conventional vision comparative group. The quality of clinical studies was evaluated using a checklist. From each study the data was extracted to elaborate the synthesis of the evidence. A structured qualitative synthesis and meta-analysis were conducted. Findings From the consulted data bases, could be obtained 1,360 articles. 61 publications were included. 35 based on stereoscopic monitors, 15 on stereoscopic head mounted displays and 11 on computer assisted surgery. Randomized clinical trials have only been found for those systems that used glasses with filters. The variable time of execution was registered in most of the studies so meta-analysis was obtained for this outcome. The devices of stereoscopic vision on monitors do not allow the fastest accomplishment of the exercises of endoscopic simulation. For the devices mounted on the head has been certain difference in the time of accomplishment of the tests in favour of them although there were not statistically significant. The stereoscopic devices incorporated in equipment of computer assisted surgery allow to produce exercises of endoscopic simulation faster that when stereoscopic vision is suppressed. Conclusions: Only were found randomized clinical trials for systems that used glasses with filters. We did not find statistically significant differences for the stereoscopic devices on monitors nor for the head mounted stereoscopic devices. Statistically significant differences for the robotic devices were found. The published studies refer to the use of these devices in exercises simulating laparoscopic surgery, reason why the accomplishment of more studies in real conditions would be necessary.

M-067

477 – INDIRECT COMPARISON OF VASCULAR ENDOTHELIAL GROWTH FACTOR (VEGF) INHIBITORS FOR THE TREATMENT OF DIABETIC MACULAR OEDEMA

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BACKGROUND: The anti-VEGF agent, bevacizumab is not licensed for treatment of diabetic macular oedema (DMO), but has been used. A molecularly similar agent, ranibizumab has recently been licensed for DMO. The difference in cost is considerable (£761 per injection for ranibizumab, £50 per injection for bevacizumab). No head-to-head trials have been conducted. Our aim was to estimate the relative efficacy of ranibizumab and bevacizumab for DMO. METHODS: All randomised controlled trials comparing bevacizumab or ranibizumab for DMO were assessed for common comparators and methodological heterogeneity. The primary outcome measure was improvement in best-corrected visual acuity (BCVA) of more than two lines as measured by ETDRS chart. Bevacizumab alone was compared to: ranibizumab alone, ranibizumab plus prompt laser and ranibizumab plus deferred laser. Available studies did not allow comparison of bevacizumab plus laser. Indirect comparisons were conducted by estimating mean odds ratios under random effects models, generated using WinBUGS Markov chain Monte-Carlo software. Sensitivity analysis was performed by excluding studies with potentially inconsistent follow-up periods. FINDINGS: Three studies were suitable for indirect comparison. Ranibizumab alone appeared to be associated with improvement in BCVA of more than two lines when compared to bevacizumab alone, although not statistically significant (OR 5.9, 95%CI 0.2, 187.3). Ranibizumab plus prompt laser had a similar effectiveness estimate as bevacizumab alone (OR 1.07, 95%CI 0.11, 14.9). However, ranibizumab plus deferred laser seemed to be less effective than bevacizumab alone, but this was not significant (OR 0.67, 95%CI 0.04, 11.4). Sensitivity analysis confirmed these results. CONCLUSION: The indirect comparison shows a non-significant, increased odds ratio in favour of ranibizumab alone compared to bevacizumab alone. Laser provided no additional benefit. The choice of anti-VEGF agent will have considerable impact on healthcare budgets. In the absence of head-to-head trials, this indirect comparison does not show a statistically significant difference.

M-068

348 – TRANSCATHETER AORTIC VALVE IMPLANTATION: IMPACT ON HEALTH-RELATED QUALITY OF LIFE

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Background Aortic stenosis (AS), the most common valvular heart disease, is increasing in prevalence as populations shift towards an aged demographic. Transcatheter aortic valve implantation (TAVI) has emerged as an alternative treatment for patients with severe AS, often considered at high risk or ineligible for surgical valve replacement (SVR) because of age and co-morbidities. Objective To determine the impact of TAVI on health-related quality of life (HRQoL) of patients with AS and significant co-morbidities. Methods and Results Interim results are reported from an ongoing 48 month, non-comparative study of TAVI patients (n=126) treated with the Medtronic CoreValve® System (ClinicalTrials.gov NCT01051518). Study participants were considered at high risk or ineligible for SVR due to age and/or co-morbidities. Significant co-morbidities included: diabetes, stroke and coronary heart disease. The EuroQoL (EQ-5D) questionnaire was administered at baseline, and 3, 6, 12 and 24 months post-procedure. Mean health utility scores improved from 0.60 at baseline to 0.71 after 3 months ($p<0.005$), reaching 0.76 after 24 months ($p<0.05$). When compared to UK population norms for a comparable age group (≥ 75 years), utility scores for study participants (81.90±6.43 yrs) reached the normal range by 12 months. Patient perceived HRQoL also improved: visual analog scale scores increased from 53.05 at baseline to 64.39 after 3 months ($p<0.0001$), reaching 69.05 after 24 months ($p<0.0001$). For individual patients significant improvements for pain/discomfort ($p<0.05$) and anxiety/depression ($p\leq0.005$) were observed up to 12 months. Conclusions Improved wellbeing is an important goal of therapy for elderly patients with AS and significant co-morbidities. This analysis demonstrates that regardless of co-morbidities, TAVI provides rapid improvements in HRQoL, which are maintained over the longer term. Although TAVI has proven efficacy for cardiac symptoms and survival in severe AS patients, the full benefits of TAVI are captured through assessment of HRQoL.

M-069

14 – THE CHIRALITY AND THE QUALITY OF BIOEQUIVALENCE STUDIES TO ESTABLISHED GENERICS' EFFECTIVENESS

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The author discusses the question of enantioselective dosing in bioequivalence studies to evaluate the effectiveness of generic medicines. To get this objective a critical reading of the international bibliography, the Brazilian laws and resolutions of health surveillance related to enantioselective determination in bioequivalence studies was done. As it has been stated for registry of medicines, the quality control done by physical-chemical and pharmaceutical equivalence is required in vitro to establish the real health risk associated to chirality, since the settlement of contents and enantiomeric ratio in various dosage forms of reference drugs. Nevertheless there was not a consensus that chirality could control the risk in bioequivalence studies. Despite the limited literature found on this topic there is evidence that enantioselective should be done in special cases of bioequivalence study.

M-070

663 – COMPARISON OF DEMOGRAPHIC PROFILES BETWEEN PATIENTS CANDIDATE TO CARDIAC RESYNCHRONIZATION AND IMPLANTABLE CARDIAC DEFIBRILLATOR. FOUR YEARS EXPERIENCE OF AN ORGANIZATION OF MEDICAL TECHNOLOGY ASSESSMENT IN HEALTH

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Aim: To compare variables of patients (pt) with dilated cardiomyopathy (DC) planned to receive cardiac resynchronizator (CR) or implantable cardiac defibrillator (ICD). Methods: A cohort of 97 patients was evaluated since 2006. Clinical, EKG, left ventricular function (EF) and dyssynchrony (Dyssc) variables were obtained in previous request form. Patients were divided in Gr.1 (CR 21 pt), Gr.2 (ICD 49 pt) and Gr.3 (CR+ICD 27 pt) and compared between (btw) Gr.1 vs Gr.2, Gr.1 vs Gr.3 and Gr.2 vs Gr.3) by univariate analysis. Findings: Age 67,2±13,5 years, 66,0% male. DC (ischemic: Gr. 1=18%, Gr. 2=52%, Gr. 3=30% - p= 0,0002 btw Gr. 2 vs Gr.1 and Gr.2 vs Gr. 3; non-ischemic: Gr.1=35%, Gr. 2=42%, Gr.3=23% p=0,012 btw Gr. 2 vs Gr.3). NYHA-FC: I (Gr. 2 =100%); II (Gr. 2=92% and Gr. 1=8% p=0,00001 btw Gr.2 vs Gr.1); III (Gr. 1=35%, Gr.2=21%, Gr. 3=44% p=0,001 btw Gr.1 vs Gr.2 e 0,0008 btw Gr. 3 vs Gr.2); IV (Gr. 1=40% vs Gr. 2=0% vs Gr. 3= 60% p= 0,0006 btw Gr.1 vs Gr. 2 and Gr. 3 vs Gr. 2). LV bundle block (Gr.1= 34%, Gr.2= 24%, Gr.3= 42% p=0,005 btw Gr. 3 vs Gr.2). NSVT (Gr.1= 12%, Gr.2= 56%, Gr.3= 32% p= 0,00001 btw Gr. 2 and 3 x Gr.1 and Gr. 2 vs Gr.3). QRS (Gr.1=162,2 ms, Gr.2= 126,2 ms, Gr.3= 150,0 ms p<0,0001 btw Gr.1 vs Gr.2). LVEF (Gr.1= 28,4%, Gr.2= 37,8%, Gr.3= 28,5% p=0,01 btw Gr.2 vs Gr.1 e 0,008 btw Gr.2 vs Gr.3). Dyssc (Gr.1=12%, Gr.2=25%, Gr.3= 67% p=0,0002 btw Gr.2 vs Gr.1, Gr. 3 x Gr.1 and Gr.3 x Gr.2). Conclusions: Compared to CR, candidates to ICD have more ischemic DC, LV arrhythmia, shorter QRS, and better NYFC and EF. Candidates to CR+ICD show worse NYFC, more LVBB and LV dyssynchrony.

M-071

675 – COMPARISON OF LEFT VENTRICLE REMODELING PARAMETERS BETWEEN CANDIDATES TO CARDIAC RESYNCHRONIZATION AND IMPLANTABLE CARDIAC DEFIBRILLATOR. FOUR YEARS EXPERIENCE OF AN ORGANIZATION OF MEDICAL TECHNOLOGY ASSESSMENT IN HEALTH

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Aim: Patients candidate to cardiac resynchronization (CR) or an implantable cardiac defibrillator (ICD) share common variables that express left ventricular remodeling (LV-R), but differences may exist and we tried do find them. Methods: A cohort of 97 patients was evaluated since 2006. Echocardiographic variables, related to RV-R, like end diastolic (Ed-d) and end systolic (Es-d) diameters, LV mass and ejection fraction (EF), were obtained from a request form, at the moment of procedure indication. Patients, divided in Gr.1 (CR- 21 pt), Gr.2 (ICD- 49 pt) and Gr.3 (CR+ICD- 27 pt), were compared by Anova and Bonferroni tests, as follow: Gr.1 vs Gr.2, Gr.1 vs Gr.3 and Gr.2 vs Gr.3. Results: Age: 67± 13,5 years, 66% male. EF: CR x ICD= 28,4±8,5 % vs 37,8±15,5 % (p=0,04); CR vs CR+ICD = 28,4±8,5% vs 28,5±8,3%, (p=0,97); ICD vs CR+ICD= 37,8±15,5% vs 28,5±8,3%, (p=0,02). Ed-d: CR vs ICD= 7,0±1,3 cm vs 6,5±1,5 cm ; CR vs CR+ICD= 7,0±1,3 cm vs 7,3±1,1 cm; ICD x CR+ICD= 6,5± 1,5 cm x 7,3±1,1 cm (p=0,20 inter all groups). Es-d: CR x ICD= 5,6± 0,9 vs x 5,7±0,9 cm ; CR x CR+ICD= 5,6± 0,9 cm vs 6,2± 1,1 cm ; ICD vs CR+ICD= 5,7±0,9 cm vs 6,2± 1,1 cm (p=0,34 inter all groups). Mass: CR vs ICD= 325,0± 121,6 g vs 315,9± 160,9 g ; CR vs TCR+ICD= 325,0± 121,6 g vs 377,9 ± 156,1 g; ICD vs CR+ICD= 315,9± 160,9 g vs 377,9 ± 156,1 g (p=0,41 inter all groups). Conclusions: Patients candidate to CR e ICD show the same degree of LV remodeling, but the depression of LV contraction is less severe in ICD group.

M-072

679 – DEMOGRAPHIC PROFILE OF PATIENTS CANDIDATE TO CARDIAC RESYNCHRONIZATION AND IMPLANTABLE CARDIAC DEFIBRILLATOR. FOUR YEARS EXPERIENCE OF AN ORGANIZATION OF MEDICAL TECHNOLOGY ASSESSMENT IN HEALTH

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Aim: To show variables of patients (pt) with cardiomyopathy (CM) planned to receive cardiac resynchronizator (CR), implantable cardiac defibrillator (ICD) or both (CR+ICD). Methods: A cohort of consecutive 97 patients (pt) was evaluated since 2006, with 04 years of follow up. Clinical and non-invasive variables, obtained in previous request form, at the moment of procedure indication are showed in the whole population, as percentage (%) and confidence intervals (IC 95%). Findings: Age 67,2± 13,15 years, 66,0% male. CR= 21 pt (21,6%, 95% CI 13% to 30%), ICD= 49 pt (50,5%, 95% CI 41% to 60%), CR+ICD= 27 pt (27,8%, 95% CI 19% to 37%). Etiology: CMP= 94 pt (97%, 95% CI 93% to 100%), 60 ischemic (63,8%, 95% CI 52% to 72%), 31 non-ischemic (33%, 95% CI 23% to 41%) and 03 unknown (3,2%, 95% CI 0% to 7%); Brugada syndrome, hyperthrophic cardiomyopathy and arrhythmogenic right ventricle dysplasia 1 case each (1,03 %). Symptoms:: dyspnea= 54 pt (56, 95% CI 46% to 66%) syncope/lipotimia= 50 pt (62%, 95% IC 52% a 72%), chest pain= 15 pt (15%, 95% IC 8% a 23%). NYHA: III/V FC= 57 pt (59%, 95% IC 49% to 69%), I/II= 19 pt (19%, 95% IC 21% to 39%). Ventricular arrhytmia: 75 pt (77%, 95% IC 69% to 86%). LBBB: 59 pt (61%, 95% IC 51% to 71%). Sust-TV em EPS: 46/73 pt (73%, 95% CI 64% a 82%).QRS lenght: 143,9± 45,7 ms. LV ejection fraction: 32,4±12,7%. Drugs used: diuretics= 91 pt (94%, 95% IC 89% to 99%), ACE inhb/ARB= 67 pt (69%, 95% CI 60% to 78%), betablocker= 61 pt (63%, 95% CI 53% to 73%), antiarrhythmic= 44 pt (45%, 95% CI 35% to 55%). Conclusions: This cohort of patients disclose a typical profile of pathologies where RC and ICD indication have scientific evidence basis.

M-073

682 – CARDÍAC PREDICTORS OF MORTALITY IN PATIENTS CANDIDATE TO CARDIAC RESYNCHRONIZATION AND IMPLANTABLE CARDIAC DEFIBRILLATOR. FOUR YEARS EXPERIENCE OF AN ORGANIZATION OF MEDICAL TECHNOLOGY ASSESSMENT IN HEALTH

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Aim: To identify mortality predictors, among non-invasive cardiac variables used during the assessment of patients with cardiomyopathy, planned to receive a cardiac resynchronizator (CR), an implantable cardiac defibrillator (ICD) or both (CR+ICD). Methods: A cohort of consecutive and non-selected 97 patients (pt) was evaluated and followed since 2006. The incidence (%) of clinical and non-invasive variables, including EKG and echocardiographic, obtained in previous request form, at the moment of procedure indication, were compared by exact Fisher and Student t texts, in patients (pt) that, in the last follow-up (November 2010), had died. Results: Mean age of 67,2± 13,5 years, 66,0% male. CR= 21 pt (21,6%), ICD= 49 pt (50,5%), CR+ICD= 27 pac (27,8%). Mortality: global= 12 pt (12,3%); CR= 02 pt, 2,1% vs ICD= 05 pt, 5,1% vs CR+ICD=05 pac, 5,1% (p=0,5). Patients who died had the same % of type of cardiomyopathy (ischemic=16,6% vs non-ischemic=6,4% -p=0,71), the same levels of NYHA FC (III/V=15,8% vs I/II= 7,5% -p=0,34), of left bundle branch block (yes=11,8% vs no= 13,1% -p=0,85), of non-sustained ventricular taquicardia (yes=17,4% vs no= 7,8%- p=0,21) and of RV/LV dyssynchronism (yes=27,2% vs no=10,4% - p=0,13). Septum-LV lateral wall dyssynchronism was more prevalent (yes=33,3% vs no=9,41% - p=0,003) and LV ejection fraction was lower (27,2±64 vs 34±13,7 % - p=0,008) in patients who died. Conclusions: In this small cohort of patients with cardiomyopathy that are candidate to cardíac ressynchonization and implantable cardiac defibrillator, left ventricle global dysfunction and septum-lateral dyssynchronism are common risk factors for mortality.

M-074

370 – USELESSNESS OF SERUM FOLIC ACID DETERMINATION IN A TERTIARY SETTING: CROSS-SECTIONAL AND NESTED CASE-CONTROL STUDIES

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Background: Few studies have evaluated the validity of serum folate analysis to clinical practice, and with this aim, we conducted a cross-sectional and nested case-control study. Methods: 1080 consecutive patients, with ages 18-90 years, attending the outpatient clinic of a tertiary care hospital (Hospital de Clínicas de Porto Alegre, Brazil), between April 1st to July 1st of 2010, for whom a serum folate was ordered, were included in this study. All patients with low folate levels (<5.38ng/mL) were selected, and matched with an aleatory sample of patients with normal folate levels (>5.38ng/mL). The medical records of these patients were reviewed and clinical and laboratory data retrieved in a standardized form. The groups with low and normal folate levels were compared regarding hematimetric outcomes (hemoglobin and mean cell volume [MCV]). Results: We found a low prevalence of low serum folate (n=36/1080 [3.3%]). This group consisted of 18 males and 18 females, median age 62 (49-72) years, with serum folate of 3.93 ± 1.13 ng/mL. The normal serum folate sample consisted of 58 patients (17 males and 39 females) with serum folate of 11.86 ± 3.85 ng/mL. The groups with low and normal folate levels were comparable regarding clinical characteristics (data not shown), and did not differ in respect of hemoglobin (11.72 ± 2.73 vs. 12.11 ± 1.97g/dL, for low vs. normal serum folate groups, respectively; p=0.433) and MCV (89.28 ± 10.46 vs. 88.04 ± 6.34; for low vs. normal serum folate groups, respectively; p=0.484). Conclusions: We found a low prevalence of low serum folate among patients attending a tertiary care hospital. Additionally, no differences in hemoglobin and MCV were detected between low and normal serum folate groups. These results suggest that serum folate measurement is clinically useless, and that maintenance of this exam in the diagnostic armamentarium should be questioned.

M-075

373 – OPTIMIZATION OF LABORATORY RESOURCE USE IN A TERTIARY CARE PUBLIC HOSPITAL IN BRAZIL

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Introduction: The number of laboratory test orders are increasing at astonishing 7%/year at our institution, averaging over 5.0 tests/patient-day to inpatients. This trend can not be explained by increments in the number of hospitalizations (that augmented at rates of 1.0%/year) or by increased complexity of patients. To reverse this trend, strategies for optimizing the use of laboratory resources, without limiting quality of care, are urgently needed. Methods: A structured strategy to optimize the use of laboratory resources, consisting of phase I (educative) and phase II (restrictive) was implemented. In phase I, educative material reinforcing the rational use of laboratory resources was delivered to the medical staff through symposiums and written material. Following this phase, restrictions for repetition of exams were applied through the electronic medical chart. To determine which tests could be restricted without compromising quality of care, the most requested tests were listed, and analyzed by a group of experts. The group selected 9 exams for which a limit of time for repetition of the exams could be applied. 48 hours (hemogram, aspartate aminotransferase, alanine aminotransferase and C-reactive protein) and 5 days (albumin, glucose, alkaline phosphatase, gamma-glutamyltransferase and amylase) were settled as the minimum time required to allow test repetition without a justification for doing so. Results: The phase I occurred along one month, and resulted in a reduction of 10% in test ordering. During the phase II intervention, test orders were reduced by an additional 13% (total reduction of 23%), approaching 3.8 tests/patient-day. The institutional key performance indicators of quality of care (data not shown) did not change when comparing the pre-intervention to the post-intervention period. Conclusion: Our findings demonstrate that a structured strategy to encourage the rational use of laboratory resources is feasible, and can bring benefits to the health system without compromising quality of care.

M-076

629 – SYSTEMATIC REVIEW AND META-ANALYSIS: EFFICACY OF THE TRANSCATHETER AORTIC VALVE IMPLANTATION IN PATIENTS WITH SEVERE AORTIC STENOSIS

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Objectives: To assess the efficacy and safety of transcatheter aortic valve implantation (TAVI) in adult patients with severe aortic stenosis. Methods: A systematic review of the available literature about the technique was performed in 2010, searching different databases. Included studies were human clinical trials and observational studies. Studies with no comparison group were excluded. A meta-analysis was undertaken to determine the mortality in follow up of TAVI compared with treatment medical, valvuloplasty and conventional surgery. Estimates of effect were calculated according to the random-effects model. Results: 8 studies met the inclusion criteria. A single randomized controlled trial, the PARTNER (Placement of Aortic Transcatheter), was recruited which compares TAVI to standard therapy (medical management and valvuloplasty) in inoperable patients. At 1 year, the rate of death from any cause was 30.7% with TAVI, as compared with 50.7% with standard therapy in PARTNER study. In our meta-analysis TAVI was associated with a significant improvement in the mortality rate versus medical treatment [relative risk (RR): 0.63 (0.45, 0.86), but was not associated with a significant modification in the mortality rate with valvuloplasty and surgery, [RR: 0.49 (0.23, 1)] and [RR: 1.23 (0.2, 2.1)], respectively. Conclusions: In patients with severe aortic stenosis who were not suitable candidates for surgery, TAVI compared with standard therapy, significantly reduced the rates of death. However, comparison TAVI vs surgery has methodological limitations related to study design. Better clinical research is required to determine the efficacy and safety of TAVI versus surgery. Key words: aortic valve stenosis, heart valve prosthesis implantation, safety efficacy treatment

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M-077

599 – COST ANALYSIS OF THE USE OF VORICONAZOL AFTER THE ASPERGILLUS GALACTOMANNAN ANTIGEN DETECTION RESULT

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Introduction: The invasive aspergillosis (IA) is a severe infection that represents an important complication in patients with hematological malignancy and generates a lot of expenses. The galactomannan test (GM) is an early marker for detection of Aspergillus sp. It presents good sensitivity and specificity, and can assist in choosing treatment (voriconazol). Objective: to realize a cost analysis of the use of voriconazol after the Aspergillus Galactomannan antigen detection result in patients admitted at a protective environment unit between July 2008 and November 2009. Methods: the cost analysis was performed through the hospital's perspective and the costs were obtained from the financial department of the institution. The GM cost analysis considered only direct costs (professionals, materials, physical structure) and the target treatment only the price of medicine (voriconazol). No discount was applied given the short time-frame of the analysis. It was performed with Microsoft Office Excel 2007 (US$1.00 = R$1.79 in July 2010). Results: 175 admissions had the GM performed for diagnosis or for monitoring of IA. The sensitivity, specificity, positive and negative predictive values were respectively 60%, 96%, 46% and 98%. There were 16 changes in the antifungal treatment in the first positive GM versus 8 in negative results. The negative GM results prevented treatment with voriconazol, saving U$39,865 (6 weeks, oral route-VO) and US$43,144 (2 weeks, intravenously route-IV), spending only US$184 with GM. Eleven cases received voriconazol due the first positive GM (US$109,628 VO and US$118,647 IV) and generated over expense. Conclusion: The GM is not expensive, but its results should be better interpreted to not generate more expenses when the voriconazol is chosen for the IA treatment.

M-078

729 – ROLE OF 18F-FDG-PET IN THE INITIAL STAGING OF DIFFUSE LARGE B-CELL NON-HODGKIN´S LYMPHOMA – EXPERIENCE OF A SINGLE CENTER IN BRAZIL

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Introduction: Diffuse Large B-Cell non-Hodgkin's Lymphoma (DLBCL) is an aggressive histological subtype and accounts for 30 to 50% of all of non-Hodgkin's Lymphoma. Conventional clinical initial staging includes clinical examination, laboratorial screening, computed tomography (CT) and bone marrow biopsy (BMB). The reliability of FDG-PET in populations of different ethnic groups is unclear, as all investigations published to date have come from developed countries. The aim of the present study was to investigate the accuracy of FDG-PET in the initial staging of DLBCL patients in a Brazilian population. Methods: All 78 patients with newly diagnosed DLBCNHL were prospectively included. All patients were staged with conventional clinical staging (CCS) methods, including computed tomography (CT) and bone marrow (BM) biopsy, and also metabolic staging with whole-body FDG-PET methods. A standard of reference for the nodal regions and the extranodal organs was determined using all available information, including the CCS methods, FDG-PET, the diagnostic histology and the follow-up examinations. The results of the CCS were then compared to the FDG-PET results. Results: Eight patients (10.25%) showed discordant metabolic stages, and six of them were upstaged. In four of this six patients, a potential change in therapy was detected, with changes from initial (I and II) to advanced stages (III and IV). FDG-PET detected BM involvement in all eight patients with biopsy proven bone marrow disease. PET also suggested disease infiltration in other eight patients without bone marrow disease detected by biopsy. BM involvement was confirmed in four of these patients (2 by clinical follow up and 2 by magnetic resonance imaging). Conclusion: FDG-PET added relevant information in staging evaluation in patients with DLBCNHL, particularly BM disease in the early stages of the disease.

M-079

828 – SUSTAINABLE VIOLENCE PREVENTION: PSYCHOLOGICAL VERSUS PHARMACOLOGICAL INTERVENTIONS AS STRATEGIES FOR CHANGE

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Background: A sustainable society is one in which conflict is successfully managed. Violent behaviour is a type of conflict which can be managed through a range of interventions, including psychological and pharmacological approaches. Psychological interventions may produce more sustainable changes in violent propensity as they seek to change personal constructions of the world, whereas pharmacological interventions often only target background arousal. An update of a systematic review conducted by the Liverpool Violence Research group explores the evidence base for violence interventions in mental health and offender populations and provides the opportunity to examine how both psychological and pharmacological interventions perform. Objective: To compare psychological and pharmacological interventions designed to reduce violence in terms of general characteristics and effectiveness. Method: The search strategy covered the period 2002-2008 and included 19 databases. Predefined inclusion/exclusion criteria were applied to citations in a two-stage process and data were extracted into SPSS. For the purpose of this analysis, included studies had to report on either a psychological and/or a pharmacological intervention Results: Application of inclusion criteria identified 154 studies (103 psychological, 47 pharmacological and 4 combined). Of these, thirty-six (23%) were RCTs (9 psychological, 25 pharmacological and 2 combined). No studies directly compared pharmacological and psychological interventions. A meta-analysis of the psychological RCTs suggested that potential reductions in aggression were low (pooled SMD =-0.26), whilst that for the pharmacological RCTs indicated moderate to large impacts (pooled SMD = -0.54). However, heterogeneity was high for psychological studies (I2=87.38) and moderate for pharmacological studies (I2=62.09). The heterogeneity was not explained by sub-group analyses of specific comparator groupings. Conclusions: As no studies directly compared a pharmacological and a psychological intervention, it was not possible to compare their relative effectiveness in reducing violence. Future research should address this lack of data.

M-080

232 – INTRAOCULAR LENS (IOL) IMPLANTATION HYDROPHILIC ACRYLIC VERSUS HYDROPHOBIC ACRYLIC

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Introduction: Cataract is the most prevalent ophthalmic disease and cataract surgery is a commonly performed surgery. Late postoperative opacification of IOL requiring explantation has been reported. Objective: To assess the safety of commonly used foldable IOLs (hydrophilic acrylic and hydrophobic acrylic IOL implants) methods: Electronic databases such as MEDLINE, PubMed, EBM Reviews-Cochrane Database of Systematic Reviews, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Reviews-HTA databases, FDA website and MHRA were searched. There was no limitation in the search. Additional articles were identified by reviewing the bibliographies of retrieved articles. All relevant literature was appraised using the Critical Appraisal Skills Programme (CASP) and evidence was graded based on guidelines from U.S./Canadian Preventive Services Task Force. Results and conclusions: A total of 56 relevant titles were identified and 56 abstracts were screened using the inclusion and exclusion criteria. Nineteen full text articles were included in the results. There was poor to fair level of evidence to suggest that the incidence of IOL opacification affecting vision was only reported in hydrophilic acrylic IOL and not with hydrophobic acrylic IOL. IOL opacification of hydrophilic acrylic IOL was caused by deposition of calcium and phosphate on the IOL surface, or within the optic material or both (on the surface and within the IOL material) depending on the designs of the hydrophilic acrylic IOL. However, the pathophysiology of the causes of such complications has not yet been fully elucidated. Diabetic patients appeared to be more often and more severely affected by IOL opacification. Based on the above review, we recommend the use of hydrophobic acrylic IOLs. Patients who had hydrophilic acrylic IOLs implantation need longer and more frequent follow-up, particularly in the presence of predisposing factors such as diabetes. KEY WORDS: Intraocular lens.

M-081

233 – PROSTATE CANCER SCREENING

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Objective: To assess the effectiveness, safety and economic implications of screening asymptomatic men for prostate cancer compared to no screening or usual care. METHODS Electronic databases such as MEDLINE, PubMed, EBM Reviews-Cochrane Database of Systematic Reviews, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Reviews-HTA databases, EBM Reviews-NHS Economic Evaluation Database, EBM Reviews-Cochrane Methodology Register, INAHTA database, HTA database and FDA database were searched. No limits were applied to the search. Additional articles were identified from bibliographies of retrieved articles. All relevant literature was appraised using the Critical Appraisal Skills Programme and evidence was graded based on guidelines from U.S./Canadian Preventive Services Task Force. Results and conclusions: Evidence on prostate cancer mortality rates was conflicting. The European Randomised Study of Screening for prostate cancer (ERSPC) reported a 20% reduction in prostate cancer mortality (rate ratio, 0.80; 95% CI, 0.65 to 0.98). However, the Prostate, Lung, Colorectal and Ovarian cancer (PLCO) cancer screening study did not show significant reduction in prostate cancer mortality (rate ratio, 1.13; 95% CI, 0.75 to 1.70). There was good level of evidence to suggest that screening for prostate cancer led to positive stage and grade shift. However, it also has led to overdetection and overtreatment. There was no retrievable evidence to determine the long term impact of prostate cancer screening on quality of life and or its economic value. False-positive Prostate Specific Antigen (PSA) test results were associated with adverse psychological effects whereas prostate cancer treatments were associated with more serious complications. There was no PSA threshold that effectively discriminates between the presence and absence of prostate cancer. Studies showed that higher PSA level, positive family history of prostate cancer and abnormal digital rectal examination (DRE) result were predictors for prostate cancer. KEY WORDS: Prostate cancer screening

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M-082

762 – TRANSCULTURAL ADAPTATION AND VALIDATION OF GENERIC QUALITY OF LIFE QUESTIONNAIRE ON HEALTH: PEDIATRIC OUTCOMES DATA COLLECTION INSTRUMENT (PODCI) AT PERNAMBUCO, BRAZIL

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Since the end of last decade, the quality of life questionnaires (QLQ) used in pediatric orthopedics have gained significant value on the evaluation of patients that underwent surgical or clinical treatments, complementing clinical and image exams. Besides that, it is an efficient method on Health researches with the purpose of correcting the biases of the dehumanization and commodification. The necessity of an efficient QLQ on pediatric orthopedics was fulfilled with the validation, on English language, of a questionnaire elaborated by American Academy of Orthopedics Surgeons, the Pediatric Outcome Data Collection Instrument. This instrument was created in order to perform a predominantly functional approach in patients with compromising musculoskeletal diseases. Over the last five years it has been having a considerable raise on the number of publications in scientific journals that use PODCI, currently the most cited. However, this has not yet been translated and validated in Brazil in all of it's three versions. In order to improve the evaluation of orthopedics patients and compare the results with international literature, it is binding the validation of PODCI to portuguese/Brazil, the current objective of this study. For this purpose, it will be done the translation, the cultural adaptation and, in the validation phase, the field test when it will be applied, to a group of children and adolescents with juvenile idiopathic arthritis (JIA), the PODCI questionnaires, another instrument (gold standard) with the same applicability already validated in Brazil (Child Health Questionnaire – Parent Form 28 – CHQ PF 28), pain scales,

examiner clinical evaluation and inflammatory activity from laboratorial proofs. It is being performed statistic analysis of 60 patients, which we hope to find statistical meaning that validate the instrument, making it a multidisciplinary reliable method on our environment.

M-083

259 – COST-EFFECTIVENESS OF HUMAN PAPILLOMAVIRUS VACCINATION FOR PREVENTION OF CERVICAL CANCER IN RORAIMA, A BRAZILIAN AMAZONIAN REGION STATE

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Invasive cervical cancer (ICC) remains an important public health problem, particularly in developing countries. The brazilian amazonian region, especially the state of Roraima, is a high incidence area of ICC, comparable to low-income countries (crude incidence rate: 46/100.000), what suggests weaknesses of current secondary prevention programs. Vaccines against oncogenic HPV serotypes have demonstrated efficacy and safety, but their real effects on the magnitude of the ICC will take decades to be available. Mathematical models can be usefull tools for the evaluation of preventive strategies, assisting medical decisions that are needed now. OBJECTIVE: To assess cost-utility of the HPV vaccination on the prevention of ICC in Roraima. METHODS: A Markov cohort model was developed to simulate the natural history of HPV and its progress to ICC, considering the current preventive programs and treatment costs. The 1-year transition probabilities were based mainly on empirical data of local and national studies. The model evaluated the addition of the vaccine to 3 cervical cancer screening scenarios (0, 3 or 10 exams throughout life). RESULTS: The scenario of three Pap tests resulted in satisfactory calibration (base case). The additi on of HPV vaccination would reduce by 35% the incidence of ICC (70% vaccination coverage). The incremental cost-effectiveness ratio (ICER) was R$1,200 (US$ 667) for each quality-adjusted life year (QALY) gained. The sensitivity analysis confirms the robustness of this result, and duration of immunity was the parameter with greater variation in ICER. CONCLUSION: Vaccination has a favorable profile in terms of cost-utility, and its inclusion in the immunization schedule would result in substantial reduction in incidence and mortality of ICC in Brazilian amazonian region.

M-084

700 – COST REDUCTION AND MONITORING IN THE TREATMENT OF CROHN´S DISEASE IN SOUTHERN BRAZIL

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Background: Crohn´s disease (CD) is an inflammatory bowel disease of unknown etiology. Its treatment, in severe cases, can be done with infliximab every eight weeks, for usually long period of time. This injectable high-cost drug is dispensed freely by the Ministry of Health (MH) of Brazil. In March 2007 it was created the reference center (RC) for CD in Rio Grande do Sul state to provide its users with medical and pharmaceutical services and ensure the rational use of drugs. The creation of the RC permitted the sharing of vials and the evaluation of treatment effectiveness. Objective: To evaluate the economical impact of the infliximab vials sharing and reasons for the treatment discontinuation. Methods: All the patients that were attended in the Crohn´s-RC receiving infliximab between 2009 and 2010 were included in this study. We considered the total demand and the dosage used for vials sharing. Results: During this period 54 patients were treated, 383 attendances were carried out and 1.487 vials used by sharing. Without this RC, this sharing wouldn't be possible and consumption would have been 1.645 infliximab vials. Considering an approximate cost to MH of R$ 1.485,00 per vial, the drug sharing over the 24 months follow-up resulted a saving of approximately R$ 235.000,00 (158 vials). Among the 54 patients, 14 (25.9%) patients discontinued treatment. Of these, 2 (14.3%) were due to treatment failure, 3 for loss of response (21.4%), 3 (21.4%) for adverse events and 6 (42.9%) for other reasons. Conclusions: The creation of the Crohn´s-RC proved to be a positive intervention, enabling better treatment monitoring, promoting rational drugs use and public resources economy.

M-085

486 – REVIEW OF ECONOMIC EVALUATIONS OF UNIVERSAL INFANT IMMUNIZATION PROGRAM AGAINST HEPATITIS A

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Background: Hepatitis A (HA) has universal distribution and may occur as sporadic cases or as outbreaks. In Brazil, there are areas of intermediate (Northeast, North and Center-West) and areas of low (Southeast and South) endemicity. HA vaccine has shown great epidemiological impact when introduced in childhood routine immunization. In Brazil, HA vaccine is available at the public health system only for persons with high risk of serious disease. Objective: To review economic evaluations of universal infant immunization program against HA. Methods: The search was conducted in six databases (EMBASE, MEDLINE, WOPEC, HealthSTAR, SciELO and LILACS) and limited to articles published between 1995 and 2010. Full economic evaluations of universal infant immunization program against HA in children <6 years of age were included. Incremental cost-effectiveness ratios (ICERs) were converted to US$, 2005 values to compare studies results. Results: The search identified 1047 studies. Ten studies met the inclusion / exclusion criteria and are discussed in this review. Most studies (7) used a static Markov model. Two studies used dynamic models. Herd immunity was taken into account in four studies and partially taken into account in another. Most studies showed favorable ICERs, less than US$ 20,000 per QALY gained. In countries with intermediate endemicity, universal infant vaccination was cost-saving in areas with highest incidence of HA. Sensitivity analysis showed vaccination costs, disease incidence and medical costs as the parameters with most impact on the results. Four studies showed robust results in favor of vaccination, and parameter variation had no impact on ICERs in the sensitivity analysis. Conclusions: It is not possible to generalize these favorable results for the Brazilian context as a whole and a national analysis, based on data contemplating regional differences and preferentially a dynamic model should be carried out.

M-086

487 – REVIEW OF ECONOMIC EVALUATIONS OF SWITCHING FROM ORAL POLIO VACCINE (OPV) TO INACTIVATED POLIOVIRUS VACCINE (IPV)

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Background: Oral polio vaccine (OPV) is easy to be administered, not expensive, and exceptionally well accepted. Its widespread use allowed elimination of wild polio in many areas of the world. However, OPV is associated to a risk of vaccine-associated paralytic poliomyelitis (VAPP) and circulating vaccine derived poliovirus (cVDPV). Many industrialized nations have since the late 1990s progressively switched from OPV to inactivated poliovirus vaccine (IPV) in their national immunization programs (NIP). Objective: To review economic evaluations of switching from OPV to IPV. Methods: The search was conducted in six databases (EMBASE, MEDLINE, WOPEC, HealthSTAR, SciELO and LILACS) and limited to articles published between 1995 and 2011. Full economic evaluations of universal infant immunization program against poliomyelitis were included. Results: The search identified 107 studies. Five studies met the inclusion / exclusion criteria and are discussed in this review. All country-specific analyses (in United States, Australia, South Africa and Colombia) concluded that changing from OPV to IPV was not cost-effective. The incremental cost-effectiveness ratios ranged from US$ 1.8 million (2008 dollars) to US$ 14 million (2002 dollars) per VAPP case averted. Although cost-effectiveness analyses did not support the switch, all these countries, but Colombia, introduced IPV either in a sequential IPV-OPV schedule or as an IPV-only schedule. IPV vaccine price and additional visits to IPV administration had the greatest effects on the sensitivity analysis. Conclusions: The decision to switch from OPV to IPV has not been determined by cost-effectiveness data. Despite the high costs, it is considered unacceptable and unethical to continue to run the risk of VAPP. In a developing tropical country like Brazil, to make an informed policy decision, it will have to consider the: anticipated IPV vaccination coverage, availability of funding to projected costs of IPV and the operational implications of introducing IPV into a well – established NIP.

M-087

575 – HEALTHCARE EXPENDITURE OF HEPATITIS C GENOTYPE 1 PATIENTS IN THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM

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Objective: To estimate healthcare costs of new hepatitis C genotype 1 (G1) patients for a year of treatment in the public Brazilian healthcare system. Methodology: A retrospective cohort study of the DATASUS database was carried out. All patients with chronic and acute Hepatitis C (CID codes B182 e B171) were identified in the database for the year of 2009. As defined by the national guidelines, all patients initiating treatment with the pegylated forms of interferon (peg-Interferon 1a and peg-Interferon 2b) were defined as hepatitis c genotype 1 (HCV G1). The cohort was defined as all new HCV G1 patients treated from Jan-Jun 2009, with a follow-up of 12 months. Unit costs were gathered from purchase disclosures by the Brazilian Ministry of Health. Results: In 2009, there were 20.889 HCV patients under treatment in the public healthcare system with a cost of R$414 million (US $242 MM). Of these, 17,659 patients were identified as HCV G1 (85%), with 9,173 initiating treatment in 2009. The cohort was defined at 5,017 patients with a total cost of R$ 187 million per year (R$ 37,247 per patient/year). The cohort represented 83% of all new HCV patients between Jan-Jun, but accounted for over 94% of costs. The bulk of this cost (83%) accounted for medication used to treat hepatitis (peg-interferon and/or ribavirin), with 15% accounting for the treatment of adverse events. The most common resource use was related to anemia, present in over 21% of all patients. The average treatment duration was 8.9 months per patient. Conclusion: HCV treatment in Brazil is limited to few patients, with prevalence data suggesting over 3 million infected. The average treatment duration is below recommendations. The cost of treatment, especially of adverse events, may be underestimated as patients may receive treatment in the private healthcare system, demanding further studies.

M-088

999 – PET-FDG IN PREOPERATIVE STAGING OF ESOPHAGEAL CANCER – A COST-EFFECTIVENESS ANALYSIS IN THE CONTEXT OF BRAZILIAN PUBLIC HEALTH SYSTEM

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Esophageal cancer is among the malignant tumors with higher incidence and mortality in Brazil. Its epidemiologic importance brought interest from the Brazilian Health Ministry in the clinical and financial impact of the PET-FDG imaging in the preoperative staging of the disease, in addition to standard staging modalities. Methodology: 51 patients with esophageal cancer were prospectively evaluated between June 2006 and March 2008. All patients underwent computed tomography (CT scans) and lesion biopsy performed during endoscopy) as their initial staging modality, and FDG-PET imaging was performed on all patients. Costs were then calculated with and without the use of PET-FDG, according to the change in management suggested by the surgeons and clinicians. Results: PET changed staging in 26 of 51 patients (51%), of which 13 were upstaged and another 13 were downstaged. 21 patients were referred to surgery with curative intent, instead of 31 planned with conventional staging methods. Total change in management was observed in 17% of the patients. The incorporation of FDG-PET was responsible for an economy of 25,5% in the financial costs. FDG-PET saved resources mostly by avoiding surgeries in the upstaged patients. Conclusion: FDG-PET reduced the number of surgeries with curative intent by half and proved to be cost-effective in the preoperative staging of esophageal cancer. Therefore, the cost reductions, when added to clinical effectiveness, should justify the reimbursement of FDG-PET from Brazilian's public health system for purposes of esophageal cancer preoperative staging.

M-089

987 – A RETROSPECTIVE COMPARISON OF CLINICAL AND ECONOMIC OUTCOMES BETWEEN OLANZAPINE AND RISPERIDONE

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Objective: To compare the clinical and economic outcomes associated with olanzapine and risperidone treatment for schizophrenia. Methods: An retrospective study. 286 patients with a Diagnostic of schizophrenia were to therapy with olanzapine 10 mg (n =179) or risperidone 2 mg (n=107) for 01 year in the ambulatory service of the Hospital Dr. João Machado, Natal, Brazil. The following variables were used: unit cost, annual cost, number of re-hospitalizations, drug combination and adverse drug reaction. RESULTS: Olanzapine costs $3.528.29 while risperidone costs $305.57 per patient-year. Risperidone has shown a little greater frequency of readmission (5.69 + 14.4) than patients who used of olanzapine (4.52 + 6.0 times) (p< 0.48). The variables medication change, drug combination and laboratory tests were not significantly different between olanzapine and risperidone (p>0.5). Among the most observed adverse effects were: weight gain (46% and 41% for olanzapine and risperidone, respectively), increased appetite (19% for olanzapine), and insomnia (17% and 11% for risperidone and olanzapine, respectively). Conclusions: The use of risperidone has shown an important cost reduction. Suggest studies to clinical assess between antipsycotics.

M-090

850 – REFERENCE CENTER FOR DYSTONIA IN RIO GRANDE DO SUL, BRAZIL: AN EXAMPLE OF COST-SAVINGS IN A PUBLIC HEALTH SERVICE

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Introduction: Dystonia is a neurological disorder characterized by involuntary and sustained spasm of isolated or muscle group. Botulinum toxin (BT) a high cost medicine granted by the Brazilian public health system is the treatment of choice for most dystonias. Objectives: To estimate the financial impact of vial sharing and clinical monitoring. Methods: A collaborative effort of the Health Department of Rio Grande do Sul, Hospital de Clínicas and the Ministry of Health created in 2003 a Reference Center (RC) for dystonia. RC conducts the assessment and prescription, and short and long-term monitoring of patients, as well as drug administration. Patients were seen in a single shift, which allows the sharing BT vials. Clinical data were stored in a database for monitoring. The total costs of vials within the CR in 2010 was compared with an estimated consumption considering that there were no RC as it is the standard treatment in Brazil. Calculations were made considering the cost per vial of U$200.00 (amount paid by State Health Secretariat). Results: we followed 650 patients with dystonia in the state of RS receiving BT (171 at RC). In the RC due to appropriate dose and vials sharing we saved an average of 190 BT vials per year generating savings of U$37,000/year. If all 650 patients would have been treated in RC, the annual savings would be U$106,400,00. Conclusion: the RC promoted better management of clinical information, saving money and promoting rational use of BT. This successful experience is being replicated in other regions and maybe useful in other countries.

M-091

152 – ECONOMIC EVALUATION OF DRUGS AND AMBULATORY APPOINTMENT IN PATIENTS WITH TYPE 2 DIABETES MELLITUS ENTERED INTO A PROGRAM OF PHARMACEUTICAL CARE IN THE PUBLIC HEALTH SYSTEM

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Purpose: To assess the costs related to ambulatory appointments, the emergency care consultations and drugs dispensed to patients with type 2 Diabetes mellitus (DM2) of the Brazilian Public Health System (SUS) entered into a Pharmaceutical Care (PC) service. Methods: A prospective and experimental study was conducted with the patients regularly seen at the Endocrinology Unit between March/2006 and February/2007 at the Training and Community Health Center of the College of Medicine of Ribeirao Preto, University of Sao Paulo. There are two groups: PC group (n=33) and the control group (n=31). The patients in the PC group had standard care and were followed up monthly by a single clinical pharmacist. At the same time, control group only received standard care. Results: Patients in the PC group were diagnosis of DM2 of 10.8 years, 69.4 years old, and 60.6% were female. The control group patients were diagnosis of DM2 of 11.3 years, 64.6 years old and 64.5% were female. The monthly costs in the PC group relating to drugs were R$20.90 per patient during the study, whereas the control group showed an increase of R$16.40 to R$18.40. Regarding the cost on ambulatory appointment the PC group showed no change during the study's remaining R$2.60 a month per patient, while the control group increases of R$2.60 to R$3.20. The total cost of drugs and ambulatory appointment monthly during the study was R$23.50 in PC group, however in the control group there was a statistically significant increase of R$ 17.80 to R$21.60. There was a 1.0% point reduction in the values of glycosylated hemoglobin in PC group and average increase of 0.7% point in control group. Conclusion: The PC service promoted maintenance costs related to drugs and ambulatory appointments and contributed effectively in glycaemic control of patients with DM2 in the PC group. Acknowledgement (FCFRP-USP; CAPES)

M-092

783 – BASED ON DATA FROM THE PLATO STUDY TICAGRELOR REDUCES NON-DRUG HEALTH-CARE COSTS COMPARED WITH CLOPIDOGREL IN PATIENTS WITH ACUTE CORONARY SYNDROME (ACS) FROM A POLISH HEALTHCARE PERSPECTIVE

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Objectives: PLATO was a multicenter, double-blind, randomized trial with 18,624 acute coronary syndrome (ACS) patients, comparing ticagrelor+ aspirin versus clopidogrel + aspirin. The PLATO trial showed that ticagrelor + aspirin reduced the risk of myocardial infarction, stroke or death from vascular causes (hazard ratio 0.84, 95% CI 0.77 to 0.92) without a significant increase in major bleeding. Decision makers also need to consider the costs associated with different treatment strategies when prioritizing scarce healthcare resources. The aim of this analysis is to estimate the direct healthcare costs from a Polish healthcare perspective. Methods: Resource use was pre-specified and collected on all PLATO patients and included bed days due to hospitalizations, interventions, investigations, and blood products. Resource use is reported in physical units. In the estimation of healthcare costs unit costs were derived from the National Health Fund in Poland and multiplied with the resource use to derive a total healthcare costs per patient in PLATO. Health-care costs at 12 months are then compared between treatment groups. Results: Ticagrelor + aspirin resulted in 1,457 fewer bed days (mean difference per patient 0.21, 95% CI: –0.16 to 0.59), 95 fewer PCI's (mean difference per patient 0.01, 95% CI: –0.01 to 0.03) and 41 fewer CABG's (mean difference per patient 0.01, 95% CI: 0.00 to 0.01) compared to clopidogrel + aspirin. The results of the cost analysis show that ticagrelor + aspirin is associated with significantly reduced healthcare costs at 12 months compared with clopidogrel+ aspirin, – €144 (95% CI: -15 to -273) using Polish unit costs (excluding drug costs). Conclusions: For patients with ACS, ticagrelor + aspirin are associated with a significant reduction in healthcare costs at 12 months compared with clopidogrel+ aspirin (excluding drug costs) from a Polish healthcare perspective.

M-093

811 – WILLINGNESS TO PAY AND FAILED OVULATION: A PILOT STUDY USING CONTINGENT VALUATION METHOD

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Objective: The main objective of this study is to measure, for the first time in the literature, the willingness to pay (WTP) of women aged 18 to 45 years to receive drug treatment against infertility in cases where they are subjected to failed ovulation (i.e. the social value of a normal cycle of ovulation for a woman of childbearing age). Method: The selection of subjects was conducted randomly within the target population (women aged 18-45 years). 136 subjects were recruited in three medical clinics and 191 subjects through an online questionnaire. The instrument used is an anonymous questionnaire. Each questionnaire consists of three parts: introduction to the problematic, socioeconomic data collection to determine factors influencing the formation of WTP, and a WTP question using the simple bid price technique. The econometric estimation method is based on the "random valuation theory". Each subject responding to our questionnaire can express her uncertainty about the answer to our WTP question by choosing the answer "I do not know". Findings and Conclusion: Results are positive and indicate an average willingness to pay exceeding CAD 5000, which is much more than the drug treatment cost.

M-094

890 – COST-EFFECTIVENESS OF RAPID TESTS FOR SCREENING OF C VIRUS

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Cost-effectiveness of rapid tests for screening of C virus Pereira, Claudia C; Portela, Margareth C; Oliveira, Ione G; Cruz, Helena C; Martins Patrícia P; Oliveira, Jaqueline C; Miguel, Juliana C; Silva, Elisangela F; Villar, Lívia M. Introduction: Screening of hepatitis C (HCV) virus using rapid tests can lead to a diagnosis in a very short time, usually taking from 10 minutes to 2 hours. Despite the fact their accuracy resembles that of conventional immunoenzymatic tests, some differences in sensitivity, specificity and predictive values are still often observed. Objective: To determine the cost-effectiveness, in Brazil, of alternative screening methods for hepatitis C virus (HCV), including rapid tests. Methods: A decision model was developed to investigate the cost-effectiveness of different screening strategies for HCV. Effectiveness was measured by number of cases correctly diagnosed. We also measured the incremental cost to increase accuracy by 1%. Prevalence of HCV and accuracy of conventional immunoenzymatic tests available were identified through systematic review of the literature. Accuracy of newly developed rapid test kits by WAMA and Bioeasy were obtained from a primary study of rapid tests carried out at the Viral Hepatitis Laboratory (LAHEP) of Oswaldo Cruz Foundation, Rio de Janeiro, Brazil. Costs related to the administration of the tests were obtained from the Brazilian Unified Health System (SUS) databases. Other relevant costs were obtained from LAHEP. A societal perspective was used. Deterministic and probabilistic sensitivity analyses were carried out to test the robustness of our model. Results: Our data show that the rapid tests developed by Bioeasy cost less and has higher accuracy compared with WAMA indicating in our preliminary base-case analysis there is dominance.

M-095

215 – THE COST OF ILLNESS ASSOCIATED WITH BEING AT HIGH RISK FOR DIABETES IN EUROPE

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Objective: With diabetes prevalence on the rise, it is important to understand patients who are at-risk for developing diabetes, but not yet diagnosed. The aim of the current study was to determine the economic impact, from a societal perspective, of being at high risk for developing diabetes. Methods: Data from the 2010 EU National Health and Wellness Survey (including France, Germany, Italy, UK, and Spain) were used. Indirect costs were calculated by multiplying hours lost due to either absenteeism or presenteeism (measured by the WPAI questionnaire) by wage rates for each country. Direct costs were estimated by multiplying annual number of emergency room visits, hospitalizations, and physician visits by costs culled from the literature. Results: Based on a previously-developed diabetes risk algorithm, 13.6% of patients (N=7884) were not diagnosed with diabetes yet had a high-risk for developing diabetes in the future. These high-risk patients were mostly male (74.1%) and had a mean age of 63.0 years (SD=8.6). Adjusting for country, age, gender, and comorbidities, patients at high-risk had significantly higher physician visit costs than controls (patients without diabetes and not at high-risk for developing diabetes; Adjusted means=€110.0 vs. €80.1, p<.05). Although emergency room and hospitalization costs were higher among those at high-risk, these differences were not significant. High-risk patients also had significantly higher work productivity losses due to absenteeism (Adjusted means=€1647.0 vs. €1064.5, p<.05) and presenteeism (Adjusted means=€3835.1 vs. €3067.7, p<.05) than controls. Conclusions: A large number of patients were considered to be at high risk for developing diabetes. These patients had significantly greater indirect costs, though differences in direct costs were mostly non-significant. These results suggest that careful monitoring of these high-risk patients, and perhaps early intervention, may alleviate some of the current and future societal economic burden.

M-096
770 – A NETWORK APPROACH TO THE IDENTIFICATION OF KEY OPINION LEADERS

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Opinion leaders are important dissemination of information with a way to influence consumer, product, purchase decisions. The aim of this present study is examine a new measure to identify opinion leaders and the concept of opinion leadership, which analyze findings within the context of available research evidence from healthcare and other settings on the role of opinion leaders in innovation and change evidence. The description of the relations among opinion leaders is possible by means of a methodology based on Social Network Analysis, which enough allows the calculation and assessment of variables such as: size and density of the network, content of the relations, multiplicity, intensity and importance of interconnections and especially the degree of centrality of the actors in the network. To do so, the software UCINET is used along with simple techniques of descriptive statistics. For to understand opinion leaders if whether might successfully influence practice in their research communities, it is important which know something of their attitudes and opinions and characteristics. Therefore as a consequence in this new methodology won't need search on interview protocols about opinion leaders for to determine and to be identified and to characterize them in terms of their demographic and professional characteristics. What makes someone a credible and influential authority is derived not just from their own personality and skills and the dynamic of their relationship with other individuals and intensity with this, but also from other context-specific factors as several potential network properties. While all the concepts to be introduced also have formalized ways to measure them, and often several different ways to measure the same concept, this new methodology will be a central for to construct studies of new product diffusion models, market access and to discern directions of research. This work was defending my Masters thesis in Rome.

M-097
52 – COSTS TO THE NATIONAL HEALTH INSURANCE SCHEME OF FREE MATERNAL HEALTH SERVICES CHALLENGES AND IMPLICATIONS FOR SUSTAINABILITY IN GHANA

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Cost to the National Health Insurance Scheme of the free maternal health services Challenges and Implications for sustainability in Ghana EMMANUEL ANKRAH ODAME1 AND PATRICIA AKWEONGO 1 SCHOOL OF PUBLIC HEALTH UNIVERSITY OF GHANA, LEGON, GHANA Reducing the maternal mortality rate of 451/100,000 live births in Ghana to meet the MDG 5 target by 2015 remains a challenge. Several factors including the lack of financial access pose a challenge. A free maternal health policy was therefore launched in 2008 with a grant from the British government to improve financial access to maternal services. The main objective of this study was therefore to examine the cost of the free maternal health services to the southern part of Ghana and explore factors that contribute to these costs. Available routine financial claim records for 2009 were used to compile the cost information for the various maternal services using a compilation sheet for the three national insurance scheme accredited facilities and the scheme office in the area. The financial cost of antenatal, postnatal, delivery, abortion and the overall costs of all the maternal health services were obtained by facility type for both services and drugs. Among other findings, we found that average cost for Ridge hospital antenatal GH¢14.28(US$9.85), postnatal GH¢63.54(US$43.82) and normal deliveries GH¢51.03(US$35.19) whereas that for Adabraka Polyclinic antenatal GH¢15.12(US$10.43), postnatal GH¢24.03(US$16.58) and normal deliveries GH¢37.64(US$25.96). This study showed that average costs of maternity services were consistently higher at hospitals. The lower health facilities were under utilized. Cost savings can be made if services such as antenatal care and normal deliveries which form the bulk of maternal health services are done with the Levels C and B facilities, for the free maternal health services to be sustained. Keywords: Maternal health care, Costs, insurance, sustainability, Ghana

M-098

207 – MAINTENANCE OF NEW TECHNOLOGIES IN HEALTH SERVICES

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The Hospital das Clínicas da Faculdade de Medicina de Ribeirão Preto (USP-HCFMRP) is a public university hospital that performs high complexity care to patients of the Brazilian public health system. Its equipment purchases must follow procedures established by the procurement law (Law No. 8666 of 1993). On purchase process of hospital equipments in public services, technical specifications are described in detail in the bids, however, these specifications generate data that are not systemically absorbed in the economic evaluation, management and control of the technology park. Examples of such data are the estimated life time, potential productive capacity and frequency of preventive maintenance, which highlight the need for studies related to the institutional process of preventive maintenance and purchase decisions. The aim of this study was to analyze the occurrence of corrective maintenance on new equipments purchased by HCFMRP-USP, between 2005 to 2008. Method The analyzed maintenance services occurred between 2005 and 2010 on equipments acquired. Data was extracted from Materials Management System and Services Order System and underwent descriptive analysis of: number of equipments fixed, number of maintenances, interval between arrival and first maintenance and time of maintenance service. Results Of the 1522 permanent materials analyzed, 875 underwent maintenance. It was performed a total of 3,975 maintenance procedures for such equipments. Correlation between age and number of maintenances is poor, given that evaluated units had a maximum of five years and two months since acquisition. Average time between arrival of equipment and its first maintenance was 13 months. Average length of service, 44 days. Conclusions This study demonstrates that the downtime of equipment evaluated is high. More sophisticated technologies had defects early, but causes of this phenomenon cannot be determined quantitatively by available data. Average age of equipment in the first corrective maintenance is low.

M-099

491 – COST-EFFECTIVENESS OF CARDIAC RESYNCHRONIZATION THERAPY IN PATIENTS WITH HEART FAILURE: THE PERSPECTIVE OF A MIDDLE-INCOME COUNTRY'S PUBLIC HEALTH SYSTEM

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Objectives: To assess the cost-effectiveness of cardiac resynchronization therapy, alone (CRT-P) or in combination with implantable cardioverter-defibrillators (CRT-D), as compared to implantable cardioverter-defibrillators (ICDs) alone or optimal medical therapy (OMT), in patients with heart failure (HF) treated in the Brazilian public health system. Methods: A Markov model was constructed, representing the follow-up of a hypothetical cohort of HF patients in New York Heart Association (NYHA) class II – IV, with a 20-year time horizon. Input data were based on information from a local cohort of 316 HF patients, as well as meta-analyses of data on effectiveness and risks of devices. Stochastic and probabilistic sensitivity analyses were performed for all important variables in the model. Costs were expressed as International Dollars (Int$), by application of current purchasing power parity conversion rate. Results: In the base-case analysis, the incremental cost-effectiveness ratio (ICER) of CRT-P over OMT was Int$ 29,411 per life years (LY) gained, and Int$ 15,723 per quality adjusted life years (QALYs) gained. For CRT-D, ICER was Int$ 43,054/LY and Int$ 36,940/QALY over ICD alone, and Int$ 62,437/LY and Int$ 84,345/QALY over CRT-P. Sensitivity analyses showed that the model was generally robust, though susceptible to the cost of the devices, their impact on HF mortality, and battery longevity. Conclusions: CRT-P is cost-effective for HF patients in the Brazilian public health system scenario. In patients eligible for CRT-P, upgrade to CRT-D has an ICER above the World Health Organization willingness-to-pay threshold of three times the nation's Gross Domestic Product per Capita (Int$ 31,689 for Brazil). However, for ICD eligible patients, upgrade to CRT-D is marginally cost-effective.

M-100
848 – THE EFFECT OF BARIATRIC SURGERY ON PRESCRIPTION DRUGS COSTS

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Introduction: Among the types of treatment for weight reduction, bariatric surgery (BS) that is gaining space for morbidly obese patients, and proved an effective technique. BS can have a significant effect on medications use and costs, even within a relatively short follow-up period. Objective: to estimate the drug´s cost which are used by morbid obese patients who perform bariatric surgery. Methodology: A longitudinal study was carried out on 27 patients. In which a bariatric surgery was performed and they had been interviewed between October 2009 and October 2010. Inclusion criteria were: age > 18 years, body mass index-BMI > 40 kg/m2 and >35 kg/m2 with comorbidities and failure in attempts of clinical treatment for obesity in the previous two years. Data collection from clinical records and the administering of a specific questionnaire on issues relating to drug use was performed prior to and six months following surgery. Prices of drugs were obtained through the Price List updated monthly based on the Consumer Price. A Student's t-test for paired sample was carried out and a descriptive analysis was also performed. Results: Most of the sample were woman (95.6%) and had a mean age of 44 years. The sample had on average 8.5 years of study and social class 81.5% belonged to Class C. The total costs decreased six month after surgery in 54.64%. Although in 5 cases (13.5%) costs had increased 37.7%. Before the surgery the drug cost to treat obesity and health problems was US$ 261.80 (SD38.10) and after the surgery US$ 118.75 (SD21.14). However, there had no reduction in the number of drugs used before and after the surgery (p> 0.05); the number of health problems had a significant reduction after the surgery (32% p< 0.01). Conclusion: Bariatric surgery is associated with reduction in the cost of medication.

M-101
485 – INCLUSION OF DIALYSIS COSTS IN COST-EFFECTIVENESS ANALYSES OF THERAPIES FOR PATIENTS ON DIALYSIS: A CASE STUDY OF SEVELAMER FOR THE TREATMENT OF HYPERPHOSPHATEMIA

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Objective: Uncertainty exists around whether dialysis costs should be included in cost-effectiveness analyses (CEA) of therapies that extend the life of a dialysis patient, but do not impact the need for or the extent of dialysis. This study examined the cost-effectiveness of sevelamer versus calcium-based binders (CBBs) as a treatment for hyperphosphatemia in dialysis patients, and within that context, the suitability of including dialysis costs in such CEAs. Methods: A Markov model estimated life years, incremental cost per life year (LY) and incremental quality-adjusted life year (QALY) gained. Treatment-specific survival was derived from the Dialysis Clinical Outcomes Revisited (DCOR) study and extrapolated using Weibull regression. Resource use and survival data for patients ≥65 years were combined with Canadian unit costs and utility weights from the literature. A 10-year time horizon was analyzed using the Alberta Health Care System perspective; costs and outcomes were discounted at 5% per year. Findings: When dialysis costs were excluded, sevelamer resulted in gains of 1.02 LYs and 0.62 QALYs per patient vs. CBBs, producing ratios of $20,847/LY and $34,175/QALY gained. Inclusion of dialysis costs resulted in ratios above $90,000/LY and $150,000/QALY gained. Conclusions: No therapy that extends the life of dialysis patients, without decreasing the need for or the extent of dialysis, can be cost-effective if dialysis costs are included. As a result, patients requiring dialysis could be denied access to life-extending therapies, simply because dialysis is costly. We conclude that dialysis costs should thus not be included in CEAs of such therapies and recommend that health economic guidelines, practice, and public policy in this area be consistent, ethical and non-discriminatory.

M-102

834 – COMPARATIVE PERFORMANCE AND COSTS OF VIRTUAL HISTOLOGY BY CORONARY INTRAVASCULAR ULTRASOUND AND MULTI-SLICE COMPUTED TOMOGRAPHY: A STUDY OF CORONARY ARTERY DIMENSIONS AND ATHEROSCLEROTIC PLAQUE COMPOSITION

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New diagnostic technologies require accuracy assessment before entering clinical practice. Intravascular ultrasound, IVUS, with virtual histology (VH), new technique, has the potential to quantify coronary plaque characteristics. Non-invasive 320-slice multidetector-computed-tomography, 320MDCT, is an emerging alternative for plaque characterization. OBJECTIVE: To analyze diagnostic and cost profiles of both methods. METHODS: Prospective study including established diagnosed coronary disease, CAD, cases referred for IVUS, MDCT previously evaluated, with minimum two-year follow-up. Endpoints included lumen & plaque parameters, death or major cardiovascular events occurrence. Index procedure and follow-up resources used were estimated through records review. Annualized 2008costs ($1US=R$1.00), excluding honoraria-fees, used micro-costing. RESULTS: Sixty-eight patients (45males, mean 59.6years) underwent MDCT and VH-IVUS. Measurements for luminal, vessel, plaque plus media area and percent burden were significantly correlated (r-Spearman: 0.81; 0.78; 0.55; 0.49; respectively - p<0,001). MDCT slightly underestimated VH-IVUS luminal area measurements (median: 0.4mm2, range: -5.6mm2 to 10.2mm2), but overestimated vessel area, arterial wall area, and plaque burden (median: 3.0mm2; 3.2mm2 e 13.9%, respectively). Both, VH-IVUS's composition patterns ([high dense calcium and necrotic core] & [low fibrofatty with low necrosis-to-calcium-ratio]) were significantly associated with MDCT's increasing plaque density. During average 36 months (95% CI:32 to 38), 2,369 patient-months follow-up, one patient died, one required CABG, another coronary angioplasty and none had infarction. Interventionist admissions average hospital operational costs were US$ 6.008,09 (95% CI: $ 5,088.15 to $ 6,928.03; 57% devices drugs 5%, MDCT & tests 10% and LOS 28%). The surgical admissions average costs were $ 24,357.66 (95% CI: $ 15,120.29 to $ 33.595,03; devices & drugs 35%, MDCT & tests 23% and LOS 42%). Follow-up actuarial survival study is ongoing. CONCLUSIONS: CAD detailed diagnosis with IVUS and MDCT presented low event rate outcome after 36 months. MDCT has similar performance to IVUS for CAD assessment and ongoing 320MDCT'sPPSUS/MS-FAPESP sponsored comparative study warrants detailed evaluation.

M-103

897 – HOSPITAL COSTS ASSOCIATED WITH BIOLOGICAL DISEASE-MODIFYING ANTIRHEUMATIC DRUGS VERSUS METHOTREXATE THERAPY IN SEVERE REFRACTORY RHEUMATOID ARTHRITIS

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Introduction: Methotrexate (MTX) therapy is an effective Rheumatoid Arthritis (RA) established treatment. However, 10.5% discontinuation is due to adverse events or insufficient RA control. Several disease-modifying-antirheumatic-drugs (DMARDs) and biological (bDMARDs) emerged and are used in therapeutic combinations. Purpose: To assess costs and effects of MTX therapy compared to bDMARDs combinations. Methods: Adults RA cohort follow-up from April 10th, 2006 to 30th May, 2010, at the Central Institute -Clinics Hospital/ São Paulo University Medical School, IC-HC/FMUSP. Patients' electronic health records and charts were reviewed retrospectively. Health Assessment Questionnaire (HAQ) and the Disease Activity Score (DAS28) are applied for bDMARDs' patients at 0 and every 6 to 12 months. Coded identification, demographic, and clinical data were

stratified by patient-periods according to bDMARD consumed. Healthcare tests and treatment resources used were quantified per stratum. Direct costs were calculated by micro-costing methods. The empirical distribution and the observed transition probabilities were considered case-base and sensitivity analysis used the 95% confidence intervals bounds. Results: 114 RA patients cumulated 136 periods-minimum 6 months follow-up, 48-MTX and 88-MTX-bDMARDs; total 264 patient-years' observation. There were decreasing scores trends in HAQ and DAS28 ($p>0.05$). Follow-up reflected general population mortality rates. Hospital admissions incidence density varied 0.07, 0.04, 0.15/MTX-bDMARDs' patient-year follow-up compared to 0.10 under MTX ($p>0.05$) and 32% switched between bDMARDs over the 4.5 years of observation. Drug costs accounted for 90% of the annual programs regardless the bDMARD. Patient surveillance, monitoring tests and visits, summed 8% to 11%. Projections estimate 210,000 Brazilian-RA-related-cohort under surveillance, 12%-20% would be eligible for MTX-bDMARDs therapy. Actually, a 10 years RA MTX-bDMARDs therapy program would require >US $12 million investments. Conclusions: Modest benefits of significant investments reflects RA-patients referred at very advanced stages, emphasizing the requirement for adapted knowledge development within a Brazilian National RA Registry, IC-HC/FMUSP's cohort study may help to develop.

M-104

781 – HTA IMPACT ON HEALTHCARE SYSTEM: ANALYSIS OF FINANCIAL CONSEQUENCES OF REIMBURSEMENT OF LONG-ACTING INSULIN ANALOGUES IN POLAND

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Objective: HTA reports regarding long-acting insulin analogues (LAIA) indicate that these drugs should be reserved for use in selected diabetic patients only. In line with recent knowledge LAIA in Poland will be reimbursed in framework of therapeutic programme (LAIA-TP). This study assess the impact of this decision on public health-payers budget. Methods: The analysis was perfomed using modelling technique, based on systematic review of LAIA, Polish epidemiologic and costing data. Two scenarios were compared: (A) LAIA not reimbursed, (B) LAIA reimbursed for patients with episodes of severe hypoglycaemia (after 6 months reimbursement continued only in patients successfully treated). In each scenario annual insulinotherapy costs were estimated in 3-years time horizon. Model was run by having the current patient cohort progress through the model accompanied by the addition each year of a new cohort of eligible patients. Extreme scenario sensitivity analyses were performed. Results: According to epidemiologic data the expected number of diabetic patients eligible for LAIA would be 12 611 in the 1st year, and each year 665 "new" patients will meet inclusion criteria. Only 25% patients with type 1 diabetes and 30% patients with type 2 diabetes will be successfully treated with LAIA.The introduction of LAIA-TP is expected to increase public-payers expenditure in years 1st -3th by 13,913,896 PLN, 9,432,015 PLN, 9,834,247 PLN, respectively (1 PLN=0.25 EURO, 2011). Sensitivity analysis shows that depending on assumptions about proportion of patients with episodes of hypoglycaemia and response rate on LAIA the additional expenditures of public payer varies between 11,005,768 -27,800,257 PLN, 6,487,195-17,234,117 PLN and 6,765,957-18,647,373 PLN in 1st, 2nd and 3rd year, respectively. Conclusion: Budget impact analysis indicates that reimbursement of LAIA-TP may be affordable to the budget holder. The story of LAIA in Poland shows how the voice of consultative bodies resulted in action by the healthcare purchasers.

M-105

247 – ESTIMATION OF THE COSTS RELATED TO RHEUMATOID ARTHRITIS IN PATIENTS TREATED THROUGH THE SPECIALIZED COMPONENT OF PHARMACEUTICAL ASSISTANCE AT THE UFSC/PMF TRAINING PHARMACY, 2008-2010

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Rheumatoid arthritis (RA) is responsible for a significant economic impact, not only on patients and health care providers, but also on society as a whole. In this context, the objective of the study was to estimate the costs related to RA in patients treated through the Specialized Component of Pharmaceutical Assistance (Componente Especializado da Assistência Farmacêutica/ MS-CEAF) at the UFSC/PMF Training Pharmacy, in 2008-2010. This was an observational and prospective study involving 103 adult patients, of both sexes, with RA, resident in Florianópolis and registered in the CEAF to receive the medicines adalimumab, infliximab, etanercept and leflunomide. The patients were monitored every month over a period of 12 months. This was achieved through specific forms for the collection of data concerning the use of resources by patients with RA. An economic assessment of the cost-of-illness type was carried out, taking the perspective of society. The direct medical costs were estimated using the technique of micro-costing, with the indirect costs calculated by the human capital method. The total direct medical cost during the period of the study was R$ 2,045,596.55, with 90.8% of this total being concerned with the purchase of medicines, 2.5% hospital admissions, 2.2% complementary examinations and 2.1% medical consultations. The remaining components totaled 2.4%. The public health service was responsible for 73.6% of this total. The total direct medical cost per patient was R$ 19,860.16 . The estimated indirect cost per patient was R$ 3,317.80, which represented 20.2% of the per capita gross domestic product, estimated based on the year 2009. The estimated total cost of rheumatoid arthritis from the perspective of society, over 13 months of monitoring, was R$ 23,177.96 per patient. Of this total, 85.7% represented direct medical costs. These primary data are considered fundamental for accomplishment of a complete economic assessment of arthritis.

M-106

275 – COST-EFFECTIVENESS STUDY OF THE 10- AND 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINES IN ARGENTINA

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Introduction: Invasive pneumococcal disease (IPD) is an importan cause of death and disability in developing countries, mainly affecting children between 2 and 24 months of age and people >65 years of age. The National Vaccination Program (NVP) proposed the introduction to the routine program of a pneumococcal conjugate vaccine providing high coverage against local serotypes and at a lower cost. Consequently, the NVP together with the Health Economics Department, in collaboration with the ProVac Initiative created by the PAHO, conducted a cost-effectiveness study in order to make an evidence-based decision related to the introduction of that vaccine. Objective: To assess the benefits predicted in healthcare, costs and cost-effectiveness derived from the introduction of different pneumococcal conjugate vaccines within pediatric population in Argentina from the perspective of the health system and society. Methods: A software designed by PAHO was used for the analysis and has been adapted to comply with requirements of the study designed in Argentina. The model provides an Incremental Cost-Effectiveness Ratio, which indicates the cost per DALY (Disability-Adjusted Life Year) averted. The study considers the introduction the 10-valent and 13-valent pneumococcal vaccine versus non-vaccination. Outcomes: The outcomes are indicated for year 2020 and for overall 20 cohorts studied. Both vaccines were cost-effective according to WHO/PAHO recommendations to determine the cost-effectiveness of an intervention. Although the 10-valent vaccine would be more cost-effective, generating higher expense savings to the healthcare system, the use of the 13-valent vaccine would provide better outcomes in terms of deaths and DALY averted. Conclusions: The introduction of the pneumococcal conjugate vaccine providing an extended coverage to local serotypes is a high-impact intervention in public health in Argentina decreasing of pneumonia and mortality due to pneumococcal disease. The relevance of pharmacologic and economic trials is empathized as a tool for evidence-based decision making.

M-107

771 – ECONOMIC EVALUATION OF COCHLEAR IMPLANTS AND HEARING AIDS IN CHILDREN IN THE PUBLIC HEALTH SYSTEM IN ARGENTINA

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Introduction: According to official national information, in Argentina between one and three thousands newborn children suffer of severe or deep hipoacusis, hence there are at least 300 children to be diagnosed and treated annually. Early detection and correct intervention of deafness and hipoacusis would make a major change on the quality of their life standard. The sanitary benefits, among others, are lower costs for the health system, better educational performances and higher work productivity, contributing to the development of the society. Aim: To perform an economic evaluation for the deafness and hipoacusis treatment in the infantile population through an estimation of the sanitary costs from the public subsystem and society's point of view in order to generate a tool for the policy makers. Methodology: Three alternatives were evaluated, considering the costs involved through a lifetime. The first one evaluates the individual cost with no intervention from the government, considering the costs of a special, public education, an invalidity pension and the future productivity loss. A second alternative was to evaluate the cost of the acquisition of the headphone and its maintenance per individual. Finally, it was estimated the cost per individual, for the placement of the cochlear implant, afforded by the government; considering the pre and post surgery implant costs. A discount rate of 5 % was considered in order to compute all possible relevant future costs and benefits at present value. Results: Taking into account all results, it was observed that the Government intervention (across a National Program) speaking in economic terms is highly profitable. Conclusions: This study has given the policy makers an economic evaluation to be used as a technical tool for the design of the National Program of Early Detection and Attention of the Hipoacusis.

M-108

996 – THE INFLUENCE OF A PHARMACOTHERAPY FOLLOW-UP PROGRAM OVER THE RATE OF CONTROL AND COSTS OF TREATMENT OF HYPERTENSION IN A REFERENCE CENTER

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Introduction: Despite the efficacy of antihypertensive treatment, the control rate of hypertension is not satisfactory worldwide. Pharmacotherapy follow-up (PF) program applied by pharmacists may improve adherence to treatment and optimize costs of care. Objectives: To estimate the cost of outpatient antihypertensive drug treatment in a reference center, which provides PF to patients with difficult-to-control hypertension, and to compare the cost with patients under conventional medical care. Methods: A case-cohort enrolled patients with hypertension between June 2005 and December 2008. The monthly cost of antihypertensive drugs at the baseline and after one year of PF was calculated. A sub-sample of patients on conventional medical care, with similar cardiovascular risk, was selected for comparison. The prices of antihypertensive drugs used in analysis were those currently in practice by the Brazilian Ministry of Health in the acquisition of drugs. Results: The initial control rate among 150 patients in PF was 13.2% and increased to 23.7% 12 months later (McNemar test P <0.01). In the control group (n = 108) the corresponding figures were 32.7% and 42.3% in the same period (McNemar test P = 0.09). Monthly cost of initial anti-hypertensive in PF group was US$ 20.12 (± 25.56) with a median of 10.71 and at the end of one year remained US$ 20.12 (± 26.68) with median of 6.74 (Wilcoxon P = 0.93) versus US$12.36 (± 16.03), median 3.84 and 11.65 (± 17.39), median 3.25 respectively (Wilcoxon P = 0.18) in the control group. Costs were significantly higher in PF group than in the control group both at the beginning and at the end of the follow-up (P <0.01). Conclusion: Patients referred for pharmaceutical follow-up had more difficult-to- control hypertension, but improved the rate of control. The costs of treatment were higher before the referral and did not increase during the follow-up.

M-109

739 – COST AND EFFECTIVENESS OF AN AUTOMATED MICROBIOLOGY GROWTH DETECTION SYSTEM IN MANAGEMENT OF CRITICALLY ILL INFECTED CHILDREN

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Introduction: in general, new technologies mean better health care, but also mean increased costs for healthcare services. Automated radiometric microbial growth detection systems are not exception: compared to conventional methods, radiometric methods provide faster and more accurate microbial identification, allowing selection of narrower spectrum, safer and less costly antimicrobial schemes. However, the high cost of such equipment is an obstacle to its incorporation by healthcare services. Objective: to assess effectiveness and cost related to an automated radiometric microbial growth detection system in management of critically ill infected children. Methods: retrospective cross-sectional study of children admitted in an intensive care unit of a teaching philanthropic hospital in Northeastern Brazil between January and October 2009. We compared blood cultures positivity and growth detection time between both 5 months periods after equipment acquisition and prior, when conventional methods were performed. Antibiotic use costs and blood cultures processing costs were also analyzed. The radiometric system was acquired by lending. This study was approved by a research ethics committee. Results: from a total of 601 blood cultures analyzed, 115 (19.1%) were positive. Radiometric method provided more positive tests than conventional method (30.7 versus 7.9%; $p < 0.01$) with lower average growth detection time (1.7 ± 0.85 versus 5.5 ± 2.2 days; $p < 0.01$). Antimicrobial cost per patient-day showed no statistical difference between both periods ($p = 0.2$). There was a 2.6-fold increase in blood cultures processing cost after radiometry equipment acquisition. Conclusion: although automated radiometric method proved to be more effective in terms of positivity and readiness in microbial growth detection when compared to conventional methods, these advantages did not result in lower antimicrobial related costs, as expected, whereas blood cultures processing costs increased. It is suggested that technology incorporation in healthcare services must be accompanied by health professionals training to its best use.

M-110

145 – ECONOMIC OF RARE DISEASE: THEORY, EVIDENCE AND PUBLIC POLICY

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Rare diseases are a public health problem that affects millions of people around the world. The aim of this paper is to review theoretical and empirical economics of rare diseases and orphan drugs trying to analyze the economic implications. Through empirical evidence presented in the literature, the paper aims to identify the magnitude of the problem, its current importance and describe the government incentives and tools used and adopted arround the world, specially in USA, Europe, Asia and Australia. Rare disease is a ill that presents a low prevalence in a given population. They are usually degenerative, chronically debilitating and require long-term treatment, affecting the physical, mental, sensory and behavioral patient. Orphan drugs are medicines used for diagnosis, prevention and treatment of rare diseases. The rarity of cases implies difficulties for proof of clinical efficacy of these medicines. Data is presented on rare diseases and orphan drugs in Brazil and around the world, even the key economic considerations related. Will present the regulatory systems for rare diseases in the United States and the European Union and the influence of these mechanisms on the development of orphan drugs. The aim of the paper is study the economic mechanism to incentive the pharmaceutical industries to develop drugs for rare disease. The main policy tools are: exclusivity of market, assitency of protocols, centrolized procedures of analysis, acess to research, patents extensions, dissemination of infomration and payment policy. It was concluded that the regulatory mechanisms are able to stimulate the development of orphan drugs and the need to intensify the debate on rare diseases in Brazil, since there isn´t a public policy issue facing in this country. This kind of researc in very important to develop institutional structutre that permits compare the results of policy tools and the development of new drugs for rare desease.

M-113

479 – KIDNEY TRANSPLANT IN BRAZIL: AN ANALYSIS OF INCENTIVE MECHANISM USING PRINCIPAL-AGENT-THEORY

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The objective of this paper is to verify and analyze institutional mechanisms and incentives offered to hospital and hospital teams that catch or collect kidneys for transplantation in Brazil. The theoretical approach used is the Principal-Agent model under asymmetric information context (when one side of the contract know more than other side). This approach is suitable to analyse the problem. It say that the well being of the principal (hospital that do the transplant) depends on the effort of hospital that cacht the organs ofr transplants. The Brazil presents the largest public program (unified health system) of transplants and occupies the second place (after the United States) on the number of such surgeries, with prominence for kidney transplantation. Between 2000 and 2009, it appears that the amount of kidney transplants in the United States showed a growing trend of 25.94% from 13,363 to 16,830 respectively. Already in Brazil, the expansion was 46.26% (increased from 2,912 to 4,259) in the period under examination. However, there is an imbalance between supply and demand for this body, which has been generating queue waits. It turns out that this problem may be related principally to remuneration not adequate hospital teams responsible for fundraising bodies; misinformation of health professionals; difficulty of maintenance of potential donors in intensive care units and lack of trained personnel for households approach process. Then is necessary to study the incentives. Thus, these factors are transplants sector arising from the information asymmetry that exists between hospital teams (agents) and the body's receptors (principal). If so, the agent performs an effort that is not verifiable and outcomes that will generate for you, given the contract. Therefore, if such professionals receive higher compensation, incentives to act shall be effectively in the process of abstraction of the organ and, consequently, a reduction in waiting

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M-114

482 – KIDNEY TRANSPLANT IN BRAZIL: AN STUDY OF USING QUEUING THEORY

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This article seeks to develop an analysis of the waiting list for kidney transplants in Brazil for the periodo 2005-2010, noting the factors that explain the existence of such a problem and propose measures to minimize it. The system queues in the healthcare industry can be defined as a process in which, from a certain population, there are patients who arrive and form a queue waiting for a service (transplant) and out of the system once it is realized. Each service unit can contain one or more servers, also known as attendants. The Brazil is the second country most kidney transplant performed worldwide and presents the largest audience of transplants. However, in the current period there are more than 34 thousand patients on the waiting list for kidney transplantation in the country (Ministry of Health, 2009). In this context, it is crucial to understand the various factors that affect the waiting list for kidney transplants, pursuing actions and public policies that try to minimise this shortage and consequently provide a fair and equitable allocation of organs. The excessive waiting time and the long queues for health services, mainly in the area of transplantation, has been an indicator of inefficient performance of this sector. The main objetives of the paper is to (i) determining the variables involved in the determination of periods of waiting in queues for transplants in the countryin for the period 2005-2010; (ii) to measure the queue issues in renal transplants system from queuing theory; (iii) to assess the impact of measures which seek, based on variables and public policy recommendations, reduce waiting times for kidney transplants.

M-115

484 – THE EFFICIENCY OF BRAZILIAN HOSPITALS: AN ANALYSIS OF RENAL TRANSPLANT SYSTEM USING THE DEA AND MALMQUIST INDEX

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The objective of this study is to analyse technical efficiency and allocational hospitals allowed to participate in the renal transplant system in Brazil, using the method of DEA (Data Envelopment Analysis). Moreover, it will evaluates the continuous improvements in the process of abstraction and advances in productivity of hospital teams, from technological innovations adopted by them using Malmquist index. Malmquist index represents the growth of Total Factor Productivity from a decision-making unit. The Brazil is the second country most kidney transplant performed worldwide and presents the largest audience of transplants. However, in the current period there are more than 34 thousand patients on the waiting list for kidney transplantation in the country. The data classified as inputs (resources) in the models are: total number of doctors and nurses; of active hospital beds; Icu beds, equipment and expenses with surgeries, medical procedures associated with the transplantation, medicines pre and post transplant (financial resources received from single health system-SUS). As outputs (product) have: amount of kidneys transplanted and waiting time in the queue. The review period is 2000 through 2009. Note that in the Brazilian States, discrepancies in relation to the capture and the number of transplants of kidneys are significant, which creates an imbalance between supply and demand for it. Such a fact may occur due to inadequate functioning of the central State of transplants; national rules are not followed (e.g., linking team centers transplanters; adequate distribution of suppressive; forwarding organs not leveraged for next States; implementation of HLA typing of the entire kidney waiting list) that cause harm to patients; intra-hospital committees not active; overloaded hospital staff (many professionals participate in more than four teams of transplants). It is fundamental to understand tha causes of efficience and inefficencies in the Brazilian hospitals that perform kidney transplant to improve the allocation

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M-116

688 – STUDY OF HOSPITAL COSTS AND THE SATISFACTION OF PATIENTS UNDERGOING BARIATRIC SURGERY BY MEANS OF ACCESS AND CONVENTIONAL LAPAROSCOPIC

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Objective: To evaluate the hospital cost of bariatric surgery and satisfaction of patients operated by laparoscopic approach and open surgery. Methods: Retrospective, comparative and quantitative approach carried out with the records of a private health maintenance organization from Vitória-ES, in 180 patients. In these patients, 42 underwent open surgery and 138 a laparoscopic surgery. Cost and patient satisfaction were compared between the two routes of access. We considered as hospital costs the physician fees, materials, drugs, fees, accommodation fees and disposable instruments. Satisfaction was assessed by two questions asked by telephone: Do you feel better or worse after surgery? Get it back, you would undergo surgery again? Tests used were Student t test (continuous variables) and Fisher exact (categorical variables). P-value ≤ 0.05 was considered significant. Results: The technique of bariatric surgery Fobi-Capella was the most used in both the open approach (92.9%) and the laparoscopic (67.4%). The cost of open surgery was R$ 6,319.36 (SD R$ 1,212.79) of laparoscopic and R$ 12,687.25 (SD R$ 3,837.79) (p <0.05). Of patients who underwent open surgery, 97.6% said they felt better, as well as all patients that underwent laparoscopic surgery (p> 0.05). Of patients who underwent open surgery, 95.2% said they would submit to surgery again, and among those who underwent laparoscopic surgery, 99.3% said the same (p> 0.05). Conclusion: Bariatric surgery through the laparoscopic approach had higher hospital costs, but there is no difference in the degree of satisfaction in relation to the access open.

M-117

211 – MANAGEMENT OF OVERACTIVE BLADDER WITH OXYBUTYNIN AND TOLTERODINE: EXAMINING THE QUALITY OF HEALTH ECONOMIC ANALYSES

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Introduction: The treatment of overactive bladder (OAB) is mainly based on pharmacological approach, because it is widely believed that detrusor overactivity is mediated by the stimulation of muscarinic receptors. Most of the patients are managed pharmacologically with oral antimuscarinic agents such as oxybutynin and tolterodine, currently the treatment of choice for OAB. Objectives: To identify and to provide a critical review of economic evaluations published about the treatment of OAB with oral antimuscarinic therapy, specifically oxybutynin and tolterodine, in both formulations – immediate (IR) and extended-release (ER). Methods: A comprehensive literature search was performed for papers published up to September 2010. Studies to be included had to be an economic evaluation, compare at least one of the 2 oral antimuscurinic agents targeted – oxybutynin and/or tolterodine (IR or ER) and have patients diagnosed with OAB. Articles that met these inclusion criteria were subsequently reviewed and graded using the Quality of Health Economic Studies (QHES) instrument, by two independent reviewers. Results: A total of 17 articles were identified and scrutinized, but only 12 were included. The majority of the studies were published from 2004 (75%), only one was published in 1998. Three types of economic analyses were identified: cost-effectiveness, cost-utility and cost-minimization analyses, and half of them were cost-effectiveness studies. Almost all the studies (99%) had a mean quality score of 91.5 (SD=11.32). Tolterodine ER was cited by 33.33% of the publications as the most cost-effective antimuscarinic (QHES=80, SD=17.43), while IR formulations had the lowest profile of cost-effectiveness ratio. Conclusion: The health economic analyses published on the topic of management of OAB with oral antimuscarinics (specifically oxybutynin and tolterodine) had a high quality score; however, no Brazilian health economic study was found in this area which addresses the necessity of conducting such analyses in national perspective.

M-118

435 – HEALTHCARE UTILIZATION AND COSTS ASSOCIATED WITH THE DIAGNOSIS OF MENTAL HEALTH COMORBIDITIES IN AN ADULT ADHD POPULATION IN A LARGE MANAGED CARE ORGANIZATION IN SOUTHERN CALIFORNIA

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Objectives: To estimate the incremental economic burden of adult ADHD patients diagnosed with mental health (MH) comorbidities. Methods: Using Kaiser Permanente Southern California (KPSC) electronic medical records (01/01/2005-12/31/2009), adults with >1 ADHD diagnosis and >2 ADHD-specific prescription claims present after diagnosis were identified. The first new MH comorbidity diagnosis occurring after index ADHD diagnosis was defined as the index transition date (ITD). Continuous eligibility was required for pre-transition and post-transition periods; defined as 12-months prior to and following the ITD, respectively. For patients with >1 transition, the post-transition period reflected the 12-months following the second transition. All-cause inpatient (IP), outpatient (OP), emergency room (ER), behavioral therapy (BT), ADHD prescription fill counts and mean patient costs were summarized. Negative binomial models were used to evaluate differences in utilization; generalized linear models (log-link function & gamma distribution) were used to compare cost differences. Findings: 6,014 ADHD patients were identified [mean age: 31.5 years (SD=14.1); 54% male]. Of these, 1,449 had >1 transition for a new MH condition following ADHD diagnosis: (519 had only 1 and 930 had >2 transitions). For patients with only one transition mean(SE) visits increased from the pre- to post-transition period: OP 8.2(0.42) to 9.3(0.54), ER: 0.57(0.06) to 1.01(0.08), IP: 0.44(0.11) to 0.91(0.13), IP length of stay (LOS): 1.05(0.45) to 2.07(0.37), and ADHD prescription fills: 2.38(0.12) to 2.85(0.14) (all $p<0.05$, except for LOS $p=0.18$). BT visits decreased from 2.15(0.38) to 0.79(0.17) ($p=0.001$). All costs associated with these visits significantly increased following transition, except for OP visits ($p=0.08$) and BT which decreased significantly. For patients with >1 transition similar changes in mean (SE) resource use and costs were observed from pre- to post-transition. Conclusions: In adult ADHD patients, the development of MH comorbidities was associated with an increase in healthcare utilization and costs compared to the period with no MH comorbidities.

M-119

690 – STANDARDIZATION SYSTEM FOR SETTING AND PAYMENT OF DRUGS IN HEALTH INSURANCE PROVIDER IN CEARÁ: INCORPORATING THE ECONOMIC EVALUATIONS IN THE SERVICE

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Introduction: The generic drug contains the same active ingredient, dose pharmaceutical form, route of administration and therapeutic drug reference and present the same safety and effectiveness and lower cost, being interchangeable with it. Objetivos: To evaluate the normalization incorporation of standard drugs for reimbursement in a health insurance carrier from Fortaleza-CE. Metodologia: In May/2008, the operator was agreed, in the process of cost-minimization, regulatory payment reference products only when a doctor requires a written non-interchangeability. The flow of the reference drug release was thus established: if the doctor does not accept the generic drug, it must technically justify such a choice and forward to the release of the auditor's medical provider, the report is forwarded to the audit team that audits the Pharmaceutical prescriptions and the drugs used for conference of the reference product and the team of Nursing Audit audits the account of the patient with drugs used and confirmed by the audit of Pharmacy by electronic feedback. Economic: From the August/2010 May/2008 followed up 57,951 prescription drugs. The pharmaceutical audit coverage was 70.35% (40,767). The reference drugs accounted for 72.74% of prescription drugs and 50.21% of the audited. The request for non-interchangeability of the generic was 13.46% (5673). Generic drugs accounted for 21.14% of prescription drugs and 45.56% of the audited. The ruling echoed in a savings of 44.87% in drug costs from the operator. Conclusão: The standardization of the use of generic drugs might be an economically attractive from the perspective of the operator of health plans, not contravene the right of choice on prescription by a doctor, and rationalization of ensuring pharmacotherapeutic arsenal and of using fotalecimento backed with quality products.

M-120

769 – MUCOPOLYSACCHARIDOSES TYPE I: NATURAL HYSTORY, ENZYME REPLACEMENT THERAPY AND ECONOMIC ASPECTS

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Mucopolysaccharidosis type I (MPSI) is a rare chronic and progressive disease.Aiming to contribute to the characterization of the economic aspects of the disease in Brazil,we conducted a retrospective and longitudinal study including the 13 individuals who have been regularly evaluated since their MPSI diagnosis was established at the MPS Clinics of the Medical Genetics Service of Hospital de Clinicas de Porto Alegre,Brazil.Patients were analyzed according to the following parameters:the number per year of medical appointments,hospitalizations,surgeries and exams;and the number of times medications were used.These parameters were analyzed regarding pre(n=13 patients) and post(n=9/13) periods of Enzyme Replacement Therapy (ERT), the severity of MPSI (attenuated phenotype=7/13;severe=6/13),and the time of illness.Mean age at onset of ERT was 108 months.Results:1) Medical appointments:the mean number per year of pre-ERT medical appointments(n=13;7.95±1.61) did n differ from the number of post-ERT appointments(n=9;6.03±1.40),from the phenotype(attenuated=6.54±1.20; severe=7.34±2.56), or from the time of illness(p=0.646).2)Hospitalizations:the mean number per year of pre-ERT hospitalizations differed significantly in relation to post-ERT(p<0.001),to the phenotype (p=0.013),and to the time of illness(p<0.001).3)Surgeries:the mean number per year of pre-ERT surgeries didn't differ from post-ERT(p=0.866),from the phenotype(p=0.712),or from the time of illness(p=0.292).4) Exams: post-ERT patients are submitted to more exams(31.36±2.80/year) when compared to pre-ERT patients(13.17±3.39year;p=0.002),mainly during the first year of therapy.No significant difference was found in relation to the phenotype (attenuated=19.87±1.46;severe=20.78±4.73) or the time of illness(p=0.078).5) Drugs: Post-ERT patients used more medications(n=9; 27.66±3.14) when compared to pre-ERT patients (n=13;7.00±2.16,p<0.001),and severe patients(n=6;22.33±3.05) showed the same tendency to use more drugs as attenuated patients(n=9;12.33±2.16,p=0.050).Discuss/conclusions:Our data are limited by the small sample size and the broad heterogeneity of the sample but suggest that,in our Center,ERT didn't change the natural course of MPSI in relation to the parameters studied.This can be explained by the relatively high age of initiation of therapy.It's hoped that this study may contribute to further cost-effectiveness studies in the field.Support:MCT/CNPq/MS-SCTIE-DECIT033/2007and 037/2008

M-121

634 – CLINICAL PRACTICE GUIDELINE (CPG) PRODUCTION IN IBEROAMERICA AND ITS RELATION WITH COUNTRIES' INCOMES

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CPGs production in Iberoamerica has been related to non-homogeneous governmental and/or scientific societies' initiatives. In fact some countries have established initiatives and clearing houses while others still depend on private initiatives. Purpose: To analyze the influence of economic situation of Iberoamerican countries on CPG production and topics addressed. Methods: we performed a systematic bibliographic and complementary hand-search in: generic databases EMBASE, Medline, Lilacs. The possible CPG included were produced from 1995 to 2005 in 10 Iberoamerican countries including Portugal and Spain. CPG were independently selected by two reviewers on the basis of explicit criteria and according to the CPG definition accepted by GIN. We correlate guidelines production with mean gross domestic product in the studied period. Results: 5,512 pCPG were identified: 1,559 were obtained from international databases, 2,910 from national databases, 443 from different guidelines clearinghouses and 600 from Internet searching. Almost 1,000 potential producers belonging to the macro, meso and micro level of the health system of the participant countries were identified. They were located mainly in Spain (417), in Argentina (368) and in Brazil (214). Among all pCPG that were retrieved in international databases (Lilacs, Medline, EMBASE), 311 out of 1,559 were considered CPG. The correlation with mean GDP in the period was high R2>0.8. We observed significant differences in the issues addressed by CPGs depending on countries' incomes. Discussion: Iberoamerican countries' production of CPGs is distributed among different sources of information and is related to the economic development of countries. The topics addressed by the guidelines also depend on the economic income of the countries, in low-income countries, according to OECD classification, they mainly addressed public health issues, while in medium and high income countries chronic diseases are the main topics of discussion. Economic situation is one of the main factors for CPGs production.

M-122

804 – COST-EFFECTIVENESS ANALYSIS OF QUALITATIVE MOLECULAR KITS FOR HEPATITIS C

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Introduction: Hepatitis C represents a serious Public Health problem. In approximately 80% of cases, the disease becomes chronic and the diagnosis can sometimes be made before the disease becomes severe. Different qualitative molecular diagnostic tests are available to correctly confirm diagnoses, after high sensitivity serologic tests have been performed. The use of different alternatives may lead into different trajectories with different associated costs of management and treatment for the healthcare system. Objective: To conduct cost-effectiveness analysis of different qualitative molecular diagnostic kits available for hepatitis C in Brazil. Methods: The perspective of the analysis is societal and the year 2010 is used as reference. The decision model considers as outcomes the number of cases correctly diagnosed by each kit. The epidemiologic parameters used were: the prevalence of hepatitis C in Brazil and the accuracy of the tests, which were obtained through a systematic review of the literature. We estimated direct and indirect costs, as well as the productivity loss associated. Cost data were retrieved from the inpatient care information system of SUS (Unified Health System). Other relevant costs were provided by the Viral Hepatitis Laboratory (LAHEP) of Oswaldo Cruz Foundation, Rio de Janeiro, Brazil. Results: There are five different molecular diagnostic tests currently available for hepatitis C in Brazil. Among those, the TMA test showed higher accuracy, but higher costs per case diagnosed. A newly developed test developed at LAHEP showed similar accuracy to PCR ELISA, but with significantly lower costs, indicating its use is cost-effective in the context of the Brazilian SUS.

M-123

538 – COST OF TREATMENTS OF MILD-TO-MODERATE BLEEDING EPISODES IN HAEMOPHILIA WITH INHIBITORS IN POLAND

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Objective: To evaluate the costs of treatment of mild to moderate bleedings with recombinant activated factor VII (rFVIIa) versus activated prothrombin complex concentrate (aPCC) in adult haemophilia patients with inhibitors in Poland. Methods: Only drug acquisition costs (determined by dosage) were identified as Cparameters differentiating treatment options. There are no country specific, real-life data concerning the dose of rVIIa and aPCC needed to manage bleeding episodes. In the base-case analysis parameters from survey carried out among six Polish experts, who are well experienced in the treatment of haemophilia, were used. Key factors covered: mean weight 74 kg (range: 70-80 kg); number of bleedings per year 12.5 (range: 6-20 bleedings/y); mean dose of rFVIIa and aPCC needed to manage one bleeding episode: 219 µg/kg (range: 180-270 µg/kg) and 176 UI/kg (range: 100-300 UI/kg), respectively. The results of the base-case analysis were verified in alternative scenarios based on the best published data. The unit costs of treatment were derived from Polish official tariff lists for healthcare services paid by public payer. RESULTS: In the base-case analysis, the average annual cost of rFVIIa was 571k PLN (range 313-1,140k PLN) and 611k PLN for aPCC (ranged 354-788k PLN). rFVIIa was associated with higher costs of treatment only in one set of parameters reported by one expert. The lower costs of treatment with rFVIIa than with aPCC were confirmed in three alternative scenarios (the difference in annual costs in favour of rFVIIa were from 181 to 514k PLN). Conclusion: Costs of treatment of bleedings in haemophilia patients with inhibitors are lower for rFVIIa than aPCC. The usage of rFVIIa in mild-to-moderate bleeds can be considered economically reasonable.

M-124

678 – TREATMENT OF ALCOHOL-DEPENDENT PATIENTS IN POLAND – IS IT COST-EFFECTIVE?

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Objective: Alcohol abuse is one of the most important social problem in Poland. Apart from the social implications of alcoholism, there are also huge health consequences. Our aim was to check, if treatment with naltrexone in combination with psychotherapy is cost-effective strategy in Poland. Methods: According to the State Agency for the Prevention of Alcohol Related Problems about 2% of the Polish population suffer from alcohol dependence. Polish system of alcohol-dependence treatment is well-developed and comprises outpatient clinics for alcohol-dependence and co-dependence treatment, day-only centres and 24-hour centres for alcohol dependence treatment and centres for treatment of alcohol withdrawal syndromes. Treatment of alcohol abusers consists mainly of psychotherapy, however part of the patients is also treated with pharmacotherapy (usually acamprosate). In addition to treatment of alcohol dependence, there are also many alcohol-related complications i.a. hepatic, gastrointestinal, cardiac, neurological and mental. Costs of treatment of alcohol dependence and alcohol-related complications burden the Polish public payer and patients. There are also indirect costs borne by the society. We decided to prepare cost-utility analysis to compare naltrexone with acamprosate as concomitant therapies in alcohol-dependent patients attending the psychotherapy programmes in Poland. Data concerning efficacy of compared therapies were taken from the clinical-effectiveness analysis which was based on the systematic literature review. Due to the fact, that the health consequences of alcohol dependence manifest themselves during the whole subsequent life of the patient, Markov decision model was designed for a lifetime horizon. Findings: Cost-utility analysis conducted from the social perspective showed, that treatment of alcoholism with naltrexone in combination with psychotherapy is more effective and less expensive compared to acamprosate + psychotherapy. Stability of basic analysis outcomes was confirmed within sensitivity analysis. Conclusions: In Poland treatment of alcohol-dependent patients with naltrexone and psychotherapy is more effective and less expensive option than acamprosate and psychotherapy.

M-125

622 – WILLINGNESS TO PAY FOR PREVENTING MAJOR OSTEOPOROTIC FRACTURES IN KOREA

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Objectives: To examine willingness-to-pay (WTP) and factors influencing WTP for treatment to prevent osteoporotic fracture with the stated preference data in Korean population. Methods: A questionnaire was administered via a trained interviewer to adult Korean general population. Subjects were selected by a non-probability sampling via a quota-sampling to reflect the national distribution of gender, age, and region in Korea. Each respondent answered questions about eight different scenarios, each of which specified as different types of fracture (hip and vertebrae), the risk of fracture (10% and 100% for hip; 20% and 100% for vertebrae), and efficacy of treatment (25% and 50%). WTP per annum was elicited with a double-bounded, dichotomous-choice approach accompanied with an open question per scenario. The initial bidding values were decided based on the pilot survey result with one hundred and one respondents. The demographic characteristics of respondents were also collected. A multiple linear regression was performed to identify factors influencing the level of WTP. Results: Of five hundred and six respondents who completed the survey, the average of WTP per annum when having 100% of vertebral fracture risk was 750,000 KRW (652 USD) and 820,000 KRW (713 USD) for treatment with 25% and 50% efficacy to reduce vertebral fracture risk, respectively. For 100% of hip fracture risk, the annual WTP was 1,020,000 KRW (887 USD) and 1,160,000 KRW (1,009 USD) for treatment with 25% and 50% efficacy to reduce hip fracture risk, respectively. The risk of fracture, age, gender, region, family size, income level, insurance status, and self-rated health status were significantly associated with the level of WTP. Conclusions: Respondents' preferences for osteoporosis treatment to reduce fracture risk reflected health and non-health related factors. This research provides useful information to expand the coverage of osteoporosis treatment which reduces the risk of costly fractures under a budget constraint.

M-126

25 – LONG-TERM DISABILITY COST IN TUBEROUS SCLEROSIS COMPLEX (TSC) IN BRAZIL

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Objectives: To estimate long-term disability costs associated with tuberous sclerosis complex, a rare multisystem genetic disease, in Brazil. Methods: Literature review for TSC long-term disability and economic burden was performed (Pubmed, LILACS, SciELO, CRDs). Cost estimation was limited to epilepsy (most prevalent TSC disorder). Cost of lost productivity in patients since epilepsy onset in childhood and carried in adulthood as well as caregivers' productivity costs were estimated. The Human Capital Method was adopted and potential lost working years estimated till an active age of 65 years. It was assumed a caregiver for all ages. Average income, unemployment rate due to epilepsy, productivity growth and epidemiology data were obtained from the literature and from the Brazilian Institute of Geography and Statistics. Mean annual productivity cost per patient, total productivity cost per patient and the total productivity burden of TSC-related epilepsy were calculated. Costs were estimated in 2008 Reals and discounted at 5%. Univariate sensitivity analysis was conducted for epidemiology data, employment status rate, productivity growth, discount rate and time horizon. Results: Productivity loss was 47, 30 and 65 years for epilepsy onset in childhood and adulthood and caregivers, respectively. The discounted and not discounted mean annual productivity cost per patient were R$1,970 and R$11,323, total productivity cost per patient R$97,882 and R$691,150 and total productivity burden of TSC-related epilepsy in Brazil R$1,568,965,961 and R$11,078,536,271, respectively (1Euro= 3.24Reals). Results were sensitive to all the parameters varied in the sensitivity analysis, especially discount rate. Conclusions: TSC-related epilepsy is a chronic disorder associated with loss of productivity with a significant economic burden in Brazil. Although significant, the economic burden related to productivity loss is expected to be even higher since there are still costs deriving from absenteeism of patients and caregivers when employed looking for health services to be included in further analysis.

M-127

26 – NUMBER NEEDED TO TREAT (NNT) AND COST ESTIMATION TO ACHIEVE A MAJOR MOLECULAR RESPONSE IN NEWLY DIAGNOSED CHRONIC – PHASE CHRONIC MYELOID LEUKEMIA IN BRAZIL

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Objectives: (1) To estimate the 'Number Needed to Treat' (NNT) to achieve one MMR by 12 months (2) To provide a relative measure of the cost of attaining treatment objective defined by MMR and hematologic adverse events (AEs) with 2 novel targeted therapies in the treatment of newly diagnosed CP-CML from SUS perspective. Methods: MMR and AE data were evaluated from two phase 3 studies comparing IM 400mg once daily with DAS 100mg (DASISION) and NIL 300mg twice daily (ENESTnd) in newly diagnosed CP-CML patients. MMR rates by 12 months were used to calculate the NNT as the inverse of the MMR rate. The costs of managing neutropenia, thrombocytopenia and anemia were estimated from SUS perspective in local currency (2008 BRL) using administrative databases, literature and survey with clinical experts. The costs of managing the AEs were then multiplied by the incidence of the AEs. Results: The number of newly diagnosed CML-CP patients needed to treat to achieve 1 MMR with nilotinib (NNT=1,82) is 50.8% lower than imatinib. The dasatinib NNT of 2.17 is 39.2% lower than imatinib. The NNT analysis highlights that CML treatment with NIL600mg or DAS100mg provides greater efficacy when compared with IM400mg, and that nilotinib is the most efficient in producing MMR among BCR-ABL inhibitors. Dasatinib produced more hematologic events, resulting in an estimated 8.2% higher cost of managing AEs compared to imatinib. Nilotinib produced lower incidence of AEs, providing savings around 38.5% lower than imatinib. Conclusion: Although comparisons between published studies have some limitations, such an approach may be useful in the absence of direct comparative data. The NNT findings and the differential cost of managing AEs in each treatment from this evaluation suggests that nilotinib provides better clinical in lower costs for hematologic outcomes and would result in lower costs for hematologic AE.

M-128

632 – SYSTEMATIC REVIEW OF EFFICACY AND ECONOMIC IMPACT OF GENETIC TESTS IN BREAST CANCER TREATMENT

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Objective: To assess efficacy of genetic tests in the detection of failures in the response of the pharmacological treatments in patients with breast cancer. To evaluate economic impact derived from the tests use. Methods: A systematic review of the literature was performed in 2010. Comprehensive search strategy included the Cochrane Database, HTA, DARE and the Cinahl, Medline, Embase databases. Only commercialized tests studies were included. Quality of studies was assessed. Findings: 7 HTA reports, 4 systematic reviews, 2 meta-analysis, 19 clinical studies mainly retrospective and 7 economic studies met the inclusion criteria. Overall rate of reproducibility assay of Oncotype DX (analytical validity) ranged from 79% to 99%. Recurrence Score (RS) was significantly correlated with disease-free survival ($p<0.001$) and overall survival ($p<0.001$). Patients with low RS are associated with a less use of adjuvant chemotherapy. Criteria for women with intermediate RS that receive chemotherapy is not defined. Few number studies on analytical validity of MammaPrint were obtained. Overall success rate it was about 81%. Overall survival within 10 years in poor prognosis group of patients was 55%-69% and in good prognosis group was 85%-88%. Studies for AmpliChip CYP450 test show a correlation between slow metabolism of tamoxifen (poor metabolisers) and a high rate of disease recurrence and poor disease-free survival. Current evidence from economic outcomes suggests that Oncotype DX and MammaPrint are cost-effective though budget impact is high. Conclusions: Oncotype DX is the test with the highest number of published articles. It is needed a confirmation of the better prediction of risk in women with breast cancer with Oncotype DX and Mammaprint. For analytical validity it is necessary to define standards for tests reproducibility measure. It has not been found good clinical utility studies about the benefits of the results in commercialized tests. The future results of the clinical trials TAYLORx

M-129

535 – NEAR PATIENT TESTING, USING DCA-2000 DEVICE GLYCATED HAEMOGLOBIN (HBA1C) ANALYZER IN PATIENTS WITH TYPE 2 DIABETES MELLITUS MANAGED IN ENDOCRINOLOGY OUTPATIENT CLINIC: COST ANALYSIS

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AIM: To assess and compare, in endocrinology outpatient clinic, the cost of a near patient testing (NPT) for glycated haemoglobin (HbA1c), using DCA-2000 device, in people with Type 2 diabetes mellitus in comparison with the standard of care (laboratory test). Method: Direct costs were calculated for both procedures taking into account the number of patient insulin independent Type 2 diabetes mellitus (IIT2DM) and insulin-dependent Type 2 diabetes mellitus (IDT2DM) treated in endocrinology outpatient clinic in the Cruces Hospital area during the year 2009. The standard of care consisted on assessing the cost of the first and final outpatient visit, HbA1c test and haematology and biochemical profile in laboratory, laboratory test request management and blood collection. In the NPT for HbA1c using DCA-2000 device, the costs of the nurse and endocrinology outpatient visit and HbA1c test were assessed. We carried out a univariate sensitivity analysis to prove the reliability of the cost-analysis results. Results: The annual cost of the standard of care for a patient with IDT2DM was estimated to be 203.52€ and 169.60€ for a patient with IIT2DM and in the case of NPT 108.92€ and 98.65€, respectively. The total cost per annum for 3,150 potential patients was estimated to be 583,424€ following the standard of care compared with the 257,785€ estimated for NPT. The univariate sensitivity analysis showed that the NPT intervention remained cheaper than the currently available standard of care. Conclusions: The implementation of the NPT procedure by DCA-2000 analyzer would reduce the total cost per annum in a 44.18%. It would also reduce the number of outpatient visits and the possible loss of productivity for the patient.

M-130

192 – CONSISTENCY OF FDG-PET ACCURACY AND COST-EFFECTIVENESS IN INITIAL STAGING OF HODGKIN LYMPHOMA PATIENTS ACROSS JURISDICTIONS

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Purpose: Were consecutively enrolled in this prospective trial patients newly diagnosed with Hodgkin's lymphoma (HL) to evaluate the cost-effectiveness of 18-F-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET) scan in initial staging of HL patients. Methods: All 210 patients were staged with conventional clinical staging (CCS) methods, including computed tomography (CT), bone marrow biopsy and laboratory. Patients were also submitted to metabolic staging (MS) with whole-body PET scan before the beginning of treatment. A standard of reference for staging was determined with all staging procedures, histology and follow-up exams. The accuracy of the CCS was compared to MS. Local unit costs of procedures and tests were evaluated. Incremental cost-effectiveness ratio (ICER) was calculated for both strategies. Results: In the 210 HL patients, the sensitivity of FDG-PET was higher than CT and BMB in initial staging (97.9% vs. 87.3%, P<0.001 and 94.2% vs. 71.4%, P 0.003 respectively). The incorporation of FDG-PET in the staging procedure upstaged 50 (24%) and downstaged 17 (8%) patients. Changing in treatment would be seen in 32 (15%) patients. Local CCS costs strategy was $3,751 compared to $4,588 with PET/CT. The ICER of PET/CT strategy was $162 per modified treatment patient. PET/CT costs in initial and in the end of treatment would increase only 2% of total costs of HL staging and first line treatment. Conclusion: FDG-PET is more accurate than CT and BMB in HL staging. Given observed probabilities, FDG-PET is highly cost-effective in the public healthcare program in Brazil.

M-131

646 – INVESTIGATION OF THE METHODS OF EVALUATION IN PATIENTS WITH STABLE CORONARY ARTERY DISEASE AND THE RELATION WITH REVASCULARIZATION TREATMENT (IMPACT)

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Background: Guidelines recommend characterization of ischemia in patients with stable coronary artery disease (CAD) prior to elective myocardial revascularization, assuring appropriate indication where there is a reasonable expectation of benefit from the procedure. The aim of this study was to evaluate the sequence of diagnostic tests used in CAD patients and the posterior incidence of revascularization (percutaneous or surgical). Methods: A retrospective review of 59,798 patient's medical charts procedures was performed from January 2007 to June 2010. Patients were stratified in three workgroup strategies based on the initial diagnostic test: 1) exercise treadmill stress test, 2) single-photon emission computed tomography myocardial perfusion imaging (SPECT-MPI) and 3) invasive coronary angiography. Primary outcome was incidence of revascularization. Results: Of the 34,626 patients initially evaluated by exercise treadmill stress test, coronary angiography was the following test in 899 (2.6%) patients; SPECT-MPI in 1,973 (5.7%) patients followed by coronary angiography in 207 (0.6%) patients; the remaining 31,925 (92.2%) patients were followed clinically with no subsequent coronary angiography or SPECT-MPI. In this group the overall myocardial revascularization incidence was 1.1%. In the 16,221 patients initially evaluated by SPECT-MPI, 12.1% were further submitted to invasive coronary angiography with overall incidence of revascularization of 5.3%. Invasive coronary angiography was the initial diagnostic test in 8,951 patients, with a revascularization incidence of 28.8%. Finally, the myocardial revascularization incidence after the invasive coronary angiography in the strategy initiated by exercise treadmill stress test, by SPECT-MPI and by directly invasive coronary angiography were 44.2%, 43.9% and 28.8% respectively. Conclusion: Non-invasive initial approach strategies for stable CAD evaluation leads to a better relation between revascularization after coronary angiography when compared to directly invasive coronary angiography approach. Lower levels of revascularizations may also contribute to lower reimbursement rates, influence facility's sustainability, as well as the costs of care.

M-132

919 – FDG-PET IS COST-EFFECTIVE IN PREOPERATIVE STAGING OF NON–SMALL CELL LUNG CANCER IN BRAZIL

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Purpose: Previous studies have shown that positron emission tomography (PET) is more accurate than computed tomography (CT) for the staging of non–small cell lung carcinoma. In the present study the cost-effectiveness metabolic staging (MS) with FDG-PET is compared to conventional clinical staging (CCS) strategy for preoperative staging of NSCLC. Methods: Two decision strategies were compared CCS and CCS coupled with FDG-PET in all 83 patients before the beginning of treatment. A standard of reference was determined with CT, FDG-PET, histology and follow-up exams. The results of the CCS were compared to the MS with FDG-PET results. Local unit costs of procedures and tests were evaluated. Results: The incorporation of FDG-PET coupled with CCS in the staging procedure upstaged 72.3% (60/83) and downstaged 2.4% (2/83) of the patients. As a result of these changes in staging, 45.0% (38/83) of the patients would have received a different therapeutic regimen, and 42.1% (35/83) would not be submitted to surgery. Local average CCS costs without PET were $ 3,037 compared to $ 4,161 with PET. However, due to treatment modifications, average treatment cost per patient with CCS was $17,285 and with PET staging was $16,665, with a 3.6% decrease in costs. Conclusion: FDG-PET is more accurate than CT in NSCLC staging. Given observed probabilities, FDG-PET is highly cost-effective and would reduce costs for the public healthcare program in Brazil.

M-133

585 – COST REDUCTION OF HEPATITIS C TREATMENT WITH PEGINTERFERON ALFA-2A AND 2B USING CLINICAL EFFECTIVENESS TECHNOLOGY IN THE UNIFIED PUBLIC HEALTH SYSTEM OF BRAZIL

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Hepatitis C is a viral disease that primarily affects the liver and is a public health problem worldwide. For Ministry of Health, the current average cost of treating a patient for 48 weeks with peginterferon alfa is U$10.266,67. Monitoring treatment effects and sharing peginterferon alfa-2b vials can lead to a significant reduction in ampoules used. In 2003, we created in the south of Brazil the first specialized service for systematic monitoring of patients treated with peginterferon alfa-2a and 2b. Objective: Compare the costs of treatment done in the context of a specialized service carried out with pharmaceutical care and clinical monitoring with the standard treatment. Methods: All patients were interviewed monthly by pharmacist and the injections were made every week under observation. In a cohort of 752 genotype 1 patients we calculated the direct costs with of the drug, assessing time and treatment interruption due to adverse events or due to no reduction in viral load at 12 weeks and due to sharing vials of peginterferon alfa-2b. The average cost of peginterferon alfa-2b used for the calculations was U$213,89 (4 presentations available in Brazil). Results: In a scenario without the service costs would have been U$7.720.533,33 for 752 patients. Considering the monitoring of treatment, the cost was U$6.152.513,89, which generated savings of U$1.568.019,44. Of the 752 patients, 425 used peginterferon alfa-2b, presentation that can be shared. The total costs with sharing of the vials was estimated to be U$2.151.686,30. Without the sharing would have been spent U$3.331.464,44. Cutting costs by sharing amounted to U$1.179.778,14. In total, the estimated savings from this new service was 2.747.797,58 (36%). Conclusions: The creation of specialized service was an alternative for significantly reducing costs of treatment of hepatitis C. Other services in our state and in Brazil are already following this strategy.

M-134

574 – DOES THE INNOVATION MATCH THE MARKET? THE ROLE AND EVALUATION OF TELEMONITORING SERVICES IN CZECH REPUBLIC

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Introduction: There are various technologies based on eHealth concept with the potential to have a significant future impact on patient care and tend to worldwide health care progress. Marketing studies suggest that there are only about 3000 Telecare users and the use of Telemonitoring is rare in the Czech Republic. For the purpose to improve decision-making process and assessing of future challenges of an innovation the implementation of HTA is considered to be very helpful.

The current situation in Czech health care is dealing with the financial crisis of recent years and negative attitudes regarding to the costs rising. Due to the age structure of patients the overall costs for health care rapidly increased. The support of main efforts as long-term prosperity, economic stability and sustainability of health care systems can be seen especially in certain sophisticated technology applications. There is scientific evidence of successful Telemonitoring projects established in clinical praxis furthermore the use of HTA can promote implementation of Telemonitoring services in Czech Republic.

Aim and tasks: The study explored circumstances for providing health care using Telemonitoring services based on the market analysis and HTA approach. The research presents results of graduation students project that attend the marketing courses offered at FBME CTU. The scope of observation focus on three main points:

- Identify the target market and explore the opportunities for Telemonitoring services
- Evaluate and assess the application of Telemonitoring services according to the HTA practice
- Define the impact of Telemonitoring services on the quality and efficiency of medical care

Conclusion: Further investigation and research of the application of Telemonitoring system are warranted because it might have a valuable role for the management both in quality and economic aspects.

M-135
998 – COST-EFFECTIVENESS OF ALTERNATIVES TO POSTPONE END STAGE CHRONIC RENAL DISEASE IN BRAZIL

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The objective of this study was to estimate the cost-effectiveness of alternatives of postponement of end stage of Chronic Renal Disease (CRD) related to hypertension and diabetes under the Brazilian public health system (SUS) perspective. The alternatives assessed were: current practice in SUS including Angiotensin-converting enzyme (ACE) inhibitors to treat hypertension (traditional care) ; a multidisciplinary approach performed at the University of Rio de Janeiro (UERJ), an actual prospective study (program 1); a hypothetical basic postponement program based on current guidelines, including the prescription of statins but without antagonist receptor of angiotensin II (ARA II) (program 2); a hypothetical basic program based on current guidelines, including the prescription of ARA II (program 3); a hypothetical program based on current guidelines, including the prescription of ARA II and statins (program 4). Estimates of effectiveness were based on local and international studies that have produced evidence related to the efficacy and effectiveness of postponement procedures. Brazilian health system (SUS) figures were used to estimate costs. The CMED list was adopted for costing drugs. Results showed that SUS patients (traditional care) with diabetic nephropathy have a life expectancy of 6,66 years while UERJ patients have 11,56 years. Both alternatives program 3 and 4, increase the SUS quality-adjusted life expectancy in about 10 years. The results of cost-effectiveness ratios discounted at 5% a.a. showed that the dominant strategy was program 3, indicating costs savings of R$ 10.525,27 for each year of life added when compared to SUS (traditional care). These results derived from de fact that program 3 patients would not need hemodialysis during their lifetime. In conclusion, end stage CRD postponement programs can be effective in Brazil; the most-cost-effective end stage CRD postponement program for the Brazilian SUS should include ARA II drugs and disregard statins.

M-136
912 – UNDERSTANDING THE EVOLUTION OF HTA IN EMERGING MARKET HEALTH CARE SYSTEMS: STUDY APPROACH AND FINDINGS

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This study developed categorisations of health care systems (HCS) and health technology assessment (HTA) in order to examine how the role of HTA in a HCS depends on the development stage and structure of the HCS. This framework was used to interpret the status of HTA evolution in three emerging markets: Brazil, China, and Taiwan. In this framework, HCSs were differentiated in terms of level of spend (the quantity of resources are available) and the degree of centralization (who decides how healthcare is funded). HTA processes varied in terms of the focus of HTA (e.g., whether efficacy/safety or cost-effectiveness) and its breadth (e.g., all or only new technologies). An important distinction was drawn between appraising only “micro-technologies,” such as new drugs or devices that are marginal to a HCS, and assessing the efficiency of “macro-technologies,” i.e., organizational systems or architecture of a HCS. Among the key findings and observations were the following. In emerging markets, increases in income and healthcare funding are likely to be outpaced by rising demands and expectations: HTA can help a HCS to reconcile this. HTA need not be a “black box”, but can provide a means to handle resource allocation in a more explicit and transparent way, promoting public debate about priorities. However, addressing “rationing” in this way requires a willingness to engage in active debate about coordinating demand and supply. Furthermore, HTA of individual technologies is not a substitute for the reform of health care systems. Where health care systems create obviously bad incentives, a focus of HTA on only micro-technologies is unlikely to compensate for these failings. “One-size-fits-all” HTA processes and methods are unlikely to be appropriate for emerging markets. There needs to be clarity about the purpose of HTA, and the methods and processes which are adopted need to be “fit-for-purpose.”

M-137

852 – COST EFFECTIVENESS ANALYSIS OF FINASTERIDE IN THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA FROM THE PERSPECTIVE OF BRAZILIAN PUBLIC HEALTHCARE SYSTEM

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Background: Benign prostatic hyperplasia (BPH) is one of the most common medical conditions in older men, often associated with a reduction in quality of life. The long-term use of finasteride may reduce prostate volume, acute urinary retention (AUR) episodes and surgeries. Objective: To perform a cost effectiveness analysis of finasteride versus placebo in the treatment of BPH in men over 55 years from the perspective of the Public Healthcare System. Method: Epidemiological and efficacy data were derived from the published literature. A Markov model was developed to estimate the costs and consequences of finasteride treatment compared to placebo. The outcomes were expressed as AUR-avoided and surgery-avoided. Only direct medical costs were included. The health resource utilization and treatment patterns in Brazilian public hospitals were obtained from specialist's panel. Drug costs were obtained from public list prices (BPS). Surgery and exams costs were extracted from a public reimbursement database (SIGTAB). Costs and benefits were discounted at 5% yearly and reported in 2010 Brazilian currency. Sensitivity analysis was conducted to assess model robustness. Results: Considering a treatment dropout of 34%, finasteride use reduced 59.6% of AUR episodes and 57.9% of surgeries over 6-year time-horizon. Average costs were R$764.11 and R$579.57 per patient in finasteride and placebo group, respectively. Incremental cost-effectiveness ratio (ICER) were R$4,130 for AUR episode avoided and R$2,735 for surgery avoided. The sensitivity analysis demonstrated that the compliance rate and drug price significantly influenced the results. Conclusion: The findings suggest that finasteride is cost-effective against placebo in treating BPH in Brazil. The budget impact of this drug incorporation will depend on the compliance rate, that is very low in real life because of drug cost and adverse effects.

M-138

853 – COST EFFECTIVENESS ANALYSIS OF FINASTERIDE ALONE OR IN COMBINATION WITH DOXAZOSIN IN THE TREATMENT OF BENIGN PROSTATIC HYPERPLASIA FROM THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM PERSPECTIVE

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Background: Benign prostatic hyperplasia (BPH) is one of the most common medical conditions in older men. The long-term use of the finasteride (FIN) may reduce prostate volume, acute urinary retention (AUR) and surgeries, whereas doxazosin (DOX) improves symptons and quality of life without effects on these events. Objective: To perform a cost effectiveness analysis of FIN alone or in combination with DOX against placebo (PBO) in the treatment of BPH in men over 55 years from the perspective of the Brazilian Public Healthcare System. Method: Epidemiological and efficacy data derived from the published literature. A Markov model was developed to estimate the costs and consequences of the FIN treatment with or without DOX against PBO. The outcomes were expressed as AUR-avoided and surgery-avoided. Only direct medical costs were included. The health resource utilization and treatment patterns in Brazilian public hospitals were obtained from specialist's panel. Drug costs were obtained from public list prices (BPS). Surgery and exams costs were extracted from a public reimbursement database (SIGTAB). Costs and benefits were discounted at 5% yearly and reported in 2010 Brazilian currency. Results: In comparison to placebo, FIN reduced 64.2% of AUR and 60.4% of surgeries and FIN+DOX reduced 75.7% of AUR and 66.8% of surgeries over 4 year time-horizon. The dropout rate was 24% for FIN and 18% for combination therapy. TREATMENT TOTAL COSTS (R$) ICER for AUR avoided (R$) ICER for surgery avoided (R$) PLACEBO 349.58 - - FINASTERIDE 558.34 16,830.05 8,613.59 FINASTERIDE + DOXAZOSIN 670.50 21,960.63 11,979.87 The sensitivity analysis demonstrated that the compliance rate and drug price significantly influenced the results. Conclusion: The findings suggest that FIN is cost-effective against PBO in treating BPH in Brazil. The combination therapy results in higher efficacy and better relief of symptons, although there is an increase in costs that must be considered.

M-139

578 – ECONOMIC ANALYSIS OF HYDROGEL (CARBOXIMETHYLCELLULOSIS 2%) MANUFACTURED IN PHARMACY COLLEGE TO TREATMENT OF LEG ULCERS

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Objective: To evaluate the cost of hydrogels produced in a pharmacy university compared to hydrogels available on the fair. Methods: A prospective study of quantitative approach, a clinical study with evaluation and monitoring volunteers with lower limb ulcers treated at the Outpatient Wound Repair at University Hospital Antônio Pedro. Data collection was performed by instrument filed and pre-approved by the institution and throughout the nursing visits.This study was approved by Ethics in Research of Federal Fluminense University (FFU) under Protocol 196/2008, CAAE: 0154.0.258.000-08. The costs were measured in the value of national currency (Real). Results: The protocol included in this study 20 volunteers, 68% female and 32% male, mean age 60.94 years with standard deviation of 10.89 years. In the group studied there was an average use of 202.78 g product per month with an average monthly cost of $ 9.12 per patient. The cost of the hydrogel produced in pharmacy university of FFU was $ 4.50 per bottle containing 100g. A cost analysis of five brands of hydrogels made from February 2010 showed a variation in price from $ 123.00 to $ 296.50 per 100g of product. Conclusions: Regarding the hydrogel sold on the fair from February 2010, there was variation in price from $ 123.00 to $ 296.50 per 100g of product. Thus, a volunteer of project, which required 200g/mês using commercial hydrogel would cost between $ 246.00 and $ 593.00 monthly with the purchase of medicine. With the hydrogel produced at the University the cost was $ 9.00 for the same patient. The product has shown effective results and low price makes it even more accessible to the population and reduce public spending on the treatment of wounds.

M-140

777 – INCORPORATION OF TECHNOLOGY FOR EMERGENCY MEDICAL SERVICES: EVALUATION ISCHEMIC HEART DISEASE HOSPITAL OUTCOMES IN RIO DE JANEIRO STATE, BRAZIL

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Objectives: To analyze the association between the incorporation of selected technologies for Emergency Medical Services (EMS) and Ischemic Heart Disease (IHD) hospital outcomes in Rio de Janeiro State, Brazil. Methods: Data were collected from the Brazilian official Health Information Systems available at the Ministry of Health's Department of Informatics website. The technologies to be evaluated and the health indicators were selected according to their relationship to the EMS. The technologies and the IHD outcomes (admission rate and average length of stay) were analyzed for two periods: 2001 to 2004 (before the implementation of the public EMS) and 2005 to 2007 (after the implementation of the public EMS). Multivariate analysis was performed by panel regression, being the time unit the year and the observation unit all municipalities in Rio de Janeiro State where the patients resided. Findings: The referral rate from primary care settings to emergency care was directly associated to the admission rate and the average length of stay for both sexes. The number of pre-hospital care ambulances was inversely associated to the admission rate by IHD for the female sex. Conclusions: In Rio de Janeiro State, for the period 2001-2007, the incorporation of technology in EMS showed association to the IHD hospital outcomes: the referral rate from primary care settings increased the hospital admission and the average length of stay and the availability of ambulances decreased the hospital admission in some cases. The results show that the incorporation of technology in EMS has impact when associated to the primary care policies and the improvement of patient mobility.

M-141

48 – COSTS FOR THE DIAGNOSIS AND TREATMENT OF PULMONARY TUBERCULOSIS IN HOSPITAL UNIT OF PUBLIC HEALTH IN BRAZIL

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Investments for the control of tuberculosis has increased every year. The expected expenditures for 2010 is around U.S. $ 4.1 billion. The consensus sentiment of public officials that spending involving the diagnosis and hospital treatment exceeds the resources available to control this disease. Through a descriptive study the direct and indirect costs for diagnosis and treatment of Pulmonary Tuberculosis in patients infected by HIV or not, admitted to a Hospital Unit of Public Health (Hospital Sanatorium Parthenon (benchmark for treating TB and HIV in the State of Rio Grande do Sul / Brazil). Through a convenience sample will be evaluated the records of patients hospitalized from September 2009 to October 2010 By checking the patient's records and record an instrument of data collection costs was be assessed. The cost for each procedure including patient costs, laboratory costs, medication costs, costs of inputs and equipment costs were raised by examining the number of times each procedure or process was performed during hospitalization. These costs were confronted with the resources provided by the hospital with the diagnosis and treatment of TB. Preliminary results showed that 301 patients were hospitalized from September 2009 to October 2010 with Pulmonary Tuberculosis. The month with more hospitalization were August (33 patients were hospitalized). The dates of direct and indirect costs was being assessed. The survey of direct and indirect costs attributed to the diagnosis and treatment of TB in this setting may contribute to the managers to define resources to control the TB epidemic. Projeto de Pesquisa ICOHRTA AIDS/TB-2010

M-142

49 – COST-EFFECTIVENESS ANALYSIS OF PCR FOR THE RAPID DIAGNOSIS OF PULMONARY TUBERCULOSIS IN HIV PATIENTS

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Tuberculosis is one of the most prominent health problems in the world, causing 1.75 million deaths each year. Rapid clinical diagnosis is important in patients who have co-morbidities such as Human Immunodeficiency Virus (HIV) infection. In a public reference TB/HIV hospital in Brazil, we compared the cost-effectiveness of diagnostic strategies for diagnosis of pulmonary TB: Acid fast bacilli smear microscopy by Ziehl-Neelsen staining (AFB smear) plus culture and AFB smear plus colorimetric test (PCR dot-blot) for use in HIV patients. From May 2003 to May 2004, sputum was collected consecutively from PTB suspects attending the Parthenon Reference Hospital. The gold standard was a positive culture combined with the definition of clinical PTB. Cost analysis included health services and patient costs. The AFB smear plus PCR dot-blot require the lowest laboratory investment for equipment (US$ 20,000). The total screening costs are 3.8 times for AFB smear plus culture versus for AFB smear plus PCR dot blot costs (US$ 5,635,760 versus US$ 1,498, 660). Costs per correctly diagnosed case were US$ 176,611 and US$ 52,198 for AFB smear plus culture and AFB smear plus PCR dot-blot, respectively. AFB smear plus PCR dot-blot was more cost-effective than AFB smear plus culture, when the cost of treating all correctly diagnosed cases was considered. The cost of returning patients, which are not treated due to a negative result, to the health service, was higher in AFB smear plus culture than for AFB smear plus PCR dot-blot, US$ 375,828,745 and US$ 112,018,255, respectively.

M-143

701 – COST-EFFECTIVENESS OF BIPHASIC INSULIN ASPART 30 IN TYPE 2 DIABETES IN BULGARIA

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Objectives: To evaluate the long-term health and economic outcomes of biphasic insulin aspart 30 (BiAsp30) in uncontrolled patients with type 2 diabetes mellitus switching from human biphasic insulin (BHI) in the Bulgarian setting. Methods: The extensively published and validated CORE Diabetes Model was populated with the clinical data from IMPROVE(TM), a large, multi-centre, six-month observational study assessing the safety and efficacy of BIAsp30 in patients with type 2 diabetes. Conversion from BHI to BiAsp30 was associated with a significant decrease in HbA1c (-1.84 %, $p<0.05$). In the base-case analysis a time horizon of 30 years has been chosen to reflect the all relevant long-term costs and outcomes of diabetes. The analysis used health state utility values derived from the literature. The unit costs of treatment and complications were derived from published sources, expert opinion survey and official tariff lists for healthcare services (1 BGN = 0.51 EUR). Costs and health outcomes were discounted at 5% and 3% respectively. RESULTS: BIAsp30 was projected to improve quality-adjusted life expectancy by 0.67 QALYs compared to BHI (6.22 ± 0.11 versus 5.55 ± 0.10). Direct costs decreased by BGN 2,882 per patient (BGN 19,944 ± 506 versus BGN 22,826 ± 558) from a societal perspective and by BGN 2,348 (BGN 15,954 ± 415 versus BGN 18,302 ± 472) per patient from a third party-payer perspective. Conclusions: Therapy conversion from BHI to BiAsp30 in T2DM patients was associated with both quality of life improvements and reduced costs over patient lifetimes. BIAsp30 was hence shown to be a dominant alternative over BHI from both a third-party payer and societal perspective.

M-144

193 – THE APPLICATIONS OF THE PHARMACOECONOMICS ANTIRETROVIRAL TREATMENTS FOR THE AIDS/HIV WITH NATIONAL DRUGS. CUBA 2001-2006

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Objective: To assess the economic and social impact on health of the national AIDS/HIV antiretroviral treatments with national drugs on the base of the results reached in the proportion of the patients and the savings obtained of the costs like an economic benefit, in comparison with the drugs innovators antiretroviral of their administration during six years in Cuba. Methods: A retrospective study was made to evaluate effectiveness. It was measured as a clinical, immunology and virology health improvement of patients. The more relevant direct cost was estimated as pharmacotherapy and hospitalization annual costs. It was made a through analytical technique of cost-minimization to compare different therapies and select the most efficient, as well to estimate saving in treatment total cost for Cuban drug generics, comparing these ones with innovators drugs on the base of its therapeutic equivalence demonstrated by bio-equivalence studies. Results: Patient's health conditions are improved from clinical, immunologic and virology point of view. As the retroviral treatment begins, it rebounds in a decrease of morbidity and mortality patients' amount. With the national production of antiretroviral, the country will save for this concept around 66 % of the total of the annual necessary resources, what would imply to have a relationship cost benefit of 1:3 in favour of the antiretroviral of internal billing during the years 2001- 2006. Conclusion: The implementation of global treatment with national antiretroviral generics drugs has demonstrated the political will of Cuban Government treatments to solve accessibility for all the patients. It was produces a patient health betterment with a lower cost, it is why was confirmed the economical convenience to produce this drugs in Cuba.

M-145

704 – NEUROMONITORING IN THYROID SURGERY: A MICRO-COSTING ANALYSIS

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Objective: One of the principal reasons for malpractice claims in otorhinolaryngology is the damage to the Recurrent Laryngeal Nerve (RLN). Intraoperative neuromonitoring (IONM) facilitates preservation of RLN in thyroid surgery and reduce intraoperative risks. Today this technology is most prevalent in countries with private insurance schemes and less in countries as Italy. Aim of this study was to evaluate the additional hospitalization costs for thyroidectomy due to IONM use and to facilitate its penetration in order to reduce intraoperative risks. Methods: The study was performed in an Italian University Hospital, in which the learning curve for this technology is considered completed. To assess the impact of IONM on hospital management three scenarios were considered: 1) traditional thyroidectomy; 2) thyroidectomy with IONM in a high-volume setting (5 procedures per week); 3) thyroidectomy with IONM in a low-volume setting (1 procedure per week). Patient care processes were costed considering direct costs only (staff time, consumables, equipment, drugs, operating room and general expenses) and according to the hospital perspective. Unit costs were collected from hospital accounting and standard tariff lists. A differential analysis was performed to highlight additional resource consumption (time effort, consumables, technology equipment) due to IONM usage. Findings: The hospitalization costs for a thyroidectomy with IONM range from €3,713 to €3,770, 7-9% higher than those for traditional base case scenario. Apart from general expenses (35%), main cost drivers are: consumables and technologies (25%), operating room (16%), staff (14%). Surgery costs are 58% of hospitalization costs, while IONM costs represent the 6-7%. Conclusions: This study, the first economic evaluation on IONM, confirms that technology approach for thyroidectomy is effective to reduce damage to RLN against a low impact on hospital budget. It finally provides useful information in terms of decision-making to assess the impact of IONM in new diagnostic and therapeutic pathways.

M-146

888 – COSTS OF RADIOLOGICAL EXAMINATIONS FOR PICTURE ARCHIVING AND COMMUNICATION SYSTEM (PACS) AND WITH THE SYSTEM OF PLAIN FILMS

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Objective: To calculate the costs of radiological examinations carried through in the Sector of Radiology of a university hospital for Picture Archiving and Communication System (PACS) and with the system of plain films. Methods: This observational and quantitative study included a descriptive analysis of data collected of documents at the Botucatu Medical School Hospital of São Paulo State University (BMSH-Unesp). The materials of consumption for each radiological examination carried through by PACS and with system of plain films had been identified. Moreover, the costs with human resources, telephone, water, sewer, electric energy, maintenance and cleanness of the sector had been identified. Results: The cost of the radiological examinations for PACS was US$17.39. Already the cost of radiological examinations with system of plain films was US$18.54. Conclusion: The analysis of cost showed that radiological examination for PACS was more economically advantageous than system of plain films.

M-147

782 – EVALUATION OF PET EFFICACY IN SELECTED CANCERS

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Introduction: Positron Emission Tomography (PET) is an imaging method of growing development in recent years. In Uruguay, a PET scanner was recently installed. Main applications refer to oncologic area, whose evidence is evaluated permanently. Objective: Evaluation of the efficacy of PET scan in diagnosis, staging and evaluation of recurrence in patients with lung, head and neck, colo-rectal, liver, breast, esophagus, stomach, thyroid, cervix, ovary, central nervous system, pancreas and malignant melanoma cancer . Methods: Revision of information published in MEDLINE, NHS, NICE, DARE, Health Technology Assessment Agencies, related colleges and Medicare, Medicaid, CHMM, AETNA between 2000 and 2009. Results: Use: In diagnosis being indicated when it can avoid an invasive procedure or help in it. In staging when doubt persist after the usual evaluation. Lung: In solitary pulmonary nodule > 1 cm, for initial and mediastinal staging, In Small Cell Lung Cancer for staging and restaging. Little evidence not allow conclusions for response treatment or residual tumor detection, without clinics. Head and neck: could be used in diagnosis when the CT/MRI is not conclusive. Colorectal: diagnostic accuracy for potentially resectable hepatic metastases with colorectal primary, evidence in case of recurrence, especially hepatic recurrence as additional diagnostic method in patients with high carcinogenic embryonic antigen (CEA). Breast: no evidence support its recommendation in diagnosis and staging of axillary node. Esophagus: useful for initial staging. Stomach: no evidence. Thyroid: some evidence on diagnostic in recurrent medullar thyroid cancer with increased biomarkers no confirmed by iodine-131. Cervical cancer: Sensibility less than 90% on detection and staging of recurrence, being similar in Ovarian cancer. Central nervous system: best results for distinguishing up to low-grade gliomas. Pancreatic cancer: not proven utility. Melanoma: not seem conclusive. Conclusion: For certain indications, PET has clinical value, but new evidence is necessary for others.

M-148

588 – IGY ANTI-HAV: A NEW TOOL FOR THE DIAGNOSTIC OF HEPATITIS A IN A IMMUNOENZYMATIC ASSAY

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Hepatitis A is an endemic disease in Brazil and Latin America. Prevalence of this infection is related to the low degree of hygiene and sanitation. Nowadays, due to better sanitation conditions, the epidemiological profile of disease is changing to older ages resulting in the occurrence of outbreaks. Diagnostic kits for detection of total anti-HAV generally use mammals immunoglobulin G (IgG) in the convalescent period of disease for production of capture and conjugated antibodies. An alternative to the application of mammals antibodies in the diagnosis is the use of Immunoglobulin Y (IgY) from birds and reptiles. The IgY has several advantages when compared to IgG: high response against mammals antigens, reduction of the background in imunoenzymatic assays and it is obtained by a non-invasive method, through the harvest of the egg yolks. The aim of this study was to develop an immunoenzymatic assay for total anti-HAV detection using IgY anti-HAV produced in immunized chickens against Hepatitis A virus as capture and conjugated. For evaluation of the immunoenzymatic “in-house” assay with IgY anti-HAV, a panel composed of two hundred samples was tested for total anti-HAV, one hundred positive samples and one hundred negative samples. The “in-house” assay showed sensibility of 88%, specificity of 98% and efficiency of 80%. The utilization of IgY anti-HAV in the “in-house” immunoenzymatic assay was efficient and demonstrated a good sensitivity and specificity. The advantages of IgY anti-HAV when compared to IgG anti-HAV and the high sensibility and specificity of the assay showed that IgY anti-HAV can be used as an alternative to the IgG in immunoenzymatic assays.

M-149

661 – INFORMATION SYSTEM ON INTERACTIVE NETWORK FOR CUTANEOUS LEISHMANIASIS

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Introduction: Cutaneous leishmaniasis (CL) is an infectious disease, caused by a protozoan (Leishmania), and transmitted to the man by the bite of infected sand flies. It is endemic in Brazil, with epidemiological and clinical characteristics related to the diversity of agents, vectors, reservoirs and transmission patterns. The aim was to describe a strategy to contribute to the surveillance and control of CL. Material and Methods: Due to a technical cooperation between Samuel Pessoa Department of Endemic Diseases/National School of Public Health/Fiocruz and Health Surveillance Secretariat (HSS)/Ministry of Health (MOH), a home page was developed (http://www4.ensp.fiocruz.br/Leishmaniasis/lt) as an auxiliary tool for surveillance and monitoring of CL in Brazil. The study was started in 2006, by the Technical Group of Leishmaniasis. In 2007 adjustments were made after a pilot test with Epidemiological Surveillance State Coordinators of Leishmaniasis during the Leishmaniasis National Meeting. The final version of the site was presented on the second semester of 2009. Results: The home page consists of three presentation modules: the first is a free access page with information about CL; the second one presents the epidemiological situation of CL since 2006 - restricted to those involved in epidemiological surveillance of leishmaniasis in national and state level, collaborators and representatives of the Public Health Laboratories; and the third part of the system is a communication forum. Discussion: The information system on interactive network provides space for discussion and information exchange, enabling sharing of experiences among states, Leishmaniasis Technical Group of the HSS / MOH, researchers and others involved on control of this endemic disease. Conclusion: The Home-Page is a useful tool for improving the surveillance and monitoring system, nevertheless, there is a need for joint participation of all involved people to establish and help the CL control in Brazil.

M-150

300 – COST – EFFECTIVENESS STUDIES IN DEPRESSION: SHOULD DECISION-MAKERS BE SATISFIED WITH AVAILABLE EVIDENCE?

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Objective: To evaluate methodological issues of cost-effectiveness studies in pharmacological and /or psychosocial interventions depression disorders. Method: Literature search was based on major database up to October 2010: Medline, Centre for Reviews and Dissemination, Cochrane Database and INAHTA (International Network of Agencies for Health Technology Assessment). Individuals aged from 18 to 65 years with Major Depressive disorder were included. The uniterms Cost – effectiveness, Cost-utility and cost-benefit analyses, major depression disorders, Pharmacological and/or psychosocial treatments were used. Results: Seventy studies were found. Most of them were economic models or systematic reviews. Modeling studies presented good methodological quality in most of them. However, some important items of methodology were lacking in some studies, for example, the data sources: if from systematic review or primary data, the design and population of the selected studies. It was not clear if the best available evidence was used in the models. There were few studies with primary data through randomized controlled trials or naturalistic follow- ups. These studies were well conducted. Regarding the outcomes used in cost-effectiveness studies, remission rate or free days of depression were the most common in the literature .Few studies included quality of life measures, for example utility rates or QALYS (quality- adjusted life - years).Conclusion: However the majority of studies are methodologically well conducted, more trials with primary data and measures that reflect the impact of the interventions on a patients' quality of life are needed.

M-151
174 – HEALTH CARE QUALITY IMPROVEMENT AGENCIES: EXAMPLES FROM EUROPE

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Background: Across Europe, a number of independent agencies are addressing quality improvement in health care and supporting more comprehensive public policies in this area. Objective: To compare the activities and financial capacity of the agencies. Design: Comparative analyses of nine agencies in six European countries. Data Sources: Data were collected from each agencies' annual reports, documents, strategic plans and website. Results: HAS (France) was created in 2004. Its activities include scientific assessment and evaluation, training programs, hospital accreditation, and advising on national health insurance policy. IQWiG (Germany), established in 2004, conducts evaluations of pharmaceutical and non-pharmaceutical procedures, and makes recommendations on disease management programs. ISQSH (Ireland) was founded in 1994 to lead the improvement of quality and safety in health care. CBO (Netherlands) was formed in 1979. Its main activity is training medical professionals. Ireland's NIAZ was created in 1998 to improve quality of care through hospital accreditation programs. In Spain, CAHTA was formed in Catalonia in 1994 and AESTA was created in Andalusia in 1996. These agencies support the better use of clinical resources by decision makers, and research and planning assessments at the regional level. NICE (UK) is known for their comprehensive guidance in public health promotion. King's Fund (also UK) focuses on research, leadership programs, and knowledge sharing. Financial capacity was found by comparing total budget to total catchment population. The agencies with the highest per capita budgets were HAS (1.09€), CBO (0.65 €), NICE (0.57€) and CAHTA (0.56€). IQWiG (0.13€), ISQSH (0.08€), NIAZ (0.10 €), AETSA (0.16€) and King's Fund (0.17€) had 6-14 times less financial capacity than HAS. Conclusion: Independent agencies in Europe have had a positive impact on quality of health care. Despite varying financial capacities, they have been able to promote comprehensive quality policies in their respective national and regional health systems.

M-152
933 – ORGANISATION OF DIAGNOSIS AND TREATMENT OF DIABETIC FOOT ULCERS

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Objective: The aim was to assess a large range of technologies for diagnosis and treatment of diabetic foot ulcers and to analysis the existing organisation of treatment in order to give input to an improved organisation of treatment of patients with diabetic foot ulcers. Methods: A systematic review of literature on different technologies for diagnosis and treatment of diabetic foot ulcers was conducted. Based on literature reviews and interviews with health care professionals the existing organisational models for treatment were assessed and possible models for future organisation were considered. Also an economic analysis of current cost of treatment of diabetic foot ulcers and the possible future organisational models were included. Finally a literature review and interviews with patients and health care professionals contributed to an analysis of patients' needs related to the future organisation of treatment Results: The review revealed that the evidence regarding the diagnosis and treatment of diabetic foot ulcers is lacking. In relation to almost every included technology more research is needed. The organisational analysis showed that there is a great degree of cross-regional differences in the present organisation of diagnosis and treatment of diabetic foot ulcers and the criteria for referral of patients between sectors are vague and varying. Furthermore, the patients wish for security, consistency, communication and a holistic approach in the course of events. The economic analysis estimates the minimum socio-economic consequences of the diagnosis and treatment of diabetic foot ulcers to 793 million DKK each year. Conclusions: The HTA outlines expedient organisational strategies for the diagnosis and treatment of diabetic foot ulcers. National clinical guidelines should be developed to function as a linkage between the present knowledge and future organisation. The future changes should allow for better cross sector cooperation. Future developments should include an improved possibility to collect systematic evidence.

M-153

149 – USE OF DATABASE AS TOOL TO PHARMACOTHERAPEUTIC PROFILE ANALYSIS OF DIABETES MELLITUS PATIENTS

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Introduction The diabetes prevalence is estimated to reach 7.8% of the adult world population in 2030. The drugs are the main technology in the treatment, being the most costly item for the health systems. Thus, it is necessary to develop tools that contribute to the rationalization and individualization of pharmacotherapy of the non-transmissible chronic disease. Purpose to study through a database the pharmacotherapeutic profile of patients with diabetes attended by the Public Health System (SUS) in Ribeirão Preto-SP, Brazil. Casuistic and Methods Retrospective cross-sectional study was conducted. Patient selection was based on a survey of the database from the Ribeirao Preto-SP. There were selected those patients that received a prescription of at least one of the oral antidiabetic drug (glibenclamide; metformin; gliclazide) or insulin available through SUS in the period of March/2006 and February/2007. The project was approved by the Ethics Committee. Results Patients selected (3927 patients) were, on average, 60.4 years old, 61.0% were females and 55.0% were elderly. Five patients used the combination of glibenclamide+gliclazide, an inappropriate drug combination. Approximately 34.0% of patients present drug addition and/or increased dose for the treatment of diabetes. According to dose, 10 patients received doses of glibenclamide or metformin above the recommended maximum dose and other 128 patients received metformin dose lower the minimum recommended. These findings have clinical relevance, as they evidenced risk of toxicity or ineffectiveness therapy. In addition, dosages of oral antidiabetics drugs were lower in monotherapy than in polytherapy. Moreover, in elderly patients there was no reduction of the dose. Regarding comorbidities, there was prevalent hypertension (73.5%) and dyslipidemia (25.9%). Conclusion The use of database for analysis and monitoring pharmacotherapy becomes a useful tool in optimization of the Diabetes Mellitus treatment since it is a financially inexpensive tool, easy to apply and quickly. Acknowledgement (FCFRP-USP; CNPq)

M-154

335 – A SYSTEMATIC REVIEW OF BREAST CANCER INCIDENCE PREDICTION MODELS

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Background: Risk or prediction models are statistical tools used to estimate the probability of an individual with specific risk factors developing a condition within a certain time (such as 5 years or lifetime). Two ways to compare prediction models are by systematic review and by applying all models to one dataset to assess relative accuracy. There are numerous breast-cancer prediction models so a systematic review was conducted to establish the more accurate ones. Methods: Sensitive searches in Cochrane library (CDSR, CENTRAL, HTA, DARE, NHSEED), MEDLINE, EMBASE, CAB Abstracts and PsychINFO databases were conducted to June 2010. Standard systematic review methods where possible were used. No validated quality assessment checklists for prediction modelling studies exist so recently published criteria for prognostic studies were adapted. No meta-analysis was appropriate because of population and study-design heterogeneity, and different sets of included variables in the prediction model. Any performance metric such as expected divided by observed rates (E/O), c-statistics, Hosmer-Lemeshow test, sensitivity, specificity, positive predictive values or ROC curves were reported. Results: Database searches found 7317 references of which 1265 were duplicates. Eighteen papers proposing one or more new or modified models (sometimes with validation), and eight trying to validate existing models were found. Each incorporated several factors and most used a regression model framework, such as logistic regression. The standard of reporting was poor. The predictive ability of all models was modest. The Gail2, Colditz & Rosner, Tice and Tyrer & Cuzick models all had similar predictive accuracy. Conclusion: For individual women, many 'low-risk' women go on to develop breast cancer whereas many 'high-risk' women do not. More recent models were developed to determine eligibility for breast-cancer adjuvant trials. Drug companies would have a vested interest in more women being eligible, which may have biased the studies. More accurate predictive models are required.

M-155

526 – SYSTEMATIC REVIEWS ON ETHICAL ISSUES IN HEALTH TECHNOLOGY ASSESSMENT: HOW TO PERFORM THE INFORMATION RETRIEVAL?

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Objective: Reflections on ethical issues associated with health technologies, their use and value-based decisions in the assessment process are part of comprehensive health technology assessments (HTAs). Effectiveness assessments as well as reviews on ethical issues should be based on systematic literature searches and analyses. As ethical issues in HTA are multifaceted the more or less standardized methods of information retrieval for effectiveness assessments are not applicable to ethical issues. Thus, our aim was - in the absence of existing adapted methods – to develop a specific methodological approach for the systematic retrieval of information on ethical issues related to health technologies. Method and findings: We conducted a systematic literature search to verify the non-existence of published comprehensive methodological approaches. This resulted in no hits. We therefore developed a step-by-step approach following the workflow of information retrieval for effectiveness assessments, but prepended a definition phase to frame the methodological approach on ethical issues to be used, to identify the technology-related benefit and harm, the inclusion and exclusion criteria for information retrieval and screening etc.: Step 1: Translation of the search question using the PICO scheme and additional components. Step 2: Concept building by modeling and linking search components. Step 3: Identification of synonyms in all relevant languages. Step 4: Selection of relevant information sources. Step 5: Design of search strategies for bibliographic databases. Step 6: Execution of search strategies and information seeking, including hand-searching. Step 7: Saving of retrieval results and standardized reporting of the process and results. Step 8: Final quality check and calculation of precision and recall. Conclusions: Systematic searching for information on ethical issues related to health technologies can be performed similar to the common retrieval workflow for effectiveness assessments, but should be performed separately applying adapted procedures and search terms on ethical issues relevant to the research question.

M-156

528 – BENEFIT AND HARM IN SYSTEMATIC REVIEWS ON ETHICAL ISSUES IN HTA: ASKING THE RIGHT QUESTIONS TO IDENTIFY BOTH COMPREHENSIVELY

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Objective: Identifying technology-related benefit and harm is the most important objective in reflecting the ethical implications of the use of health technologies. While identifying benefit and harm in effectiveness assessments are described in detail by the methods of Evidence-based Medicine and HTA no similar standards exist to address these terms in their broader definitions of ethics. Thus, our aim was to develop a procedure to identify possible technology-related benefit and harm in terms of ethics-relevant outcomes. Methods: We analysed the pre-searched methodological publications on reviewing ethical issues in HTA and we searched systematically, reviews on ethical issues in health technologies and published HTAs which address ethical issues. We extracted the ethical relevant benefit and harm by the categories screening, confirmatory testing/diagnostics, drugs and non-pharmaceutical interventions, and synthesized them regarding the mentioned outcome-areas. From these results we derived a set of questions and incorporated them into a check-list. Finally we tested this check-list on three examples. Findings: Our search resulted in 9 relevant methodological publications and 198 applications on ethical issues in health technologies. 3 publications addressed methods to identify the plethora of technology-related harm. Extraction and synthesis of the included publications resulted in a check-list of 24 questions: 4 questions are relevant to all assessments, 8 questions are screening-related (e.g. consequences of false-positive or false-negative test results). In confirmatory tests/diagnostics most questions are similar to screening-related questions, 2 questions are additional. 8 questions are therapy-related (two of them drug-specific). Most of the questions are related to individuals, 2 questions are related to comparative assessments. Conclusions: A check-list like our proposed is helpful to identify – besides other ethical issues – technology-related benefit and harm comprehensively. As additional guidance it could be integrated in the existing methodological approaches (e.g. axiological or eclectic approach) on addressing ethical issues in HTA.

M-157

672 – EVOLUTION OF THE HTAI VORTAL: A USER-CENTERED APPROACH

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Background: The HTAi vortal was established in 2005 by the HTAi Interest Sub-Group on Information Resources (IRG). This Web directory lists selected online resources aimed at supporting the HTA doers' day to day work; resources are categorized by topics and briefly described; HTAi members can rate the resources and suggest new links through an online form. A customized search engine is also provided. It limits the Web search to the websites listed by the vortal. Objective: To evaluate the overall use and satisfaction of the vortal and to get suggestions for further enhancements. Methods: A questionnaire aimed at users and non users of the vortal has been developed using an online facility. The questionnaire was first tested by the IRG members in December 2010 and their feedback helped to create an amended version aimed at all HTA doers and others interested in this field. Completion requires less than 10 minutes; results can be exported to a dedicated software for further analysis. Questions explore the content and functionalities of the vortal. Participants are also asked to rate proposals for new functionalities and suggest new ones. The survey was conducted in February 2011. The invitation to participate in this survey has been disseminated through the HTAi Newsletter. INAHTA and EUnetHTA were also requested to disseminate the invitation to their respective members. Findings and Conclusion: Results of the online survey will be presented and the preliminary plans for further development of the vortal will be outlined. Based on the survey results, the HTAi vortal editorial group will design a new version of the vortal. Volunteers are invited to participate to the maintenance of (sub) sections of the vortal. The new, user centric, vortal will be released in 2012 and users' satisfaction will be evaluated after one year.

M-158

903 – COMPARATIVE ANALYSIS OF THE GERMAN AND ENGLISH LEGAL FRAMEWORKS FOR HEALTH TECHNOLOGY ASSESSMENT

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Objective: Methods for health technology assessment (HTA) are a key factor for ensuring the sustainability of national health care systems. The German Institute for Quality and Efficiency in Health Care (IQWiG) proposes the efficiency frontier method for HTA in Germany. Contrary to the National Institute of Health and Clinical Excellence, IQWiG rejects quality-adjusted life years (QALYs) as a global measure of health outcomes in its efficiency frontier method. The objective of this analysis is to assess the legal option to introduce QALYs for HTA in Germany by comparatively analyzing the English and German legal frameworks. Methods: The comparative legal analysis includes specific pharmacoeconomic provisions, constitutional constraints and jurisdiction in the English and German legal systems. Findings: We found major differences in the legal setup of health care services in both countries. Justiciable rights are more extensive in Germany. Contrary to the English legal system, Germany's constitution strictly prohibits putting a monetary value on life and health. The Federal Constitutional Court of Germany consistently confirms this. The application of QALYs to HTA would imply putting an explicit or implicit threshold value on life and health. Therefore, QALYs may not be introduced in the current German legal context. Conclusions: Our analysis shows legal constraints which prohibit the introduction of QALYs in Germany. The lack of a global measure of health outcomes may pose a thread to the sustainability of the German health care system. It is a major challenge for German legislators to ensure the sustainability of the Statutory Health Insurance funds while adhering to legal constitutional constraints.

M-159

170 – EDUCATION IN INTERNATIONAL HEALTH TECHNOLOGY ASSESSMENT, PRICING AND REIMBURSEMENT: THE DEVELOPMENT OF A FRAMEWORK FOR THE DELIVERY OF A MASTERS LEVEL DISTANCE-LEARNING COURSE

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Background: Health technology assessment (HTA), pricing and reimbursement are relatively new areas of expertise that have developed across the world to enable the synoptic evaluation of new health technologies in terms of effectiveness, cost-effectiveness, and relationship to markets. The skills for undertaking effective HTA evaluation are disparate and cannot currently be gained from a single educational outlet. The aim of our project was to create an online part-time postgraduate course for people and organisations seeking to build the full set of HTA skills. Methods: The proposed framework has been developed with experts in a number of 'sub-disciplines' of HTA and with informal discussion with stakeholders from international HTA agencies, industry, consultancy firms and academia. The framework involves modules to provide students with critical understanding of the entire process of health technology development from several different perspectives, i.e. commissioning, development and assessment. Results: The curriculum includes both core and optional modules in the areas of evidence synthesis, economic evaluation, cost-effectiveness modelling, and pricing and reimbursement strategies to develop value propositions in multiple jurisdictions. It was decided to deliver the course part-time by online distance-learning methods to optimise take-up among participants from industry, assessment bodies and academia in both developed and low and middle-income countries. Pedagogically, the approach is 'blended-learning', i.e. using both textual materials and online resources such as podcasts and discussion forums, group-working, problem-solving, case-study-based activities and guided independent study. The aim is to facilitate reciprocal learning among a potentially technically advanced student population and to enable students to relate unit content to their own needs and professional situation. Conclusions: It has been possible to generate a Masters-level course design that we anticipate can meet the educational needs of participants from a range of backgrounds working in the professional area of HTA. The full course will begin in Autumn 2011.

M-160

780 – DISSEMINATION ANALYSIS OF THE BRAZILIAN HEALTH TECHNOLOGY ASSESSMENT BULLETIN (BRATS)

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Goals: Brazilian Health Technology Assessment Bulletin (BRATS) is an electronic bulletin prepared jointly by the Brazilian Health Surveillance Agency (Anvisa), the National Supplementary Healthcare Agency (ANS) and the Secretary of Science and Technology at the Ministry of Health. The goal of this study is to evaluate some issues regarding the dissemination of BRATS. Methods: The data used was obtained from the subscribers database, which provided the following information: 1) Variation in the number of subscribers between 2007 and 2010; 2) Regional distribution of subscribers; 3) Profile of the subscribers in terms of age and occupation in 2010. Results In November 2010, there were 33,612 BRATS subscribers. In almost four years, there was an increase of 800% in the number of subscribers, compared to January 2007 (3,752 subscribers). The State of São Paulo has the largest number of subscribers, 10,739 (November 2010). In this period, there were other states with more than 1000 subscribers such as: RJ (3798), MG (3719), RS (2317), BA (1244). The occupation informed by the largest number of subscribers was pharmacist. Other occupations reported by over 1,000 subscribers were: teacher, doctor and nurse. The most frequent age group of subscribers is the one from 26 to 35 years old. Conclusion: For an electronic publishing and content-specific as BRATS, there was a rapid and consistent increase in the number of subscribers. The number of subscribers most likely not to match exactly the number of readers, bearing in mind that some subscribers may not read all issues; on the other hand, the bulletin can be also read by non-subscribers, through direct access to the Anvisa website or other websites, which provides the bulletin. Besides enhancing the dissemination of the bulletin, an issue to be considered is the evaluation of the impact of BRATS on the decision-making process in health.

M-161
812 – HEALTH TECHNOLOGY ASSESSMENT FOR USE IN HOME CARE: THE MEDICAL DEVICES

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Introduction: The home care uses medical devices in another environment and different security conditions at the hospital, causing new sources of risk to the patient, family and care system. The aim of this paper is; propose the main points to consider when evaluating medical devices for use in home considering main risks and hazards that may occur in the home care, as a new scenary of health care. Material and methods: The methods used to evaluate new technologies are oriented towards the consolidation of the best evidence, for it is necessary to collect, analyze and synthesize information. The method used to formulate questions that the evaluation of medical devices used in home care, must answer was: build a list of cross-questioning, between components of health technology assessment with the main risk factors and hazards presented in the use of medical devices in home care. From this crossing was obtained guide of directives for assessing these technologies. Results: The detailed output of crossing between the variables, produced a list of itens to assess: the parameters of safety, effectiveness, impact and economic analysis of biomedical devices in home care versus the hazard and risk factors related to: The new operating environment of the equipment, human factors, functional failures and use, biological agents, use of electricity, electromagnetic interference and use of hazardous substances by the equipment. Conclusion: The evaluation of medical device technology for use in home care should include: planning (need, prioritization, technology assessment, life cycle) the purchase and use, and assessing their risks and hazards. After the evaluation applying the suggested methodology can be concluded by answering the following questions: how does this technology work for use in home care? What kind of home care is this technology? Is the economic evaluation appropriate? How does it compare with other technology assessed?

M-162
527 – ASSISTIVE TECHNOLOGY IN THE CONTEXT OF SEXUAL HEALTH FOR THE VISUALLY IMPAIRED

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Introduction: Visually impaired people face health information access difficulties, especially regarding sexual health, as this demands a distinguished approach. For disabled people, using Assistive Technology (AT) is fundamental, as it refers to any tool or technological device aimed at developing the Independence of people with sensory or physical limitations. By emphasizing the use of this technology in the health context, nurses, as trained professionals for health education, can create different strategies in their work environment to enhance the dynamics of nursing care. AIM: To develop AT for visually impaired men and women to learn about the characteristics of the main STD's. Method: AT development study. A rhymed educative text was created, addressing the main STD's, citing family planning and condom use. A workshop was held with male and female visually impaired people. The workshop was recorded and statements were transcribed and subject to qualitative analysis through the content analysis method. Ethical aspects were respected. Results: Study participants were 15 visually impaired people, including seven men and eight women. Most subjects' discourse contained many doubts. Therefore, communication was easy to understand and time was made available for discussions with the disabled people. It was also identified that the rhymed text contributed to learning and also enhanced critical thinking about safe sex. Conclusion: The developed AT effectively assisted the visually impaired people regarding knowledge transmitted on STD's. Through the use of AT, the care clients' special needs can be attended to.

M-163

520 – WHAT IS THE IMPACT OF THE TIME GAP BETWEEN THE FINAL SEARCH AND PUBLICATION OF HTA SYSTEMATIC REVIEWS ON THE USEFULNESS OF THEIR RESULTS?

Dr Sheetal Parekh, Netscc - University of Southampton, United Kingdom; Dr Andrew Cook, NETSCC - University of Southampton, United Kingdom; Dr Aileen Clarke, University of Warwick, United Kingdom

Background: Systematic reviews (SRs) are a gold standard for evidence-based decision making, and are the key building blocks for clinical practice guidelines (CPGs), and health technology assessment (HTAs) reports. SRs should be up to date to maintain their importance in informing healthcare policy and practice. However, little guidance is available about when and how to update SRs. Moreover, the updating policies and practices of some organizations that commission or produce SRs are unclear. Objectives: We investigated the impact of the time gap between the final search and publication on the usefulness of results or conclusions of HTA systematic reviews and how these can be mitigated for HTA reviews to ensure their currency. Our secondary objective was to identify if any pace of change of research existed and what factors were related to this pace of change in research. Methods: We identified and included reviews published by the NIHR HTA programme from 2005-2007, with each review including atleast one randomized trial and at least one meta-analysis. We estimated the probability of trials being missed during the period between the date of last search performed by authors and the date of publication of the review. For reviews, where significant numbers of trials had been missed, we repeated the original searches to identify missed trials, and assessed their impact on results using cumulative meta-analysis. Results: We will make recommendations for conduct of systematic reviews by the HTA programme, and others. Our study will also contribute to understanding best practice for updating systematic reviews.

M-164

843 – STRENGTHENING THE EVIDENCE BASE OF PATIENT AND PUBLIC INVOLVEMENT IN HTA: GUIDANCE FOR REPORTING

Dr Sophie Staniszewska, University of Warwick, United Kingdom; Jo Brett, University of Warwick, United Kingdom; Dr Carole Mockford, University of Warwick, United Kingdom; Dr Rosemary Barber, University of Sheffield, United Kingdom

Background: Interest in the impact of patient and public involvement (PPI) in health technology assessment and other forms of research has increased internationally. However, the evidence base underpinning the assessment of PPI impact has weaknesses and the contribution that PPI makes to research is thus difficult to evaluate. A key problem is the poor quality of impact reporting. Objective: To report on a synthesis of key issues in PPI evidence, based on two recent systematic reviews and to present guidance which addresses these issues and will enhance the quality of PPI reporting in the future. Design: The PIRICOM and PAPIRIS systematic reviews utilised the Centre for Reviews and Dissemination Guidance (2009) for systematic reviews. The development of the guidance utilised a form of narrative synthesis to draw together key issues identified in the systematic reviews. Results: Key weaknesses in the evidence base were found, including poor reporting. The poor quality of PPI impact reporting included unclear content validity in studies, limited detail about impact, little formal evaluation of the quality of involvement, limited focus on negative impacts, poor capture or measurement of impact, limited acknowledgement of the need to consider the complexity of impact and a lack of critical reflection and interpretation. Discussion and conclusion: The reporting of patient and public involvement impact in health technology assessment needs significant enhancement, through CONSORT-like guidance, to develop a clearer and more robust evidence base, to enable evaluation of what works, for whom, in what circumstances and why. This paper presents the first stage in developing this guidance. It will outline the key weaknesses in the evidence base and present the new CONSORT-like guidance for reporting, and the process of consensus development which will be carried out in collaboration with EQUATOR.

M-165

3 – HEALTH METHODOLOGIES AND TECHNOLOGIES IN EVALUATING PESTICIDE EXPOSURES

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Objectives: This is a study about need for health assessment technologies on site for pesticide poisoning cases among agricultural workers. Methods: The study was conducted among 212 vegetable growers in Benquet, Philippines. Methods included environmental sampling of pesticide exposures and biological sampling of blood cholinesterase. Findings: Results have shown that ninety four percent (94%) have worked with or used pesticides in their lifetime. The study showed that 66% of those who are highly exposed to pesticide are symptomatic of acute pesticide poisoning, and only 8% of those in low exposure group are symptomatic of acute pesticide poisoning. The relative risk of having an abnormal RBC Cholinesterase is 1.048. Blood cholinesterase instrument was used to determine the effect of absorbed dose of pesticide residues in the body. However, this presented several issues such as: subjects were hesitant to undergo blood extraction, the transport of blood sample from the community site to the hospital (it took two days, and sample may not be as fresh), and ethical issues. These issues were resolved by proposing the following: to get pesticide metabolites in urine rather than just blood cholinesterase, that sample preparation of the blood or urine sample be done on site prior to delivery to laboratory be done. As a result of this assessment, it was recommended that a new equipment be used for the assessment of urine sample, and that which can also determine many pesticide types. The technology currently used limited to just analysis of blood cholinesterase. Conclusion: The study has shown that there is indeed a relationship between exposure and pesticide poisoning which suggests the need for health assessment technologies related to pesticide poisoning. Also, socio-ethical analysis of health technologies be done to better serve our clients and researches. Key Words: health technology assessment, pesticide exposure

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M-166

801 – SYSTEMATIC OVERVIEW OF GENERAL HTA PROCEDURES AND SPECIFIC APPROACHES TO PERSONALIZED CANCER MEDICINE IN TEN COUNTRIES IN AMERICA, AUSTRALIA, ASIA, AND EUROPE

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Background: Meanwhile established in four continents of the world, health technology assessment (HTA) assists in ensuring sustainability of health care systems by providing decision support on adequate quantity and quality of health care. Along with this spread, variation in HTA methods guidelines and contextual characteristics was recognized lacking overview and standardization. In particular, early assessment of emerging technologies of the 21st century such as personalized cancer medicine challenges methodological and financial issues. Objectives: (1) To provide a systematic framework for describing and comparing HTA evaluation (2) to compare similarities and differences between agencies, and (3) to provide expert panels on early assessment of personalized cancer medicine with input. Methods: A conceptual evaluation framework covering the HTA life cycle was developed comprising eight domains, 93 items and 350 indicators. We enhanced our previous selection of only European HTA agencies from high income level countries (IQWiG, DAHTA@DIMDI, NICE, HAS, SBU) by AHRQ, MSAC, LBI, BIQG / GOEG, CADTH, DECIT-CGATS, HITAP. We entered information collected systematically into the database. Similarities and differences were compared within and interpreted across agencies quantitatively and qualitatively. Results: First five agencies differed highly in eight domains (organization scope, processes, methods, dissemination, decision, implementation, and impact). Disagreement in domains ranges from 60-83%. Enhancement by further agencies indicates continued heterogeneity. Regarding decision criteria, no cost-effectiveness threshold specific to personalized medicine and/or oncology was identified. Only UK considers exception rules for end-of-life-treatments. However, UK (US$32.000-48.000) and Thailand (US$3.283-9.852) indicated explicit but unspecific threshold ranges; four countries used implicit ones (Australia, Brazil, Sweden, USA). Conclusions: We developed a highly comprehensive, contextual framework displaying HTA in 10 countries of four continents from its organization to its impact. Specific guidance for innovative and costly cancer interventions is insufficient.

M-167

1006 – CROSSCULTURAL ADAPTATION OF AN ASSESSMENT INSTRUMENT FOR THE SUPPORT TO THE STRATEGIES IN PUBLIC HEALTH AND ENVIRONMENT IN BRAZIL

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The efforts for improving practices in Health-care Waste Management (HCWM) is a matter of worldwide concern where the technologies of systems management has been poorly employed. Therefore, in the present work it was aimed to carry out a crosscultural adaptation and validation of the WHO instrument Health-care waste management - Rapid assessment tool" (HCWM-RAT). Thanks to its transnational approach (presently available only in English and Russian), the instrument HCWM has the potential to play an important role on the development of the strategies in public health and environment in Brazil. The objective of the present work is to repport the strategies and preliminary results pertaining to the first four steps of the crosscultural adaptation process. The methodology includes; Translation by two independent translators; Synthesis of the translations; Back-translation by two other independent translators (native English speakers); acquisition of consensus by the Committee of Experts and Pretest the obtained version. Some terms were preserved from the original culture, because they are broadly used in the field of management in both countries, e.g., "stakeholders"; standardized HCW management terms according to Brazilian regulations; included regulated terms like "Temporary Storage (internal)" in the glossary; used technical references in the target country and public's culture for conceptual equivalence of terms without correspondence in Portuguese. It is discussed that the evaluation technology in Portuguese broaden the access to the Portuguese Speaking Countries (CPLP). The use of a crosscultural instrument that is consistent and validated may facilitate the improvement of the Health-care wastes management, allowing the sharing of the information and practices, constituting an innovator element, with a direct influence on the quality of the support to the decision taking in the local level, but also in the global level. Keywords – Health-care waste management; Assessment tool; Cross-cultural adaptation; Health technology assessment

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M-168

432 – REVIEWING THE EVIDENCE USED IN COST-EFFECTIVENESS MODELS IN HEALTH TECHNOLOGY ASSESSMENT: A QUALITATIVE INVESTIGATION OF CURRENT CONCERNS AND FUTURE RESEARCH PRIORITIES

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Background: Health technology assessments typically include a systematic review of clinical effectiveness evidence and a cost effectiveness model. The development of the model always requires additional information beyond costs and clinical efficacy. Depending on the timing, size and number of information requirements the researcher faces considerable difficulties ensuring that reviewing activity to inform model development is both timely and systematic. There is a tension in terms of the need to ensure that this process is both transparent and reproducible. While there has been research on searching for model parameters and issues have been highlighted in detail there appears to be very little guidance with regard to best practice in this area. This study reports the use of qualitative methods to identify these issues and to explore options for their resolution. Methods: A series of focus groups were held with experienced systematic reviewers, information specialists and cost effectiveness modellers. Framework analysis was used to analyse themes within the qualitative data. Results: Six key themes were identified including: problem structuring, current practice, adequate information, timing, ideal practice and areas for further research. Reviewing, searching and modelling were seen as integrated tasks and the respondents felt that the whole team should be involved in structuring the decision problem. Good communication was deemed to be essential with more time spent on the most important information requirements. Assessments of the quality and relevance of information were also considered important. Future research needs include training for focussed searching, problem structuring, quality assessment and the validation of parameter estimates. Conclusions: These preliminary investigations highlights numerous concerns and potential deficiencies in the process of identifying, selecting and using evidence to inform models. Further guidance is required to ensure that such research activity is transparent, timely and rigorous.

M-169
322 – WEBSITE FOR CRITICAL APPRAISAL: WWW.LECTURACRITICA.COM

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Despite a rapid growth in the provision of health information, the quality of the information remains variable. The critical appraisal of medical literature is a demanding process that requires epidemiological skills and careful reading of the selected evidence. Time consumption is one of the biggest problems when there is a deadline for decision. Related to these difficulties we decided to develop instruments in order to facilitate the critical appraisal process and the summary of scientific evidence. Therefore we carried out a systematic review to identify critical appraisal tools and articles about the criteria to be applied to critical appraisal. Afterwards a software application was designed and validated by an assessment of its "content and face validity". These critical appraisal tools have been updated and translated from Spanish into English. Furthermore, a Web platform has been developed containing 7 different instruments for critical appraisal depending on different study designs. Each instrument consists of a checklist divided into 10 domains, a glossary about epidemiological concepts and a menu to facilitate the correct answer of the items. The Web platform 2.0 has some very interesting features to facilitate the critical appraisal including: a guided process to complete the appraisals, criteria to evaluate some epidemiological designs that have a few instruments available, automatic generation of evidence tables meanwhile you can easily complete the evaluation, bilingual glossary of epidemiological terms, immediate access from any computer connected to internet, automatic updates of the version online, option to share your appraisals with other researchers, etc. Although several instruments for critical appraisal have been already published until now, www.lecturacritica.com is the first website to offer both appraisal of medical information and resources of the Web 2.0 to share our assessments and outcomes.

M-170
830 – IMPROVEMENTS OF INFORMATION MANAGEMENT IN HEALTH EDUCATION: A PATH FOR EVALUATION AND SUSTAINABILITY OF TECHNOLOGIES AND HEALTH PRACTICES

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Introduction: The creation and operation of the Virtual Health Sciences Education Library, EDUC_VHL in the context of the Virtual_ Health_Library, is sponsored by PAHO/WHO through its Latin American Center and Caribbean Health Sciences Information, BIREME/PAHO, and intends to create, strengthen and develop capacities and infrastructures for national scientific and technical information, promoting equitable access to relevant knowledge and up-to-date scientific evidence. The broader requirements to approach education in health sciences and of the professional training have led the Library and Documentation ivision - DBD/ São Paulo - University Medical School/FMUSP to coordinate and assume the EDUC_VHL's executive secretary. Objectives and methods: EDUC_VHL aims to promote efficient and effective use of scientific and technical information intended to support the activities, processes and decision making on this domain. EDUC_VHL is based on the information paradigm, where the user interacts with other users, networks and information sources, when performing the functions and activities for information production, intermediation, use and its communication. Thus, it brings diverse health sciences education stakeholder's together, contact and exchange between institutions, researchers, teachers and students and other professionals. The implementation of specific projects, targeted for different products and information services, is the main EDUC_VHL strategy, always using the LILACS_database. EDUC_VHL structure has embedded the management components: - of their own design and operation; - of content, construction and maintenance of its access portal; - of dissemination and marketing; - of the actors participating in the project and their interactions; - and of information technology, - as well as its infrastructure for hardware and software, installation and transfer. Expected Results: Although all the products and services are not yet available, expected results are: 1 - a common space for producers, mediators and users of information about Health Sciences Education, 2 - network of health scientific and technical information available at the internet in regular operation, 3 - information technologies in use by the users.

M-171

2 – UNIVERSAL PAIN QUANTIFICATION METHOD

Felipe Reitz, Icimmedics LTD., Brazil

The objective is to demonstrate the first universal pain quantification method. Following an extensive international literature search, the most appropriate components of current methods of assessment of physical and cognitive abilities have been incorporated into this method with appropriate modifications to suit the specific requirements of the individual. The initial part of the evaluation and quantification of pain assessment consists of standard case history-taking, principally focusing on the patient self-reported physical and cognitive abilities and disabilities as well as the completion of established pain and description scales, and relevant disability questionnaires. Following this physical and cognitive abilities history-taking the patient is objectively assessed utilizing Computerized Thermographic Imaging, weight scale, auricular thermometer, height measurement, blood pressure monitor and caliper. Specific standard motor function tests are also applied as an integral component of the assessment. All results are the subject to specific computerized analysis and compared to each variable in the model generating a significant number placed on a pain scale divided between mild, significant and severe. The designed system produces reliable, consistent and reproducible results. It also proves capable of deflecting any possible assessor bias. The Identification, evaluation and quantification of corporal pain is a multiple process of specific medical exams to improve the diagnosis of an individual presenting bodily pain alleging incapacity to perform physical movement in which would be normal in the majority of the population and/or pain when in an inactive state. This method can assess disability due to injury, reducing the number of individuals registering false claims and identifying the ones attempting fraud. It is also beneficial for contest allegations of the individual in question. It also is to serve as medical evidence in a future declaration of physical incapacity or abandonment of work and/or formation or worsening of pain during the fulfillment of the required

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M-172

749 – HEALTH TECHNOLOGY ASSESSMENT APPLIED TO MEDICAL DEVICES: WHAT MUST BE ASSESSED

Fernanda Gimenes, Medtronic Brasil, Brazil

Health technology assessment (HTA), comparing medical devices with established therapies, is often used by governments or private payers to aid decision making regarding the value of new technologies. A Medical Device can be defined as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that does not achieve its primary intended action in or on the human body solely by pharmacological, immunological or metabolic means. From 2006 to 2010, the Commission for Incorporation of New Technologies in Brazil (CITEC) adopted 60 new technologies, with only 7 classified as a Medical Device. The expertise with which HTA is applied to Drugs seems to be greater than that relating to devices. Methodological requirements must consider differences between medical devices and drugs. In order to evaluate the efficacy of certain types of devices and to account for certain clinical indications or settings, a broader source of evidence should be considered within HTA. Patient and/or investigator blinding is impractical or impossible for many medical devices and most surgical procedures. Observational studies, such as registries, should be considered relevant sources of data for HTA, as randomized clinical trials do not provide real life data and are not always technically or ethically feasible for devices. Medical devices have a shorter development time than pharmaceuticals and are quicker to become obsolete. The life cycle of a device is approximately 24-36 months and is incompatible with the current HTA cycle which may take up to 4 years for a robust assessment. HTA must recognize market dynamics in order to make an appropriate assessment of medical devices.

M-173

478 – HEALTH TECHNOLOGY ASSESSMENT: HOW TO CHOOSE THE BEST MEDICAL DECISION SUPPORT SYSTEM TO IMPLEMENT IN YOUR WARDS

Filippo Bartoccioni, San Camillo-Forlanini Hospital, Italy; Antonella Pugliese, San Camillo-Forlanini Hospital, Italy; Nello Donnini, San Camillo-Forlanini Hospital, Italy; Giordano Bruna, San Camillo-Forlanini Hospital, Italy; Ce Amoddeo, San Camillo-Forlanini Hospital, Italy

Objectives: The aim of this study is to define the best MDSS (Medical Decision Support System) to implement in the hospital optimizing the available resources. Materials and method: The analysis was conducted step by step and we evaluated also all the free available MDSS in the market. In order to make an objective and transparent choice, we defined several questions in which are summarized the main characteristics of the ideal MDSS. To assign specific weight to every single question we use a survey. The survey was answer by clinicians and other health professionals and helped us to choose the best MDSS for our everyday reality. To avoid bias we compare the engineers evaluation with the sales manager one, this permits also a feedback on consistency and reliability of the sales manager and on our evaluation team. To obtain the results we used the decision tree model, a classic and fundamental tool in the decisions analysis, because it permits to express the logical structure of decision-making process. The final weight was linked to the economical factors and price and finally we created a indexes chart to make the graphical comparison of results intuitive. Results: The HTA allowed us to explore all the possible MDSS, to identify the best choices available and to optimize and rationalize the investment.

M-174

480 – HEALTH TECHNOLOGY ASSESSMENT ON CARDIAC DIAGNOSTIC MARKERS: CLINICO-ECONOMICAL IMPACT

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Objective: The need of a fast and sure diagnosis in order to offer appropriate therapy to patients with chest pain and the changing in the guidelines recommendations induced S. Camillo-Forlanini Hospital in Rome to re-examine its cardiac markers prescription activity. The aim of this work is to evaluate the biochemical analysis prescription appropriateness. Material And Methods: We created a “dashboard”, where the guidelines recommendations are crossed with the clinical presentations. An inappropriate use is revealed by an elevated number of prescriptions associated with clinic presentation to which corresponds a low or null recommendation. We started an initial implementation of HTA in the First Aid removing the Myoglobin from the chest pain package and then we evaluated its clinical and economical impact and the we move to the cardiologic and cardiac surgery departments. Results: A statistical analysis revealed a significant decrease of Myoglobin request, but not for Troponin one. We calculated the odd ratio of the hospitalization among the admitted for chest pain in First Aid before and after the Myoglobin removal. The result, supported by a confidence interval, confirms the Null Hypotesis, that there is no association between our intervention and hospitalization rate. An economical analysis was then performed to evaluate the resources saving. Myoglobin dosage removal from chest pain prescription package without removing it from the allowed exams lead to a great decrease of inappropriate tests use. The estimation of one-year costs reduction is relevant. This becomes a mile stone for the implementation of the same intervention in other hospital units and it becomes the first step of new HTA interventions.

M-175

481 – HEALTH TECHNOLOGY ASSESSMENT: WHICH USEFUL TOOLS THE WEB 2.0 CAN OFFER YOU TODAY FREE OF CHARGE FOR YOUR MEDICAL ACTIVITY

Filippo Bartoccioni, San Camillo-Forlanini Hospital, Italy; Bruna Giordano, San Camillo-Forlanini Hospital, Italy; Antonella Pugliese, San Camillo-Forlanini Hospital, Italy; Nello Donnini, San Camillo-Forlanini Hospital, Italy; D. Pacchiarini, San Camillo-Forlanini Hospital, Italy; Ce Amoddeo, San Camillo-Forlanini Hospital, Italy

Objectives: The aim of this study is to offer a panoramic view of the most useful tools, apps (application), widgets and service available in the web today free of charge and how to implement them in your everyday working activity. Materials and method: Thanks to an deep technological research on the web and a constant updating on the news and innovation channels was possible to highlight the newest tools and services available free of charge. The multidisciplinary team verify and test every single tool, widget, application and service found. Thanks to the variety of equipment available in the team was possible to check also the compatibility with the most common operative system for personal computers and smartphone. The fields of interest include: social networks and how to use them in your daily practice, how to share your medical activity or lessons, tips to be updated on specific news and scientific literature, tools to create a web tv or use cloud computing, but also how to protect your privacy and which tools are dangerous and are not to be used. Results: The result is an complete update on the newest tools available and a short demonstration of them (a sort of “web 2.0 wetlab”) that will help physicians to increase their working performance using free tools.

M-176

680 – DECISION PROCESS MODEL TO THE HEALTH TECHNOLOGY INCORPORATION

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Aiming to assist in the challenge of the Health Technology (HT) incorporation process, we have designed a model to help gather indicators for the incorporation of medical devices that is based on three domains: Decision Making, Health Technology Assessment (HTA), and Health Technology Incorporation. In the decision making domain, a context is discussed in terms of analysis, synthesis and evaluation. The analysis consists of separating a whole into its consistent parts, synthesis and imagination are the inverse of analysis, that is, presenting or putting things together to form a whole. The evaluation process only comes into play in mental activities, such as the establishment of success criteria, performance evaluation, and people judging. The HTA domain corresponds to the choice and application of systematic tools and decision support, such as monitoring technological horizon, Fuzzy Logic and others. Finally, in the field of HT incorporation, three steps are presented: planning, preparing the proposal and reception, and installation. These three stages have multiple parameters to be evaluated, considering the need, impact, costs and benefits of the technology. Thus, the architecture of the model is formed by the relationship between the domains, where the domain of HT incorporation relates to the field of decision making and technology assessment, with multiple parameters and actors involved. As an application of the model we conducted a survey in the literature in search of evidence about the system of robotic surgery Da Vinci, where we only considered studies of high methodological rigor. From this research it was possible to identify the need and relevance of technology assessment focused on medical devices, in view of the contribution of the assessments to the health system. Furthermore, it is important to note the scarcity of HTA in the incorporation process directed to medical devices, where the model may encourage new studies.

M-177

939 – THE DECISION-MAKING PROCESS IN THE BRAZILIAN PUBLIC HEALTH SYSTEM – A RETROSPECTIVE OF DECIT´S ROLE

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The impact of Health Technology Assessment (HTA) on the health decision-making practice regarding the incorporation of health technologies into the health system has been discussed in many countries. In Brazil, the HTA area of the Department of Science and Technology (DECIT) at the Ministry of Health (MoH), since 2006, supports the Commission for Health Technology Incorporation (CITEC) of the MoH on decision-making regarding health technology reimbursement. CITEC is a permanent commission which analyzes requests for incorporating new technologies into the Brazilian Public Health System in line with social health needs. Objective: To analyze the profile of DECIT's HTA studies used to support CITEC's decisions from 2006 to 2010. Results: In this period CITEC requests 199 assessments. The majority of the requests (85%) are pharmacotherapy and the remainder (15%) are medical devices or vaccines. In total, 78% (157/199) of CITEC's technology demands were answered based on 148 studies that were done by DECIT´s team or University partners: 64 rapid response reports, 54 rapid HTAs, 21 systematic reviews, 3 budget impact studies, 4 economic analyses, 1 HTA bulletin and 1 Randomized Controlled Trial. Conclusion: These numbers show despite the HTA culture in Brazil were in the initial stage, DECIT is increasing its capacity to respond to CITEC's demands and improving the number of studies used as material to support the decision-making process.

M-178

523 – SORTEK-ZAHARTEK NETWORK: FROM INNOVATION TO DISUSE

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Health technologies (HT) have a natural life-cycle since they are innovation until their use is gradually replaced with substitutive ones. Objective: To detect new and emerging and obsolete HT and to interrelate them towards the same indication. To undertake a more proactive and coordinated detection and assessment of new HT, as well as remove those considered low added-value. Methods: We built a participatory network of health professionals (companies included) and generated a platform that comprises the technology life-cycle. Both professionals and companies have access to the software provided by SorTek-ZaharTek, and can identify both new technologies and the low added value technologies they replace. The identified technologies are evaluated by experts who generate assessment reports which are available to decision makers, professionals and companies. Results: Thirty-two technologies have been included in the database. There has been established a multidisciplinary team of technology identifiers (more than 160), which makes a more rational process of evaluation possible and offers decision makers a more up-to-date information about technologies used in our health system. The process has been evaluated positively by the industry (40 visits, 2010). A real-time technology management tool has been offered to professionals and managers which gives information concerning available evidence and status of each technology identified and evaluated. Conclusions: Sortek-Zahartek aims to increase the efficiency of the Basque health system and improve the implementation of innovation, impacting positively on health outcomes and reducing the impact of the know-do gap. It is necessary to introduce assessment systems that comprise the life cycle of technologies in a coordinated manner to be able to detect and make an initial assessment of those considered emerging HT, to observe and monitor their effectiveness in different clinical scenarios once they are introduced into the health system and, finally, identify and assess candidate technologies to be delisted.

M-179

880 - INCORPORATION OF MAMMOGRAPHY IN HEALTH FACILITIES UNDER THE DIRECT MANAGEMENT OF THE SECRETARY OF HEALTH OF THE STATE OF BAHIA, BRAZIL

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Breast cancer is the second frequent cancer in the world, and the most common among women. It is suggested that to succeed in reducing its mortality, the screening and diagnosis should be made by appropiate provision and use of mammography in health services distributed across the country. It is assumed that the adoption of criteria for incorporation of this technology in healthcare facilities is essential for this process. This study aims at identifying the criteria for the inclusion of mammography in health facilities under Health Care System (Sistema Único de Saúde - SUS) direct management by the Secretary of Health of the State of Bahia (SESAB), Brazil. The methodology of this research has basic, exploratory and qualitative nature. 80% of staff who participate directly in decision-making of this technology at the SESAB were interviewed obtaining the following results: In general, all criteria an sub-criteria used by decision makers are consistent with those used in the literature on technology assessment. Particularly, the criteria 'health regions' and 'health policies' showed a significant degree of determination in decision – making , especially in the state of Bahia, Brazil, to the detriment of the criteria already established by the evaluations of technologies health. The adoption of the model as a multi-criteria methodology for decision making for the incorporation of mammography in health services under the direct management SESAB provided a more accurate characterization of this process, since that from 11 criteria examined, almost 91% are essential to the process of incorporation of this technology.

M-180

681 – COST-EFFECTIVENESS ANALYSIS OF CASPOFUNGIN FOR EMPIRICAL TREATMENT OF CANDIDEMIA IN PATIENTS AFTER CARDIAC SURGERY

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Introduction: Candidemia is the fourth most common cause of bloodstream infection in tertiary hospitals in the U.S. and Brazil with similar results. The main risk factors for the development of candidemia are common complications in patients undergoing cardiac surgical procedures and include prolonged hospitalization, exposure to multiple invasive procedures, antibiotic therapy, among others. With difficult diagnosis and limited therapeutic options, the candidemia remains highly lethal and has been associated with increased length of stay and increased hospital costs. Adequate empirical antifungal therapy is still used in a minority of patients and criteria for its use in non-neutropenic patients remain poorly defined. Despite the proven efficacy, the cost of therapy with caspofungin doses and dosing regimens recommended by the IDSA is about 90 times higher than with fluconazole. Objective: To determine cost-effectiveness of caspofungin compared to fluconazole for empirical treatment of candidemia in patients after cardiac surgery, from the perspective of the Brasilian Public Healthcare System (SUS). Methods: Using a software constructed a decision analytic model (decision tree). Data entered into the model were obtained from the literature review. The model considers the mean direct cost of administering the drug, hospitalization and laboratory tests of SUS. The clinical outcomes used to evaluate the efficacy was death attributed to candidemia. We performed probabilistic sensitivity analysis to assess the robustness of the results.Results: Treatment costs attributed to caspofungin was R$ 117,578.86 and fluconazole was R$ 65,543.84. According to the Tornado Diagram made the biggest impact of variables in the model were likely to improve with fluconazole, given death improves with fluconazole, caspofungin and improves with death as no improvement with fluconazole. In the sensitivity analysis, simulations performed with modifications of these variables showed no significant influence on the initial result. Conclusion: fluconazole was more cost effective than caspofungin for empirical treatment of candidemia.

M-181

778 – COST-EFFECTIVENESS OF NUCLEOSIDE/NUCLEOTIDE ANALOGUES IN THE TREATMENT OF HBEAG-NEGATIVE CHRONIC HEPATITIS B: ADEFOVIR DIPIVOXIL, ENTECAVIR AND TELBIVUDINE

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Chronic Hepatitis B (CHB) is a serious public health problem that affects about 400 million people worldwide. This study aims to determine, from a perspective of the Brazilian Public Health System, the cost-effectiveness of treatment with adefovir dipivoxil (ADV), entecavir (ETV) and telbivudine (TBV) compared to already established treatment – lamivudine (LAM) in patients with HBeAg-negative CHB. A Markov model was developed to simulate a cohort, with time-horizon of 40 years, given that most of the patients in the cohort would be dead after this period. Costs and effectiveness were discounted at 5%. Annual rates of disease progression and efficacy of the drugs were obtained from literature. In the first 10 years, the cumulative incidence of compensated cirrhosis was lower for patients who were treated with ETV (26.38%) compared with TBV (26.70%), LAM (27.86%) and ADV (28.79%). There was less development of resistance to ETV (0.44%) compared to ADV (20.96%), TBV (22.37%) and LAM (27.51%). Treatment with ETV showed more life years (LY) (12.42) compared with TBV (12.31), LAM (12.07) and ADV (11.92). The cost-effectiveness ratio (CER) was lower in treatment with LAM (U$2,752.67/LY), followed by ETV (U$2,999.88/LY), TBV (U$4,028.81/LY) and ADV (U$4,126.18/LY). The incremental cost-effectiveness ratio (ICER) of ETV compared to LAM was U$11,559.37/LY, below the Brazilian cost-effectiveness threshold (three times the GDP per capita = U$ 28,629.07). Start treatment with ETV provided the best net benefit and the results of CER and ICER were more sensitive to the probabilities of progression to compensated cirrhosis. Thus, entecavir provides better cost-effectiveness compared to other drugs evaluated in the treatment of HBeAg-negative CHB.

M-182

475 – HOW TO VALUATE 'THE VALUE' OF MEDICAL DEVICES IN KOREA-VALUE APPRAISAL STANDARD 1 AND II

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Background: Pricing mechanism for medical devices has been evolving with the principle of appreciation of clinical and economic values. The 'Value Appraisal Standard (VAS) Ⅰ and Ⅱ' was invented as a tool to set premium prices on top of existing technology devices up to 50%. Objective: Introducing 'VAS Ⅰ and Ⅱ' and carrying out case study of using premium price granted by reimbursement authorities. Method: 1) Evaluation aspects of 'VAS Ⅰ' consist of procedural aspect, functional aspect, cost, patients' benefits and so on. Improvement level of each aspect is evaluated by 5 stages from 'no improvement' to 'maximum improvement'. With 'VAS Ⅰ' a device can pursue maximum of 10% premium price on top of existing technology devices. 2) Evaluation aspects of 'VAS Ⅱ' consist of therapeutic effects, cost effectiveness, and quality of life. Level of improvement of each aspect is also evaluated by 5 stages. There is designated point for each level of each aspect. Every level of each aspect has different points. Final premium percentage of a device is set by the band of aggregated points. With 'VAS Ⅱ' a device can pursue maximum 50% premium price on top of existing technology devices. Result: Only several products were granted premium price with VAS II. The examples of VAS benefits are Thoracic Stent-Graft System and Deep Brain Stimulation over the last one year. Considering the fact that more than 100 devices are listed in the reimbursement schedule on a monthly basis, the application of VAS is rarely granted. Conclusion: The 'VAS Ⅰ and Ⅱ' have balanced and universal perspective to evaluate value of medical devices. However, very few devices get the benefits this approach. Clear cut objectives and precise decision-making processes should be established to persuade the stakeholders to get to buy the idea - especially the clinicians and the industry.

M-183

805 – LAPAROSCOPY FOR THE MANAGEMENT OF ACUTE LOWER ABDOMINAL PAIN IN WOMEN OF CHILDBEARING AGE

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Background: Acute lower abdominal pain is common and making a diagnosis is particularly challenging in premenopausal woman as ovulation and menstruation symptoms overlap with the symptoms of appendicitis and pelvic infection. A management strategy involving early laparoscopy could potentially provide a more accurate diagnosis, earlier treatment and reduced risk of complications. Objective: To evaluate the effectiveness and harms of laparoscopy for the management of acute lower abdominal pain in women of childbearing age. Methodology: Search strategy: The Menstrual Disorders and Subfertility Group Specialised Register, Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, PsycINFO, LILACS and CINHAL were searched (to April 2010).Selection criteria: Randomised controlled trials (RCTs) that included women of childbearing age who presented with acute lower abdominal pain, nonspecific lower abdominal pain (NSLAP) or suspected appendicitis were included. Data from studies that met the inclusion criteria were independently extracted by two authors and the risk of bias assessed. Main results: Laparoscopy was compared with open appendicectomy in eight RCTs. Laparoscopy was associated with an increased rate of specific diagnoses (7 RCTs, 561 participants; OR 4.10, 95% CI 2.50 to 6.71; I2 18%), there was no evidence of reduced rate for any adverse event (8 RCTs, 623 participants; OR 0.46, 95% CI 0.19 to 1.10; I2 0%).Laparoscopic diagnosis versus a 'wait and see' strategy was investigated in four RCTs. There was a significant difference favouring laparoscopy in the rate of specific diagnoses (4 RCTs, 395 participants; OR 6.07, 95% CI 1.85 to 29.88; I2 79%), there was no evidence of a difference in the rates of adverse events (OR 0.87, 95% CI 0.45 to 1.67; I2 0%). Conclusions: The advantages of laparoscopy in women with NSLAP and suspected appendicitis include a higher rate of specific diagnoses being made, and a lower rate of removal of normal appendices

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M-184

813 – TECHNOLOGY ASSESSMENT OF E-HEALTH FOLLOWING A CRISIS: A FOCUS GROUP STUDY OF THE SICHUAN "5.12" EARTHQUAKE

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Objective: To understand the performance of health care delivery system in the settings following the Sichuan "5.12" Earthquake in 2008 occurred in a relatively underdeveloped area in China. Adopting a communication perspective, this study applies the diffusion of innovation theory to investigate how health care professionals diffused health technologies during the rescue and relief work. The lessons learned from China battle against earthquake could be very relevant for the preparedness of the emergency work of many of the world's earthquake-prone areas. Methods: The authors conducted three focus group sessions with the health professionals in Haikou, China involving in the rescue and relief work of the Sichuan "5.12" Earthquake in 2008. Questions regarding the diffusion of innovations were raised. Findings: The health professionals used cell phones to communicate, disseminated health knowledge to affected residents with pamphlets and posters, and attended daily meetings at the local government offices. They reported on the shortage of maritime satellite cell phones and large-size tents for medical use, and the absence of fully equipped ambulances. Volunteers, local health professionals and local officials facilitated their diffusion of health information and services in different ways. Conclusions: New communication devices like cell phones and the mobile Internet facilitated the coordination among professionals in the rescue and relief work after the disaster. In future, the mobile Internet could be used as a means to collect bottom-up disaster reports so that the media will not neglect any disaster areas as they did during the Sichuan Earthquake. This work would have been easier if medical teams had been equipped with advanced appliances like maritime satellite cell phones. 'Disaster medical services' should be treated as a separate discipline in medical schools and should receive more investment. A system for public health emergency response is needed for more efficient dispatch and coordination in future.

M-185

531 – ETHICAL PERSPECTIVE'S USE IN HTA AND EARLY AWARENESS AND ALERT SYSTEMS (EAAS)

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Aim: To map the capability of INAHTA and EuroScan members and the human and economic resources they dedicated to perform an ethical approach in HTA reports and EAAS. To describe and to analyse the ethical approaches used ain EAAS and HTA in real life by these agencies. Material and methods: A survey on these aspects, including questions on use, utility, ethical approach used and resources to commit the analysis, was designed and sent to INAHTA and EuroScan agencies (46 and 20 members, respectively). To analyse the existence and type of ethical approach used in EAAS and HTA reports, 100 documents from EuroScan and INAHTA databases were randomly selected and analyzed. Descriptive and comparative analysis among systems was performed. Results: The response rate among INAHTA members was 50% (26/50 including 4 not INAHTA member Latin American agencies?) and 100% (20/20) among EuroScan members. We showed statistically significant differences when comparing ethical analysis use in EAAS and by HTA agencies ($p<0.003$). The use was higher in the case of EAAS. Ethical analysis was performed in the identification and evaluation phases of EAAS and in the evaluation and external review processes of HTA documents. Principialism was the main ethical approach used in both EAAS and HTA, although utilitarianism and other ones, like personalism or axiological approaches, were also used. The main reasons why agencies did not perform ethical analysis were the lack of funds and the lack of funds and skilled personal (in EAAS and HTA agencies, respectively). Conclusion: The use of ethical approaches in HTA and EAAS is still low. The existence of agreed manuals or toolkits improves the ratios as it has happened in EAAS. The development of methodological tools to make and manage ethical analysis in HTA and EAAS could aid in the process.

M-186

586 – RECOMMENDATIONS FOR INCLUSION OF MEDICATIONS IN THE BENEFITS PLAN FROM CLINICAL PRACTICE GUIDELINES AND COST MINIMIZATION ANALYSIS

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This work is part of the process of review and updating the Plan of benefits in Colombia in 2006, in a context of finite resources and using the prioritization of activities, interventions and procedures more cost effectives and responding to the morbidity of the population. The analysis and approval of the proposals for inclusion of medicines and activities, was held by the CNSSS according to the recommended items in the Guide of Clinical Practice for the care of patients with Chronic Kidney Disease, adopted by MPS, which was made in consensus with all stakeholders in the health system, looking for the rational use of resources in clinical care, helping to reduce the variability of clinical practice and allow us to improve health outcomes for patients. Having in mind the difficulties to carry out an analysis of disease burden and DALYs, needed for cost-effectiveness analysis, was used the cost minimization analysis and cost benefit of interventions, such as type of economic analysis. The inclusion in the Plan of the medicaments Losartan, Minoxidil and Clonidine for hypertension management and care of nephrons, it develops a positive impact in all environments, in the case of Chronic Kidney Disease because it reduces the annual incidence of dialysis in patients with renal damage originated from Diabetes and Hypertension, and also reduce the events of cardiovascular and brain complications in these patients. It reduces the probability of admission to dialysis and minimizes the risk of other interventions for the patient, decreasing disabilities. Additionally it reduces significantly the costs of patient care by the delay of the dialysis demand by the patients and the costs of complications in patients with CKD. The inclusion of Sevelamer medicine helps the treatment of patients in dialysis when they have increased blood levels of phosphorus and calcium in malignant way.

M-187

914 – HTA –APPLICATION OF META-ANALYSIS AND MODELLING OF DIFFERENT TYPES OF VENTILATION

Ivana Jurickova, Czech Technical University - Faculty of Biomedical Engineering, Czech Republic; Juraj Borovsky, Czech Technical University - Faculty of Biomedical Engineering, Czech Republic

This poster explains part of HTA - application of meta-analysis and modelling of different types of ventilation, which is used in children. It also explains a new application of high-frequency ventilation using heliox. This high-frequency ventilation is in a clinical study. Meta-analysis includes basic steps - specifying, identifying the problem and criteria – and than a statistical analysis combining all examined types of vetilation. Modelling comprehends a Markov model and a Monte Carlo simulation.

M-188

651 – RESULTS OF TWO SYSTEMATIC REVIEW OF METHODS FOR META-ANALYSIS AND INDIRECT COMPARISON USED IN EXISTING SYSTEMATIC REVIEWS OR POTENTIALLY AVAILABLE TO USE IN SYSTEMATIC REVIEWS

Mateusz Nikodem, Caspolska, Poland; Kamil Siedmiogrodzki, Caspolska, Poland; Anna Zapalska, Arcana Institute, Poland; Ewa Borowiack, Arcana Institute, Poland; Monika Kowalska, Arcana Institute, Poland; Jacek Walczak, Arcana Institute, Poland

Objectives: The aim of this systematic review was to gather basic information about frequency of use the particular statistical methods for meta-analyses and indirect comparisons in existing systematic reviews and HTA reports. Results of this review was then confronted with outcomes of second eBayesMet review (Statistical methods potentially available to use in systematic reviews). In consequence we were able to verify the hypothesis that there are some reliable methods which are hardly ever used in HTA reports. Methods: Database of Reviews of Effectiveness was searched for relevant reviews published between January 2009 and March 2010. Databases such as MathSciNet, Medline and Cochrane Methodology Group resources, textbooks, guidelines for preparing systematic reviews were searched in order to identify methods potentially available to use. Results: Nine main statistical methods were identified during systematic review: five methods for direct comparison: DerSimonian-Laird, Inverse Variance, Mantel-Haenszel, Peto and Bayesian approach, and four methods of indirect comparison: Bűcher, Minimal Squares, Lumley, Bayesian Mixed Treatment Comparison. The most popular methods for direct comparison was Mantel-Haenszel (36%) in case of fixed models and DerSimonian Laird (38%) for random models. Employing Bayesian methods was very rare (1%). The most commonly used methods for indirect comparison was MTC Bayesian Model (53%). Conclusions: Bayesian models have advantage over other type of statistical methods: give us possibility to include additional information as a prior knowledge. However performed analysis showed that Bayesian approach is marginal methods for performing statistical analysis.

M-189

674 – CHOOSING AN OPTIMAL METHOD OF ANALYSIS DEPENDING ON DATA YOU HAVE. MOST CREDIBLE AND PRECISE META-ANALYTICAL METHODS OF DIRECT AND INDIRECT COMPARISONS - GUIDELINES

Mateusz Nokodem, Caspolska, Poland; Kamil Siedmiogrodzki, Caspolska, Poland; Anna Zapalska, Arcana Institute, Poland; Ewa Borowiack, Arcana Institute, Poland; Monika Kowalska, Arcana Institute, Poland; Jacek Walczak, Arcana Institute, Poland

Objectives: The main aim of guidelines is to make analysts aware of multiplicity of statistical methods for meta-analysis and to show them, that the most popular method is not always the best way to get answer for given question. We want to highlight the problem of choosing proper methods for meta-analysis of dichotomous data, depending on held data, and give a clue, how to do it correctly. The second aim of these guidelines is to show possibility of using indirect evidences and observational studies. Methods: Preparing the guidelines was one of the deliverables in project EBayesMet. Following analysis, prepared during first part of the project, was used as source of data in preparing guidelines: "Systematic review of statistical methods of meta-analysis and indirect comparison potentially available to use in systematic" and "Analysis of credibility of statistical methods". Target groups of guide will be reviewers with experience in preparing systematic reviews. Results: In first part of guide, general schema of conducting meta-analysis with classical and innovative Bayesian approach was prepared. Thanks analysis of credibility of all identified statistical methods we were able to present general suggestions, which methods work well with given data sets. All selected statistical methods for direct comparison was investigated on 6 different data sets and 124 cases depending on event rates. Methods for indirect comparison were examined on 80 different cases depending on event rate and on ORs in each arm of comparison. All methods for indirect comparison, as in case of direct comparison, were divided on suggested and dissuaded methods and presented in graphs. Conclusions: In spite of many existing guidelines on the preparation of systematic reviews, there is a lack of complex statistical guide on choosing an appropriate statistical technique for "head-to-head" or an indirect comparison. Our user-friendly guide will make statistical procedures more rational.

M-190

506 – APPROACH TO A MODEL FOR ANALYSIS OF DIAGNOSTIC TECHNOLOGIES IN EVERY PHASE OF THEIR LIFE CYCLE SUPPORTED ON MANAGEMENT PROCESS SYSTEM

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The design of an approach to model that aims to the performance analysis of diagnostic technologies in every phase of their life cycle inside a health institution is presented. The characterization of the life cycle phases and the description of the processes related to technology management, allowed to identify different parameters for assess use, maintenance, financial resources and impact of the medical technology inside the clinical service. The integration of these parameters into a model provides an estimation of the current state of the technology, the estimation of the years of optimal use within the institution and the necessary information to propose an appropriate replacement. The model used uses a discrete-time Markov chain; by defining different endpoints and obtaining the corresponding transition probabilities between states, it establishes the functional status of the technology and a prediction of the time that the equipment remains in each period. The Clinical, financial and technological Information of the diagnostic equipment analyzed was obtained from the application of a series of surveys to four institutions belonging to the health systems of Mexico and Colombia. As a first iteration of the model 11 conventional X-ray and 4 tomography units were considered. The results of the model show a strong correlation with the current status of the equipment installed in the radiology services surveyed. Since the information obtained by the model is documented and organized, it can be considered reliable, in other words, it not dependent on a subjective point of view and timely because it has the elements required in advance contending with situations resulting from use of technology. Also the system provides the necessary tools to support technology management processes, as well as decisions-making-, the optimal location of the financial resources and development of strategies for the medical technology replacement process in the hospital.

M-191

517 – EVALUATION PROCEDURE OF INTUBATION OROTRACHEAL AMONG MEDICAL PROFESSIONAL

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Introduction: intubation is a procedure that must be performed by qualified medical staff,for a period less than 20 seconds at National Neonatal Resususcitation Program os the Brazilian Society of Pediatrics.Objective:analyze a sequence of items in a orotracheal intubations in a university hospital.Methodology:questionnaire in relation to patient procedure time,number of attempts and uneventful to finish the procedure.Results:nanlyzed 24 IOT procedures in patients with average of 15 days of life, gestacional age 32 2/7w,weigth 1430g,66,7%male and 33,3% female.The procedure was performed at 54,2% of cases successfully on the first try, 25% in th second attempt, on the third attempt 8,3% and 4,2% more than 3 attempts.Time spent:<20seconds at 62,5% cases, 20-30 s in 18,3% cases. Regarding failures intubation in the first attempt the causes described were: secretion 33,3%, esophageal intubation 16,7%, 11,1% lamp erased. Conclusion:the IOT must be a procedure with constant training and we need greater attention in orotracheal material by intubatio (lamp), because both are avidable with the continuing education.

M-192

457 – HAZARD ANALYSIS AND CRITICAL CONTROL POINTS APPLIED TO MAMMOGRAPHY FOR QUALITY CONTROL

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Breast cancer has become a major problem in healthcare; Latin America has double the number of cases when compared to developed countries. There are several problems associated to the disease and its treatment: one is related to the detection and the other to the diagnostic procedure. Although at present there are different types of breast cancer diagnostic imaging modalities like magnetic resonance imaging or ultrasound, mammography remains as the mostly used due to its practical application. In order to identify the most recurrent failures in the clinical procedure, a risk analysis of the breast cancer diagnosis by mammography was carried out; the hazard analysis and critical control points (HACCP) scheme was used. By observing different types of clinical facilities in Mexico City, a description of the generic procedure was implemented; then a classification of the risk types associated to the procedure and the appliance of the HACCP process to the mastography was accomplished. With the obtained information, the set of critical control points was selected and a method for their assessment as well as control measures was proposed. The risk classes under consideration were clinical, technical, radiological and others; for each of these, a severity number was assigned ranging from negligible to critical according to the damage caused to the patient. As a result from these analyses, critical control points were determined on the patient preparation procedure, the critical clinical risks on the standard exposition techniques were defined and the technical control points that lead to possible artifacts in the image and misdiagnosis were extracted. This technique is suitable to be used in these kinds of processes in order to carry out a quality program to be implemented on the clinical facilities.

M-193

544 – A PROPOSAL OF A REFERENCE MODEL FOR THE ASSESSMENT OF CONTENT-BASED MEDICAL IMAGE RETRIEVAL SYSTEMS FOCUSED ON COMPUTER-AIDED DIAGNOSIS APPLICATIONS

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GOAL: This paper presents a reference model for the assessment of CBMIR (Content-Based Medical Image Retrieval) systems. The model evaluates in a systematic and planned way CBMIR systems that support the clinical diagnosis. In this paper the case study addressed mammography images. METHODS: The proposed model is characterized by empirical and heuristic methods towards the real needs of a CAD (Computer-Aided Diagnosis). The model was applied to CBMIR systems that must be evaluated by a series of tests and controlled diagnostic tasks performed by specialists. The tests are based on three way of assessment: BI-RADS classification – which certifies the conformity between the diagnoses of images; Performance – which assesses the performance based on similarity assessment methods; and CAD – which assesses the system from the perspective of a computer-based aid to diagnosis, taking as reference the physicians diagnostic. Quantitative evaluation is based on specificity, sensitivity and ROC curves measurements. RESULTS: Results are shown in UML activity diagrams and detailed descriptions of the activities. The main diagram is composed of: 1 - Define the database, 2 – Define the search image sample, 3 - Re-validate BI-RADS classification, 4 – Assess CBMIR performance, 5 - Assess the CBIR system as CAD, 6 and 7 - Analyze the classification and intra and inter observer certainty degrees. Each activity brings work flow actions and descriptions. CONCLUSIONS: A model for the assessment of CBMIR systems as CAD tool was proposed. It has the potential to contribute to a development of a systematic process for quality improvement. Mandatories, but often non-implemented, requirements for clinical routine usability were collected, as well as requirements that are often implemented incorrectly. Based on those it is possible to suggest improvements through a reverse engineering process towards an ideal model.

M-194

720 – TRACEABILITY OF BLOOD COMPONENTS: IMPROVING PATIENT SAFETY

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Safety and quality of patient assistance that receive blood components should be guaranteed in all steps from the moment of blood sample collection until administration by the nursing staff. In this context, new technologies applied to blood components traceability may be useful. The aim of this study was to describe the electronic system to trace blood components used in the surgical intensive care unity of a cardiopulmonary specialized hospital. The electronic system was developed in accordance to the Brazilian legislation and implemented in 2010. The process begins with the medical order of blood components transfusion that enables the functionality of printing labels with a specific identification number. Blood samples for typing are collected, then identified with labels, and sent to the blood bank. When blood components are available for transfusion, two members of the nursing team proceed with the verification of information in the label of the blood components bag and its content. Afterwards, a mobile computer at bedside is used, and an electronic check is done between the label of blood components bag and the patient identification bracelet. If the system recognizes that both match, the process of transfusion begins, and the electronic system registers the initial moment. During transfusion, any event is registered too. At the end of the transfusion, the nurse registers the end of the process in the electronic system. If the patient needs to receive more than one blood component, this process is repeated to each one. The development of the electronic system for traceability of blood components guarantees safety for both patient and nursing staff. Besides traceability, the whole process is performed at bedside, and information on blood sample, blood components and donor may be rapidly accessed by health professionals.

M-195

913 – EVALUATION OF BIOELECTRICAL IMPEDANCE TO REDUCE MORTALITY IN PATIENTS WITH HEART FAILURE

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Heart failure (HF) is a syndrome resulting from a structural or functional cardiac disorder. The diagnosis is made when the patient has breathlessness, effort intolerance or fluid retention together with objective evidence of cardiac dysfunction. HF is associated with poor prognosis and poor quality of life for patients, and responsible for high health-care costs. The survival of HF with clinical treatment is estimated to be at 84% (1 year), 63% (2 years) and 52% (5 years). Hospitalization is a common event in HF and readmissions occur more frequently in the later stages of the disease. The bioelectrical impedance analysis (BIA) is a noninvasive and painless system of body composition assessment that has indications in various clinical situations including HF. The main objective of this study was to evaluate the use of BIA as a technology to reduce the mortality and length of hospitalization in patients with HF compared with echocardiography, clinical treatment or other technology. The search strategy was used for patients with HF assessed by BIA and echocardiography or other technology. We selected randomized controlled trials (RCT), since there were no systematic reviews (SR) in the searches performed. After the search, one RCT was analyzed and concluded that BIA did not substitute the pulmonary artery pressure (PAP) as a guide for clinical prognosis for HF hospitalized patients. The use of the BIA showed moderate correlation with the PAP in the evaluation of cardiac output (r = 0.4 - 0.6). The BIA did not correlate with the outcome death or readmission to hospital within six months after randomization. Further studies may evaluate the possible use of this technology in outpatients presenting less severe HF.

M-196

295 – TEACHING HOSPITALS IN SÃO PAULO STATE: SIX-YEAR FOLLOW-UP

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Abstract: In 2004, the certification and agreement process of teaching hospitals began in Brazil, guided by the Ministries of Health, Education, Science & technology and Planning, Budgeting and Management. The Interinstitutional Commission was created with the participation of the mentioned Ministers and entities representing hospitals and other entities related to assistance, research and teaching started to follow up those units, as the Health Secretary of São Paulo State created the Assessor for monitoring teaching hospitals from the Office of Health Secretary of State. Monitoring of hospitals was made by direct contact with the units, the use of DATASUS, and the creation of Teaching Hospital Evaluation System (SAHE), which includes the information for a complete analysis of production, productivity, quality and financial aspects of their activities. The whole process has been extensively documented since its beggining in periodicals, seminars, meetings, and lecturers. These events have provided integration among managers, administrators and professionals, with positive results for the management of units and quality of services to the community.

M-198

633 – LEGAL AND ETHICAL ASPECTS OF IMPLEMENTING HEALTH TECHNOLOGY ASSESSMENT IN THE REPUBLIC OF KAZAKHSTAN

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In Kazakhstan, the Government has annually increased budgetary resources allocated to the healthcare sector. Thus, in the period from 2004 to 2009, funding for a guaranteed volume of medical care rose from 90.5 to 273.1 billion KZT. The MoH of the Republic of Kazakhstan, hospital managers and doctors in their work are faced with choosing between alternative medical technologies in the medical services provision. Such decisions require careful analysis of existing data and demonstrate the need for a systematic, objective and transparent assessment methodology. In this regard, the Government attaches great importance to the development of health technology assessment (HTA), which is reflected in the State Program for Health Development. The first steps to implement the country is process of HTA begin with adoption of the Rules for application new methods of diagnosis, treatment and medical rehabilitation by MoH of the Republic of Kazakhstan in 2009. At this stage of the process is still not worked out the organizational arrangements that govern the process of HTA. With a weak update of a HTA's procedural status, a number of problems managing funding arrangements for HTA. Therefore, with the advent of a country is health system a mechanism for HTA, need to realize the following implementation stages: first - to regulate the procedure for HTA, and secondly - to develop mechanisms for financing procedures for HTA through existing legislation, and thirdly - develop effective processes to effectively identify and manage conflicts of interest at different levels of HTA. These problems must be solved in order to effectively conduct the process of HTA. There is a need for clear regulatory approaches and mechanisms of OMT. And the results should be used by managers of health decision-making aimed at improving the quality of diagnosis and treatment of diseases.

M-199

59 – COORDINATOR'S WORK IN PRIMARY HEALTH CARE AND THE INFORMATION SYSTEM OF BASIC ATENCTION

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Object: The objective of the present study was to analyze the use of the information system named Information System of Basic Attention/SIAB, by the coordinators of Primary Health Care in the city of Ribeirao Preto, Brazil, to understand the decision making process. It is a descriptive and exploratory study, with qualitative approach of the data. Method: For data collection, it was used semi-structured interviews with 08 coordinators of Primary Health Care, with questions concerning the purpose of this information system, situation in that is used and the database input, proceeding with the analysis of content. Results: In the analysis of the vision of the work of coordinator in the management of primary was considered that the engineers have different perceptions of this system information as a management tool. Conclusion: These conceptions influence directly from the local planning processes that contribute to distinct are introduced in this sphere of planning.

M-200

60 – THE RELATION BETWEEN THE USE OF INFORMATION SYSTEM OF BASIC ATTENTION FOR TEAM FAMILY HEALTH AND THE COORDINATION OF THE PRIMARY HEALTH CARE

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Objetcive: It was purposed to analyze the relation between the use of information system of basic attention for team family health and the coordination of the primary health care in the Ribeirão Preto/SP. Methods: This study is descriptive and exploratory with qualitative approach of dates. It was applied semi-structured interview with 08 coordinators, following questions relating to used and feeding the database, according to the method of thematic analysis. Results: It was identified how there is low utilization of the information system for team, with the included of unskilled workers; high staff turnover and there isn't training and actualization of team family health for to qualify the use of the information system, help with low trustworthy of the dates, reinforcing the education dimension of working of coordinators. Conclusion: This conceptions straight influences in the local planning, contributing to different processes are introduced in this sphere of planning

M-201

337 – INTRODUCING SOCIETY INTO THE HTA FIELD: A BRAZILIAN EXPERIENCE

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Introduction: Wounds have diverse etiologies and the technology proposed for this study presents a broad range of indications, therefore it is difficult to find epidemiological data for all types of wounds. Many wounds are difficult to heal, despite adequate medical and nursing care. They may result from complications from diabetes, or from surgery, constant pressure, trauma or burns. Acute and chronic wounds affect at least 1% of the population. V.A.C. therapy (Vacuum Assisted Closure) consists of Negative Pressure Wound Therapy (NPWT) (measured in mmHg) to accelerate wound healing, thus making it an aid in healing of wounds. Methods: In order to produce a synthesis using the best evidence currently available on the efficacy and safety of V.A.C. in the closure of chronic and acute wounds, an extensive search was conducted using Medline (via Pubmed), The Cochrane Library, Tripdatabase, The Centre for Reviews and Dissemination (CRD), and The National Institute for Clinical Excellence (NICE). The aim was to find systematic reviews or, failing such, randomized controlled trials, which are considered the highest quality of scientific evidence. Results: Two systematic reviews were located and the methodological quality of these studies, in spite of their limitations (small sample size, inadequate methods of randomization, large confidence intervals, mostly unproven patient eligibility criteria and characteristics), was adequate. Conclusion: A promising aid in the treatment of chronic wounds using NPWT does exist, but due to the poor quality of the publications available, more randomized clinical trials should be conducted to confirm such potential. Additionally, there are few studies on its clinical efficacy when treating acute wounds. An implementation of a Brazilian cost-effectiveness study on the different types of wounds is also recommended to compare NPWT with a specific standard therapy, be it conventional or modern, in order to define its role in the treatment of wounds.

M-202

501 – RELIABILITY AND ACCURACY OF THE SCREENING FOR ADVERSE EVENTS IN BRAZILIAN HOSPITALS

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Objective: To analyze the reliability and accuracy of the screening for adverse events (AEs) in a study conducted in three hospitals in the city of Rio de Janeiro, Brazil. Methods: A subsample of 242 medical records was randomly selected from an original sample of 1,103 previously evaluated records. Screening for AEs in the base study was performed by nurses, using screening criteria. The subsample was reviewed by internal medicine residents. The kappa coefficient and simple percentage agreement were obtained for reliability analysis. The accuracy of AE screening by nurses was calculated taking the assessment by residents as reference. The positive predictive value (PPV) of the AE screening by residents and nurses was also calculated taking the assessment performed by physicians in the base study as reference. Results: Total agreement (across all participating hospitals) between physicians and nurses on the presence of screening criteria was moderate (78.9%, K = 0.55). Specificity (81.6%) was higher than sensitivity (74.4%), and the predictive values reflected differences in prevalence among hospitals (PPV = 70.5%, NPV = 84.4%). Nurses detected more cases meeting at least one screening criterion than physicians (39.3% vs. 37.2%, respectively) and also detected more screening criteria that were later confirmed as true AEs (179 vs. 171, respectively). Conclusion: Agreement between residents and nurses in AE screening was considered satisfactory. AE screening by nurses was more specific, as physicians detected a higher number of false-negatives. Nurses also detected more screening criteria per case and were considered the most appropriate reviewers for AE screening.

M-203

726 – EVALUATING THE IMPACT OF A HOME CARE PROGRAM, SÃO PAULO, BRAZIL

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Introduction: In spite of the population ageing and the increase in chronic disease prevalence, Brazil has presenting since 1999 a decreasing number of hospitals, especially in the private sector, which lead to the reduction of 11.214 hospital beds between 2005 and 2009. Currently, the country's number of hospital beds per 1000 people is 2.3, not reaching the Ministry of Health standard between 2.5 and 3. Home Care has been considered as an alternative for this scenario by continuing the care after hospital discharge or avoiding hospitalization with infusion or physical therapy realized at home. Objectives: Evaluate the number of inpatient hospital days avoided by a home care program of a health insurance company in São Paulo, Brazil, in 2010. Methods: All the admissions between January and December of 2010 were recorded. Patients admitted with the care plan of 24 hour assistance with mechanical ventilation (24H MV), 24 hour assistance without mechanical ventilation (24H), 12 hour assistance (12H), antimicrobial infusion therapy (ATM) and grade IV pressure ulcer (PU) were considered to be hospitalized if not in home care and therefore had their days in the program accounted. For ATM we considered the period requested at the hospital discharge and for 24H MV, 24H, 12H and PU the period from the date of admission to the date of discharge, death, rehospitalization or the date of the end of the study. Results: 1.994(64.6%) admissions accounted, 98(4.9%) 24H MV, 301(15.1%) 24H, 111(5,6%) 12H, 1.411(70,8%) ATM and 73(3.7%) PU. There were 6.016(9%) inpatient hospital days avoided by 24H MV, 26.203(38%) by 24H, 11.044(16%) by 12H, 19.237(28%) by ATM and 6.263(9%) by PU, totalizing 68.763 days. Conclusion: Home Care can contribute as an alternative for the actual scenario.

M-204

734 – EVALUATING THE OUTPATIENT PARENTERAL ANTIMICROBIAL THERAPY SERVICE OF A HOME CARE PROGRAM, SÃO PAULO, BRAZIL

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Introduction: Since its introduction in the 1970s, outpatient parenteral antimicrobial therapy (OPAT) has been growing fueled by the availability of antibiotics that can be administered once or twice daily, technological advances in vascular access and infusion devices, increased acceptance by both patients and physicians, and the increasing availability of structured services. It has been shown to be safe, efficacious, practical, and cost-effective. For patients it is a more productive and comfortable alternative, allowing many of them to return to their daily activities during treatment. Objective: Evaluate the outpatient parenteral antimicrobial therapy service of a home care program of a health insurance company in São Paulo, Brazil, in 2010. Methods: All the admissions between January and December of 2010 were recorded. Patients admitted with the care plan of antimicrobial infusion therapy (ATM) were evaluated regarding their site of referral (hospital or residence), antimicrobial prescribed and period of treatment requested. Results: 44,9% (1.388) of the home care admissions were ATM, 94.8% (1.317) referred from hospital, 4.4% (61) from residence and 0,8% (10) from other. Regarding the antimicrobial therapy, 85% (1.178) were classified as monotherapy, 14.7% (205) association of two drugs and 0.3% (5) association of three drugs. The antimicrobials prescribed were 35% (605) ceftriaxone, 9% (149) vancomycin, 9% (141) piperacilin sodium/tazobactam sodium, 9% (140) teicoplanin, 8% (124) cefepime, (7%) 118 meropenem, 4%(69) ertapenem, 3% (55) imipenem-cilastatin, 2% (31) amikacin, 2% (31) clindamycin, 1% (22) ciprofloxacin, 1% (20) ceftazidime, 1% (15) linezolid, 1% (11) ganciclovir, 1% (10) metronidazole, 1% (9) clarithromycin and 3% (52) other. The mean period of treatment requested was 13,8 days (95%CI 12,5-15,0). Conclusion: In this study, the majority of the outpatient parenteral antimicrobial therapy request came from hospitals. The most frequently prescribed antimicrobial was ceftriaxone, followed by vancomycin and piperacilin sodium/tazobactam and the mean period of treatment was 13,8 days.

M-205

864 – FACTORS RELATED TO THE ORGANIZATION OF THE HEALTH SERVICES THAT DELAY THE DIAGNOSTIC OF TUBERCULOSIS

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This study aimed to analyze the discourse of the managers about the factors that influence in the delay of the tuberculosis in the city of João Pessoa-PB. It is a qualitative research, which had its empiric material built through interviews performed with 16 matrix supporters. The analysis of the empiric material gave up from the use of the technique of Analysis of the Speech of the French line. With the analysis the discourse formation was obtained “Factors related to the organization of the services that delay the diagnostic of the Tuberculosis”. The factors presented by the managers related to the users and the services of health. About the users refer the stigmatization of the disease, the resistance looking for service and the lack of knowledge about the TB. Regarding to the services of health it is observed the lack of qualified professionals for the early detection and diagnostic of the cases and structural questions, principally, conducting exams. It is perceived in the discourses that the actions and services that aim the guarantee of the Access and of the care to the Tuberculosis patient, it is shown relegated to a second plan, either by the incipient articulation between the theory and the practice or by the opacity of the discourse in the incomprehension, on what rules the municipal policy of health about the theoretical concept of the Social Determination of the Disease. In this sense it is necessary that the managers incorporate in their practices concepts such as health surveillance, co-management and humanization, which are fundamental for the (re)organization of effective services in the control of the TB.

M-206

166 – IMPLEMENTING A PAY FOR PERFORMANCE PROGRAM FOR GERIATRIC AMBULATORY CARE: PRELIMINARY RESULTS IN HEALTH SERVICES UTILIZATION

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Introduction: Population aging is critically contributing to transform chronic diseases in a major public health problem. In Brazil, 11% of the population is constituted of individuals with 60 years of age or more. This number is continually increasing and poses significant challenges to primary care providers and healthcare policy makers. The aim of this study is to measure the utilization of health care services after the implementation of a pay for performance (P4P) geriatric care program. Methodology: This cross-sectional study included 4626 patients over 60 years of age living in Belo Horizonte, Brazil. All patients had at least 6 month of follow up in our P4P program which consisted of a comprehensive geriatric evaluation, followed by a care plan tailored to the patient´s risks factors, geriatric comorbidities and clinical needs. Multidisciplinary health care professionals and telehealth monitoring teams were trained to encourage prevention and proper follow up. Each patient was referred to a single physician to avoid fragmentation of care. The main outcome was the number of emergency room visits, number of hospitalizations and number of outpatient physician visits, 6 months before and after the inclusion of the patients to the program. Results: We observed a decrease in emergency room (32.62%) and outpatient physician visits (34.23%). Nevertheless, an increase in hospitalizations (10.78%) after 6 months ocurred. Conclusions: We observed a reduction in emergency room and outpatient physician visits and an increase in hospitalizations after the implementation of our P4P program. Further investigations are needed to answer whether these results are linked to better outcomes in morbidity, mortality and quality of life for patients.

M-207

186 – REDESIGNING MENTAL HEALTH CARE: PRELIMINARY RESULTS OF A PAY FOR PERFORMANCE PSYCHIATRIC PROGRAM ON SERVICES UTILIZATION

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Introduction: About 12% of the Brazilian population need mental health support due to depression or other common psychiatric disorders, such as alcohol-abuse and psychoses. In this concerning scenario, new forms of mental health care delivery and medical reimbursement are necessary. The aim of this study is to measure the utilization of health care services after the implementation of a pay for performance (P4P) mental health program directed to psychiatrists. Methods: Psychiatrists were invited to register their patients with severe mood disorders, schizophrenia or delusional disorders in an electronic web based system. Physicians received extra-fees (33% more than usual fees) for the visits of their registered patients. It was also allowed a more frequent follow-up (up to ten visits in 60 days, twice a year) during eventual exacerbation periods. We compared outpatient physician visits, hospitalizations and emergency room admissions six-month before and after the inclusion of patients in the program. Results: From March 2009 to July 2010, 1161 patients were included (953 with severe mood disorders and 208 with schizophrenia/delusional disorders). Women predominated in the mood disorders group (70%). There was no difference in gender distribution for schizophrenia/delusional disorders group. After six month of implementation of the P4P mental health program, outpatient physician visits increased 15%. Otherwise, hospital admissions reduced 37.5% and there was a 5.14 fold reduction in emergency room visits. Conclusions: We observed a decrease in hospitalizations and emergency room visits six month after the implementation of the P4P mental health program, and an increase in outpatient physician visits. This study enforced the importance of designing adequate policies and medical payment models, including mental disorders, in order to avoid inefficient and fragmented psychiatric care.

M-208

648 – BRAZILIAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT (REBRATS): PROGRESS AND LESSONS LEARNED

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Objectives: The Brazilian Network for Health Technology Assessment (REBRATS) was implemented just over two years ago and it aims to promote and promulgate the HTA area in Brazil. The aim of this study was to analyze the progress achieved over two years of REBRATS implementation. Methods: We analyzed the products developed by the five REBRATS Working Groups, using as the parameter their expected results and the goal of expanding the network as stipulated in the qualification plan for managing the Unified Health System. Results: Of the planned actions developed by the Working Groups, the most prominent were: 1) Methodological Development and Evaluation - Revision of the guidelines for HTA and economic assessment; Development of the guidelines for budgetary impact analysis; Implementation of the assessment flow of studies registered in the REBRATS system; 2) Continuing Education and Professional Training – Financing for the implementation of 24 Health Technology Assessment Centers in teaching hospitals; 3) Horizon Scanning – Development of the guidelines for horizon scanning; Pilot program to monitor new technologies; 4) Research Prioritization and Promotion - Monitoring studies about Health Technology Assessment financed by the Ministry of Health; Competitive research bids. 5) Information and Communications Management – 246 studies registered in the REBRATS system: 24 Rapid HTA; 104 Systematic Reviews, 37 Economic Evaluations; 42 Management Studies; and 17 other studies in HTA. Regarding network expansion, the amount has been extended from 7 to 44 member institutions. Conclusion: Given the intention of REBRATS to establish link between research, policy-making and management in Health Technology Assessment field, several important actions were taken to advance the network, of which the following are worth noting: increased member institutions; methodological standardization; and the dissemination of HTA studies. Challenges to be faced are: 1) Sustainability – the need for continued funding and engagement of members; 2) Link

M-209

667 – HAS POSITION ON FIXED-DOSE COMBINATIONS (FDC): COMPARISON OF ORAL ANTIDIABETICS AND ANTIHYPERTENSIVES

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Background: The Transparency Committee (TC) of the French National Authority for Health (HAS) is required to give its opinion on the benefits provided by FDCs in view of their reimbursement by French national health insurance (NHI). Objective: Compare the different TC opinions on FDCs used in diabetology and cardiology over a five year period (2005-2010). Method: 1. In-house analysis of TC opinions. 2. Description of acceptability or refusal criteria. Results: In the period examined, 53 antihypertensive FDCs were assessed by the TC with the following conclusions: - 47 (89%) have significant actual benefit (AB) and were proposed to reimbursement, - 6 (11%) have no AB and were not proposed to reimbursement: 2 for lack of clinical data justifying combination of low doses, 4 for combination of three fixed-doses considering that the potential for misuses out weighed the advantages. In comparison, 13 FDCs were assessed in diabetology: only two (15%) were proposed to reimbursement with significant AB. The others (85%) were not proposed for reimbursement for the following reasons: no studies evaluating the fixed-dose, no relevance in active ingredients and dosages choices and risk of misuse. Conclusion: Assessment of the TC opinions reveals a difference according to therapeutic class: FDCs of antihypertensives are more often proposed for reimbursement than are FDCs of oral antidiabetics.

M-210

931 – EVALUATION OF THE EFFECT OF ERT ON THE NATURAL HISTORY OF MPS I

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Introduction: Mucopolysaccharidosis type I (MPS I) is a rare lysosomal disease caused by a deficiency of the enzyme alpha-iduronidase. The progressive accumulation of glycosaminoglycans in many organs and systems leads to a chronic and progressive disease. There are few studies regarding the natural history of MPS I. Methods: The present was a retrospective longitudinal study; data were collected from patients investigated by the MPS Brazil Network at diagnosis (T1; n=37) and follow-up (T2; n=23/37). The comparative analysis was performed only in the 23 patients who had both evaluations performed (on enzyme replacement therapy, ERT=15; not on ERT=8). Results: In 27/36 patients, clinical manifestations started during the first year of life. Initial symptoms were very heterogeneous and included spinal deformity (n=7), joint contractures (n=6), and respiratory infections (n=5). Seven patients died between T1 and T2 (median age of death=2.7 yrs). The median overall survival by the Kaplan-Meier analysis was 6.3 years. Eight patients initiated ERT before the age of 5 (median time on ERT=3 yrs). The non-ERT group consisted mainly of patients with the severe disease, whereas the ERT group included patients with the attenuated (n=9) and the severe (n=6) phenotypes. In T2, no statistical significance was found between groups regarding delayed development, ophthalmological changes, cardiomyopathy, valvulopathy, hepatomegaly, splenomegaly, joint contractures, underweight, macrocephaly, short stature, and average weight, height and head circumference. However, in the ERT group, the reported number of hospitalizations due to respiratory infections decreased in T2 (p=0.031); and an increase in reported sleep apnea was found in T2 (p=0.008). Conclusions: MPS I is a progressive disease with early onset, high mortality rates, and several comorbidities. Since ERT was mainly indicated for the attenuated phenotype, some results should focus these patients. Besides the brief analysis period and the small sample, ERT seems to be beneficial in selected patients.

M-211

665 – TOWARDS VALUE-BASED PHARMACEUTICAL PRICING IN LATIN AMERICA? GLOBAL LESSONS FROM POLICY DEVELOPMENTS IN BRAZIL AND MEXICO

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Objective: Mexico and Brazil have well-developed pharmaceutical pricing systems, with an increasing trend towards use of Health Technology Assessment in access decisions. However, there are significant differences in the prices of innovative medicines in the two countries. It is unclear to what extent local decision making criteria can account for these discrepancies and therefore which evaluation mechanisms may have international relevance. Methods: Secondary research was carried out to identify prices in Brazil and Mexico for 5 patented oncology medicines. A rating scale was then devised with the following decision domains for pricing and reimbursement: international referencing; cost-plus analysis; economic evaluation and budget impact; innovation; unmet needs; therapeutic referencing; negotiated agreements; demand side controls; and societal benefit. In primary research 4 senior stakeholders in Brazil and Mexico were asked to rate the importance of these domains in access decisions, and provide a rationale. Findings: Decision criteria in Mexico and Brazil reflect the historical origins of their respective health systems, but recent developments reflect a centralising trend in decision-making in both countries. This suggests that economic evaluation will increasingly determine access in both countries but pricing criteria will remain different, notably due to the greater role of price negotiation in Mexico. Conclusions: The mix of empirical and context-based decision criteria in Brazil and Mexico represent valuable alternative models for other countries, such as the UK National Health Service (NHS), which is currently contemplating a move towards “value-based pricing” for pharmaceuticals. In particular, Mexican and Brazilian evaluation mechanisms may inform future considerations of therapeutic innovation in the UK.

M-212

261 – CAN MULTIPLE DEMAND SIDE MEASURES ENHANCE PRESCRIBING EFFICIENCY; IMPLICATIONS FOR SUSTAINING HEALTHCARE SYSTEMS?

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Inroduction: Considerable variation in generic utilisation across Europe. Countries must learn from each other for future sustainability. Objective: To assess the influence of different demand side measures on generic utilisation to provide future guidance. Method: Retrospective analysis of the influence of demand side reforms on utilisation of different PPIs and statins (ATC Level 5) in over 20 European countries/ regions. Only administrative databases used with utilisation measured in DDDs (2010 DDDs) principally from 2001 to 2007. Classes chosen as both contain generics and patented products with limited outcome differences between them; however, considerable price differences once generics available. Years chosen as generics became available in Western EU countries during this time. Demand side reforms broken down by 4Es (Education, engineering, economics and enforcement) and validated. Main outcome measure: % change in utilisation of omeprazole (O) and esomeprazole (E), simvastatin (S) and atorvastatin (A)/ rosuvastatin (R) combined (A/R) in 2007 as % of total utilisation versus patterns seen before generic ‘O’ and ‘S’ available/ reimbursed. Findings: Considerable differences in utilisation patterns in 2007 among European countries, e.g. utilisation of ‘S’ varied between 5% to 85% and ‘A/R’ from 1% to 75% of total statins depending on the extent/ intensity of 4 Es. In addition, ‘A’ utilisation decreased from over 30% to 10% of total statins in Austria 4 years after prescribing restrictions (enforcement) alongside other measures. Increased ‘S’ utilisation in ES, SE and UK with lower or similar utilisation of ‘A/R’ following combination of 3 of the 4 Es (not enforcement) - similar patterns among PPIs. In France and Turkey, ‘A/R’ utilisation appreciably increased after generic ‘S’ with limited demand side measures. Similar changes for PPIs enhancing expenditure compared with ES, GB or SE. Conclusions: Multiple interventions typically needed to change physician prescribing. Countries are already learning from each other.

M-213

262 – TRENDS IN GENERIC PRICING POLICIES IN EUROPE: IMPLICATIONS FOR SUSTAINING EQUITABLE AND COMPREHENSIVE HEALTHCARE

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Introduction: Currently appreciable variation in generic prices across Europe. This is unsustainable given continuing resource pressures and more treatments losing their patents. Objective: To document different pricing policies for generics in over 20 European countries/ regions in an understandable format and their impact to provide future guidance. Methodology: Retrospective observational CNC study using administrative databases in over 20 European countries/ regions for generic PPIs, statins, ACEIs and SSRIs at ATC Level 5 to determine price reductions over time in 2007/ 2008 versus originator prices pre-patent loss or 2001 prices (expenditure/ DDD – 2010 DDDs). Reimbursed expenditure as health authority perspective. Generic pricing policies documented through payers/ advisers in each country coupled with narrative of pricing policies from literature searches. Policies subsequently grouped into 3 categories for comparison. Findings: Possible to group generic pricing into 3 categories: Prescriptive pricing (PP) - established reductions for reimbursement, e.g. up to 85% reduction (Norway), 33% below for first generic (Turkey); market forces (MF) - no fixed amount – however mechanisms to enhance utilisation; mixed approach (MA) – PP for first generic(s) followed by MF. Expenditure/ DDD for generic simvastatin in 2007 97% below 2001 levels in England (MF); 96% below in Sweden (MF), and 79% below in Lithuania (MA) vs. just over 50% in France (PP). Typically, less marked reductions for omeprazole. Appreciable variation in expenditure/ DDD for generic ACEIs and SSRIs within and between countries. These differences plus differences in generic utilisation resulted in considerable expenditure differences for PPIs and statins when adjusted for populations. Already examples of countries learning from each other, e.g. mandatory INN prescribing apart from minority of drugs. Conclusions: Categorisation system works and easily understandable. Examples of ways to ensure low generic prices coupled with enhancing their utilisation provide opportunities for countries to learn from each other.

M-214

605 – EFFECTIVENESS OF THE COMMUNITY HEALTH WORKER IN BRAZIL: A SYSTEMATIC REVIEW

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Introduction: The Brazilian national health care system, within its Family Health Strategy, currently employs over 240,000 community health workers (CHWs) chosen from their communities, integrated into multidisciplinary healthcare teams and receiving monthly salaries. Yet, few studies have evaluated these workers in Brazil, limiting the affirmative that the CHW is an important differential of the Brazilian primary care model. The objective of this study was to assess evidence of effectiveness interventions involving CHWs within Brazil. Methods: This systematic review, performed between 29/06/2009 and 23/03/2010, included all studies whose objective was to evaluate an intervention involving CHWs, regardless of date, language or study design. We searched databases and references of included papers, and contacted study authors for additional publications. Two independent investigators performed data extraction, quality assessment and synthesis, grouping the evidence according to CHW profile, urban/rural setting, geographic scope, study design and health outcome. We assessed the quality of evidence with GRADE. Due to the considerable heterogeneity of studies, we did not perform meta-analysis. Results: We included 23 publications, 14 (61%) of which evaluated CHW within the public primary health care model. Ten (43%) studied urban populations. Thirteen (56%) focused on maternal and child health, seven (33%) on infectious diseases, five (24%) on chronic health problems, and two (9%) on reducing inequities. Despite the low quality of evidence for most outcomes, we found significant benefit with CHW intervention (moderate evidence) for frequency of weighing children, prevalence of overall and exclusive breastfeeding and delayed introduction of bottle feeding. Studies of most other outcomes showed benefit, though evidence for all additional outcomes was low or very low. Conclusion: These findings and the current major role CHWs play in Brazil suggest that clarifying the benefit of CHW actions across a broad range of health care interventions should be a major research.

M-215

383 – POST-MARKET SAFETY AND QUALITY SURVEILLANCE ASSESSMENT PROJECTS: SURPERISTALTIC ROTARY AND LINEAR INFUSION PUMPS AND THEIR DISPOSABLE SETS STUDY

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Introduction Infusion pumps and disposable sets are critical devices for prevention of medication errors and patient safety. Alarms should indicate occlusions or air entering the line and terminate flow. Time to alarm occlusions, infusion complete, empty fluid container, flow error, set disengaged, door open, circuit malfunction or low/depleted battery should comply with Manufacturer's Operating Instructions (MOI). Quality assurance and safety of available medical devices are manufacturer's responsibility, while ANVISA's mission concerns monitoring conformity and compliance with pre-market approved safety and effectiveness reports (PMA), as well as Good Manufacturing Practices (GMP) inspections [Law: RDC No59/00]. ANVISA's mandate also includes market regulation through legislation and post-market surveillance. ANVISA established a dedicated work group to implement a surveillance project concerning the equipments and their sets available in the Brazilian market. Objective to assess compliance of non-transportable peristaltic rotary and linear infusion pumps and of their disposable sets with quality requirements and to evidence performance accuracy. Method The project involved ANVISA and the States and Municipals VISAs. Conformity of domestic and imported brands of peristaltic rotary and linear infusion pumps were evaluated according to the NBR IEC 60.601-2-24 standard and to their active PMA at ANVISA in 2006. Samples of the infusion pump and their intravenous sets were collected and segregated at their PMA legal companies and were sent for analysis at a Brazilian Conformity Assessment System, SBAC, appointed laboratory. Results This analysis revealed non-compliance issues in all devices, e.g. automatic timer to alarm failed to comply with MOI or the MOI were incomplete or inconsistent facilitating medication errors. ANVISA and VISAs joint technical inspections were made to assess the Manufacturers' and Importers quality system, leading to improvements. Conclusion Active surveillance process is an essential feature for patient safety. There are important requirements for control and to strength post-market stakeholder's partnerships in Brazil.

M-216

471 – GT EQUIPMENT- MEDICAL EQUIPMENTS POST-MARKET SURVEILLANCE: WORK GROUPS AND CONTENT PUBLICATIONS ARE STRATEGIES TO MONITOR AND PREVENT ADVERSE EVENTS

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INTRODUCTION: Medical Devices Post-Market Surveillance monitors the safety and effectiveness of Equipment, Materials and Implantable Medical Products, as well as In-Vitro Diagnostic Products. Equipments are expensive, structuring and conformant components of the healthcare. Special Techno-Surveillance programs including their quality and safety assessments are the core of proactive and preventive actions. The National Agency for Health Surveillance, ANVISA, coordinates the Brazilian regulatory system, the National System for Health Surveillance, SNVS, including States and Municipalities Health Surveillance Departments, VISAs. ANVISA is networking with other organizations, aiming to aggregate technical and scientific information to foster efforts, increment and subsidize preventive techno-surveillance measures, as well as to increment a bank of independent ad-hoc experts to expand and support techno-surveillance activities in Brazil. OBJECTIVE: To enhance, develop and implement preventive strategies to monitor quality and safety of healthcare equipments, adapted to local realities, and to disseminate Techno-Surveillance information. METHODS AND RESULTS: ANVISA has constituted a dedicated task force, a working group designated GT Equipments, with representatives of entities of the States VISAs, Universities, Health Care Facilities and stakeholders of the Brazilian society. Amid the tasks mandated, summaries of effectiveness and safety of prioritized equipments are beginning to be published in printed newsletters, as well as disseminated on-line via the Web. Elicited prioritization criteria consensus included severity and higher frequency of adverse events and of technical complaints notifications. The SNVS is using these publications to foster professional training. Impact on safer techno-surveillance practices is expected, as well as resulting healthcare system economies due to enhanced maintenance of the equipments. Further dissemination campaigns are ongoing. CONCLUSION: GT Equipments is one strategy the Techno-Surveillance Unit/ANVISA has implemented to strengthen guidance and knowledge about the safety and effectiveness of equipments currently sold in the Brazilian market. Publications uptake measures at the SNVS and healthcare facilities will be presented.

M-217

758 – INTRODUCING USER'S PERSPECTIVES TO HOSPITAL BASED HEALTH TECHNOLOGY ASSESSMENT PROCEDURE: A PILOT QUESTIONNAIRE AT POLICLINCO A. GEMELLI

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Objective: The primary aim of this pilot study was to assess the degree of satisfaction of end-users (clinicians) on HTA process implemented in a large university hospital, with the objective to analyze any process weakness and to identify any improvement area. Methods: A convenience sample of 15 clinician, from different hospital department, requiring the introduction of a new medical device in the last year, was used. As none of existing questionnaires was found suitable, after a review of literature, a questionnaire for end-user was developed by the research team for the purpose of this study. The questionnaire consisted in 5 sections and 30 items. The questionnaire had a semi-structured configuration. For closed questions the responder is asked to give a numerical score (1= Disagree strongly, 10 = agree strongly). Descriptive statistics, including frequency, percentage mean and standard deviation, were used to analyse users perception on process. Findings: 15 possible clinicians were identified, who completed and returned the questionnaire. Regarding the quantitative items, the responders had a high mean score (> 8) and subsequently, they were strongly agree when they evaluated the skill, the expertise and availability of HTA personnel responsible for evaluation phases. The score of procedure efficiency items were lower (<6). In fact in qualitative section, clinicians pointed out that the procedure could produce a bureaucratic delay of innovation due to the too much formal steps. Conclusions: The pilot study provides crucial feedback from clinicians about the acceptability and usefulness of the procedure of introduction of new medical device in clinical practices. Main issues identified in the pilot were: the possible bureaucratic delay, the need of repeated training on procedure, greater and effective users participation in the process. These findings may help hospital manager to ensure future excellent clinician satisfaction by the development of improvement strategies.

M-218

711 – TECHNOLOGICAL INNOVATION IN HEALTH EDUCATION MANAGEMENT TARGETED AT THE COMMUNITY

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This study had as its central issue at designing a virtual environment for replacement of information and organized educational materials as a resource in health care education that could provide support for action in the community and by professionals. We are presently experiencing a scenario of increasing technological incorporation in all aspects of life, with social outcomes in society, education and research and services. This requires new spaces of communication with opportunities for trade and exchange between universities, community and health services. The need to quickly and comprehensively retrieve information makes such technology incorporation a natural process in several human activities. The objective was report the development of a site for to make available educational materials produced under the supervision of professors which could guide the process in health care education with a directing role to the community and services. The period of development was 2008 to 2010, in the Department of Nursing of the Botucatu School of Medicine. The Department of Nursing has extension programs, and it works conjointly with the services provided by the local government. The phases of development involved: literature review, hypertext compilation, development of Internet material (with participation of information technology technicians), making the material available in a virtual environment and evaluation. The result is the product of the development, a virtual environment that consisted in an innovative and updated way to reach and educate individuals by means of distance learning, thus showing the University's interest and responsibility towards the population in addition to awakening nursing professionals to this distance-learning strategy. We conclude that it is important to maintain the site, which represents a reliable source of information and education and the evaluation initiated shows the importance of maintaining the website, which will be systematized in further studies.

M-219

854 – DEVELOPMENT OF FORECASTING MODEL TO ASSESS NEEDS AND DRUG COSTS TO TREAT NEGLECTED DISEASES IN BRAZIL

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Background: In Brazil visceral leishmaniasis, tegumentar leishmaniasis, tuberculosis, schisosomiasis, malaria, leprosy, dengue fever and Chagas disease are classified as neglected diseases. The number of reported cases were 2.4 million in the period 2008-09. Many patients are not treated optimally with drugs. Consequently, there is a need to forecast the potential number of patients and associated costs to improve planning and care. Forecasting models for assessing drug use and costs have been developed and successfully applied in Stockholm healthcare regions combining assessment of number of patients, drug use trends and critical expert-based needs assessments over a 2 year period. Objectives: (a) Develop a model for 5-year forecasting of needs of drug therapies and costs for patients affected by neglected diseases in Brazil based on the methodology developed in Stockholm. (b) Evaluate the performance of the forecasting model for estimating the number of treated patients and associated costs for the next 2 years of the 5-year forecasting period. Methodology (a) Estimation of the number of affected and treated patient cases and drug costs of the neglected diseases, (b) Establish a multidisciplinary expert group to help identify and quantify disease epidemiology, treatment strategies, and future needs to guide subsequent forecasts, (c) Forecast needs based on the number of cases to be treated 2012-2016 in Brazil and drug costs addressing the use of generics, (d) Follow-up 2012-2013 of number of treated patients costs as compared to forecasting models. Findings: The research group will be developing the forecast in Brazil for neglected diseases and associated costs based on proven methodologies in Stockholm, and report the findings in June. Conclusions: Forecasting models of needs of treatments and costs have been used successfully for non-infectious diseases in Europe. The model should be adaptable to neglected diseases in Brazil.

M-220

798 – REGIONAL DISPARITIES IN HEALTH TECHNOLOGY ASSESSMENT - HTA RESEARCH IN BRAZIL – 2007 TO 2010

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Since 2007, competitive research bids were prepared, consisting of HTA research topics that had been prioritized by public health care managers, in an inter- institutional partnership with the Ministry of Science and Technology. The purpose of this partnership was to support HTA elaboration and, simultaneously, to promote the capacity-building of universities in order to compose the Brazilian Network of Health Technology Assessment (REBRATS) Objective: to analyze the distribution, by federative state, of HTA projects financed in the years 2007-2010 in Brazil. Method: to systematize financed projects through a search engine in the information system http://pesquisasaude.saude.gov.br/bdgdecit/. Results: of the 152 financed HTA projects, 74% (114/152) were concentrated in the south and southeast regions, represented by the states of São Paulo (37%), Rio de Janeiro (14%), Rio Grande do Sul (11%) and Minas Gerais (8%). There was a marked increase in projects in the northeast region, which grew from 11% to 27% in these four years. Conclusion: HTA research investments in training and research could reduce regional disparities. Increasing the financing of HTA projects over the next few years is important for two reasons: i) the public health system has universal access and is decentralized, with state policymakers holding the power to decide regarding the coverage of procedures to be financed in their state; ii) in 2011, new legislation will enter into effect, altering the flow and procedure for incorporating technologies into the public health system.

M-221

727 – REGULATION OF MEDICINES AND HEALTH PRODUCTS IN BRAZIL: MONITORING OF CLINICAL TRIALS: AN IMPORTANT KEY TO SUCCESS

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SUS, the Brazilian Public Health System, provides healthcare to 190 million people with a budget of $72 billion/year. Anvisa, a governmental agency is responsible for the scientific evaluation of applications for marketing authorization for medicines and health products, as well as for authorization of clinical trials in the country. Anvisa has a scientific regulation model addressed to medicines that was audited and certified by WHO/PAHO, in 2010. New technologies receive a special attention at Anvisa, just because they bring a lot of uncertainty and high costs to the SUS. Important data are gathered in this process, basically from clinical trials and from dossiers of industries required for marketing authorization. So, a new process of monitoring of the Brazilian technologic horizon gets started. Intervention: Since 2004 Anvisa has based its regulation process for new medical products on HTA's tools. Clinical researches with regulatory purposes are also evaluated by Anvisa in the same scientific basis aiming to prevent problems in pivotal studies that could reflect in poor data on registration phase. Anvisa also focuses its actions in preventing bad interference on the functioning of Brazilian health system. Also helps reducing risks and harm to research's subjects. After 2008, any multicentre study that has a branch in Brazil must submit to Anvisa before starting. Otherwise, data can be refused at the registration phase. Both regulatory processes: research and registration, run in a synergic way. Results: Over 300 clinical trials evaluated/year Thirty elected studies inspected. Serious adverse events reported. Trends of innovation identified: cardiac stents and endovascular devices, vaccines and anti-retroviral drugs, medicines addressed to diabetes and new biologic drugs for cancer and rheumatic diseases. Conclusion: Data from the cycle of new technologies' regulation feed other processes as pricing and evaluation for incorporation at the SUS, a critical step for Brazilian health system sustainability.

M-222

175 – COMPREHENSIVENESS IN HEATHCARE AND MEDICINES PROVISION BY THE HIV/AIDS PROGRAM IN BRAZIL

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Background: Comprehensiveness, universal access and equity are Brazilian Health System principles. Comprehensiveness encompasses a broad scope of aspects related to the health system and to the individual, involving preventive and curative health actions. The Brazilian HIV/AIDS Program was designed within this paradigm. During its development and implementation considerable effort was dedicated to the practice of comprehensive healthcare for PLWHA. The aim of this work is to discuss the concept and its application to the Program medicines´ provision stategies in order to verify Program experience. Methods: A search of the literature covered the various definitions and dimensions related to comprehensiveness as well as the diverse applications of this concept in different health settings. Documents pertaining to the Brazilian HIV/AIDS Program were scanned for events and practices related to comprehensiveness and to medicines provision. A discussion on how well the Program has incorporated comprehensiveness, in its various forms and in medicines provision ensues. Results: The Brazilian HIV/AIDS Program has acted politically to adhere to and to incorporate comprehensiveness in its guidelines and practices, presumably more so than most other health programs in Brazil. Free universal access has been guaranteed by law, since 1996 and much has been accomplished in order to supply ART and medicines for oportunistic infections. The Program features a separate supply chain, including procurement and distribution. Although comprehensive medicines provision has been guaranteed, this is mostly true for ART. Other aspects of comprehensiveness, such as those related to the integration of all health efforts has not yet been achieved. Conclusions: In its 25 years of existence, the Brazilian HIV/AIDS Program has made important efforts in the direction of comprehensive medicines provision for PLWHA, perceived as one of the reasons behind its success. Nevertheless, lack of integration with other health system networks and structures may compromise comprehensiveness.

M-223

504 – COMPARING POLICIES IN BRAZIL AND EUROPE TO ENHANCE PRESCRIBING OF GENERICS AT INCREASINGLY LOWER COSTS IN HIGH VOLUME CLASSES, IMPACT AND FUTURE POSSIBILITIES TO SUSTAIN HEALTHCARE SERVICES

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Strategies addressing increasing pressure on resources include encouraging prescribing of generics and obtaining low prices for them. Currently considerable variation exists in utilisation and prices of generics, which is unsustainable given estimated sales of $100bn/year of patented products likely to lose their patent between 2008 and 2013. Cross-national studies of drug utilisation (DU) linked with health policy initiatives are a recognised methodology to evaluate the impact of different interventions for future planning. We propose to analyze recent studies assessing the influence of different reforms to enhance prescribing efficiency in Brazil and Europe, through a thorough literature review and analysis focusing on studies with generics, especially their pricing, availability and utilisation. Databases covered include: SciELO, Lilacs, Scopus, Pubmed/Medline, Web of Science. Search terms include “medicamentos genéricos / generic drugs”, “políticas públicas / public policies”, “preços de medicamentos / generic prices”, “uso de genéricos / generic utilisation”, “ políticas de uso de medicamentos / demand-side reforms”, “uso de medicamentos / drug utilisation”. Comparability between settings may be achieved through the development and application of analytical categories. In Brazil, only products that are bioequivalent to innovative products have generic status. Various legislations, which define and regulate generics and promote their prescribing, have been passed since 1999. Generics may enter the market at 40% of innovative product price driving down both prices especially in the public sector alongside the government establishing quality standards for multisource products. Strategies in Europe have lowered prices of generics in some countries to between 2% to 15% of originator prices. This coupled with multiple demand side reforms have resulted in savings in recent years among certain classes despite appreciable volume increases. There are differences in market authorisation, pricing and utilisation of generics in Brazil and Europe. However, formally studying the impact of different policies provides future guidance.

M-224

647 – DISPENSING PRACTICES IN SPECIALIZED MEDICINES SEGMENT PHARMACY FACILITIES IN BRAZIL

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Problem Statement: According to the Brazilian National Pharmaceutical Services Policy, the Specialized Component of Pharmaceutical Services (CEAF), aims to guarantee dispensing of high-cost medicines for the treatment of specific diseases that burden a limited number of patients. In spite of public financing channels for these medicines, the fact that access warrants demand through legal injunctions suggests flaws in the management of pharmaceutical services. Objective: This study analized adherence to Clinical Protocols and Therapeutic Guidelines (PCDT) in the dispensing of the medicines of CEAF in four dissimilar out-patient pharmacy facilities in the State of Rio de Janeiro. Design and development, Setting and Study Population: A qualitative evaluation of dispensing practices was carried out in four dispensing outlets in the state of Rio de Janeiro (Brazil), each presenting different structural characteristics. Analytical categories were identified.The data was collected through interviews with key actors, review of documents and direct observation technique. Data collection instruments were based on the PCDT dispensing procedures, that include requests for medicine dispensing, analysis by the dispenser, dispensing of medication and pharmacotherapeutic monitoring. Organization of data and categorization was undertaken. Results: Lack of adequate structure, including trained personnel, compromises CEAF medicines dispensing in all facilities. The CEAF dispensing procedure, heavily dependent on interaction between prescribers and dispensers, is not carried out as would be expected. Inadequate performance is also linked to flaws in planning and in organization of services. Conclusions: The results indicate barriers in adherence to PCDT by health professionals, burdening health system users and possibly leading them to access medicines judicially. Characteristics of the investigated facilities may show similarities with others in Brazil, and identified barriers may be the same, compromising healthcare in CEAF. Key words: clinical guidelines, dispensing, practice pharmacy. Funding Sources: SESDC-RJ

M-225

256 – TECHNOSURVEILLANCE: OCCURRENCES INVOLVING MEDICAL AND HOSPITAL EQUIPMENT AND SAFETY IN HEALTH CARE

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Objective: analyze the incidence of failures, technical complaints, incidents and adverse events related to the use of equipments. Method: the database of the Sentinel Hospitals Project (SHP) was used. The investigations were based on the Sundry Technosurveillance Report Form and on the Protocol for Occurrence Investigation. Results: 31 reports were observed; 74.2% were spontaneous reports; 17 manufacturing companies were involved. Hemodialysis and Medical Clinic sectors accounted for 38.7% of occurrences. Hemodialyzers (19.4%) and oximeters (12.9%) were most frequently involved. Potential risk to the patients' health was observed in 74.2% and the adverse events occurred in 8 cases: 1 patient showed pulmonary hypoventilation (ventilator); 1 patient lost the arteriovenous puncture and was repunctured (hemodialyzer); 2 patients showed finger burning (oximeters); 2 patients showed dyspnea and cyanosis symptoms (flowmeters); 1 patient showed air embolism (hemodialyzer); 1 patient evolved to death due to respiratory insufficiency (ventilator). The causes observed were: 71.7% of Technical Failure (TF); 13.3% of Human and Process Failure (HPF); 10.0% of Design Failure (DF) and 5.0% Human Failure (HF). TF were more frequently in hemodialyzers (53.5%) and oximeters (9.3%), due mainly to the lack of preventive maintenance, natural wearing and/or technological backwardness. HPF occurred more frequently in anesthesia devices (37.5%) and ventilators (25.0%); DF involved 3 bronchoscopes, 2 oximeters and 1 hemodialyzer; HF involved 2 hemodialyzers and 1 ventilator. The measures taken by health agencies were the issuance of resolutions and warnings for two cases and local investigation concerning an occurrence involving a ventilator. Conclusions: The use of the equipment still implies risk to patients, to health care professionals and to the environment. Technosurveillance actions must be developed in order to further ensure safety and quality for such products, conjointly with programs creation aiming at the preventive maintenance of devices, technological renovation, training and continuing education of the hospital's staff.

M-226

744 – FDG POSITRON EMISSION TOMOGRAPHY FOR EVALUATING ESOPHAGEAL CANCER

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Decisions on adoption of new technologies in health systems need to be supported by evidence of benefit and clinical utility. The use of Positron Emission Tomography (PET) has been proposed as an adjunct to endoscopic ultrasonography, computed tomography (CT) and magnetic resonance imaging (MRI) in staging of esophageal cancer. This assessment reviews evidence on the use of FDG-PET imaging in esophageal cancer and focuses on four specific clinical settings: (1) initial detection of primary tumors; (2) staging; (3) evaluating response to neoadjuvant therapy; and (4) detecting recurrent disease. It also examines his influence on the clinical and therapeutic decisions and impact on health outcomes. The methodology used was a rapid review of HTA. We conducted: (1) research on evaluations produced by HTA agencies belonging to the INAHTA network; (2) survey of clinical practice protocols relating to the use of PET, at the bases National Guideline Clearinghouse and National Library of Guidelines; and (3) literature search for systematic reviews and meta-analysis in MEDLINE, COCHRANE, LILACS and SciELO. FDG-PET showed moderate diagnostic accuracy for the detection of locorregional metastases, and reasonable sensitivity and specificity in detection of distant lymphatic and hematogenous metastases, usually with performance superior to CT. Few studies have evaluated PET-CT, being described better performance of the combined technology for FDG-PET alone. Their addition to the diagnostic options used in this neoplasm could potentially impact the treatment choice and may improve health outcomes by increasing the frequency of patients receiving stage-appropriate treatment, by detecting distant metastases that are likely to preclude definitive therapy. No direct evidence was found reporting the health outcomes of patients with oesophageal cancer assessed with FDG-PET. Larger prospective studies should quantify to what extent the routine use of FDG-PET leads to changes in management and better health care for these patients.

M-227

1004 – SERIOUS ADVERSE EVENTS MONITORING IN CLINICAL TRIALS: A BRAZILIAN INITIATIVE

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Since 2004, Anvisa, the National Regulatory Authority in Brazil, participates of global efforts for ensure Good Clinical Practices (GCP) on clinical trials of new medicines and health products conducted in the country. The efficacy assessment of a new health technology carries out a lot of complexities. The assessment of its safety is a real challenge. During the length of the clinical trial adverse events must be identified, analyzed to establish their causality, and reported to Anvisa. After the study finishes, the monitoring of adverse events keeps on going through programs of farmacovigilance. The monitoring of serious adverse events (SAE), one of critical requirements for WHO pre-qualification of the regulatory needs, it seemed to be an unsolvable problem. Since June 2010 Anvisa uses a DATASUS`applicative, named FormSUS, a computerized system for notification of SAEs in clinical research. There was no additional cost to Anvisa, and the system ready to use obtained the approval of the WHO during the audit of medicines` pre-qualification. The customization of filters in FormSUS allows data extracts for the assessment of causality as well as it can offer some kinds of statistics very important to evaluate if a study or a centre or even a group of volunteers are exposed to inacceptable risk. 518 reports of serious adverse events were received during this period, among them 103 deaths. This initiative presents FormSUS as a viable alternative to supply the need for configurable systems in the organizations that are part of the SUS, reducing costs and shortening time to deployment of systems, because the country is eager to grow.

M-228

319 – DEVELOPMENT OF THE NATIONAL PROGRAMME FOR REORIENTATION OF PROFESSIONAL TRAINING (HEALTH PRO II: “INTEGRATE TO TRANSFORM”) IN THE CITY OF UBERLANDIA

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Introduction: The Brazilian Government has been implementing social inclusion policies that have concrete expressions in social areas, especially in Health and Education. In health, there is a consistent effort to replace the traditional model of care organization, historically focused on disease and hospital care. In this sense, the Health Ministry and the Education Ministry, with the support of the Pan American Health Organization (PAHO), established the National Program for Vocational Training in Health (Pro-Health). In its second stage, the Pro-Health II “Integrate to Transform” interdisciplinary, integrating all health-related courses at the Federal University of Uberlandia (UFU) and complements the design of other courses previously approved. The goal is to integrate teaching and service, aimed at refocusing the training, ensuring a comprehensive approach to the health-disease process with emphasis on Primary Care, promoting changes in service delivery to the population. Methodology: Shares interdisciplinary and intersectoral are developed through the organization of interdisciplinary research lab, implementation of interdisciplinary curricular component common to courses in health, and organization of scientific events. Is an adequate health facility in the city of Uberlandia, which will be reference as a core integration between teaching and service. Results: With the development of Pro-Health II at the Federal University of Uberlandia, we expect a reorientation of training based on social approach to health-disease process; forming professionals in accordance with the needs of the SUS, change in care model and strengthening the network of social support to Health, use of research as an educational tool and processing practices and recognition of health professionals as agents of social changes. Conclusion: The Pro-Health II flows from the current needs of UFU and the Department of Health to incorporate the teaching-service integration and to integrate all courses in the area of health in the process of reorientation training.

M-229

963 – THE ELDERLY HEALTH AND THE PRINCIPLES OF PRIMARY HEALTH CARE: THE LOOK OF POPULATION ABOUT THE ACCESS TO A BASIC HEALTH UNIT IN PORTO ALEGRE-RS-BRAZIL

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This paper reflects on the attributes of Primary Health Care and an aging population, emphasizing the need for better preparation and planning of health services to meet the elderly. Therefore, the aim of this study was to assess how assistance is provided to the elderly population in a Basic Health Unit in Porto Alegre-Brazil, in the perspective of access, one of the key attributes of the Primary Health Care were conducted semi-structured interviews in 61 elderly patients, with fourteen open and closed questions based on PCA-Tool as an instrument. The main results show that the Health Unit SESC was remembered by the vast majority of the elderly population as a reference service for basic needs in health. The greatest difficulties of access were related to the characteristics of an area where the Unit is located. It is necessary to consider what measures should be taken to solve this problem. The access of older methods of medical, dental and nursing was considered easier. However, the perception of users about the strategies for prioritization in attendance did not appear so clear. It was concluded from the review of this population that, despite some difficulties pointed out, access to health services was considered easier for the elderly in this department of health. Keywords: Health of the Elderly, Primary Health Care, Health Services Accessibility.

M-230

878 – THE ETHICAL ASSESSMENT IN HTA REPORTS: THE DEVELOPMENT AND THE EVOLUTION OF THE ETHICS CONSULTATION BY INSTITUTE OF BIOETHICS OF THE UNIVERSITÀ CATTOLICA DEL SACRO CUORE, ROME (ITALY)

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The ethical assessment in an HTA report concerns both the ethical issues raised by the technology itself and the ethical issues that are related to the HTA process. Even though it is listed as one of the objectives of HTA, in practice the integration of this dimension into HTA reports has been often limited. In the Italian context, already characterized by a certain delay in the diffusion of HTA, the Institute of Bioethics of the Università Cattolica del Sacro Cuore (Rome, Italy) tried from 2007 to fill this gap, beginning to integrate ethical analyses into HTA reports in an activity of consulting for third parties. The contribution intends to show the results of the ethics consultation in various HTA reports from 2007 to 2010. The following elements will be presented: 1. to describe the methodologies/procedures used to incorporate ethical analyses into HTA reports; 2. to review the set of ethical questions dealt with; 3. to show the resources involved; 4. to analyse the difficulties arose in the assessment. Finally, the perspective is to set up an HTA ethics consultation within a broad ethics consultation service by Institute of Bioethics of UCSC.

M-231

910 – THE ETHICAL ASSESSMENT OF NANOTECHNOLOGIES WITHIN HTA PROCESSES

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The need to assess, from an ethical point of view, the use of health care technologies - expressed, for a long time, from a theoretical point of view – is nowadays acknowledged as a part of the Health Technology Assessment (HTA). It is a research methodology, widely used within the international context, to inform technology-related policymaking in health care. Nanotechnologies may be outlined as the expression of the human ability to manipulate atoms and to build, thanks to the properties typical of the size (nanometric scale), devices and materials with novel properties and function. They have been investigated within several fields; even though medicine, where they are known as “nanomedicine”, is the field were there is a greater interest in, moving from the prevention to the diagnosis and to the treatment. In particular, nanotechnologies introduce novel therapies (in the form of drug delivery), new drugs (drugs discovery) and new tools and devices (nanomaterials, nanodevices). In this perspective, nanotechnologies can be considered as health technologies and, therefore, submitted to an HTA process. With reference to the ethical domain, the process traditionally used for the evaluation of health technologies may be inadequate when applied to nanotechnologies, because of many specific ethical issues. The paper underlies those elements of “inadequacy”, trying to outline some possible strategies for intervention.

M-232

216 – THE RELATIONSHIP BETWEEN COST-CUTTING BEHAVIORS AND HEALTH OUTCOMES AMONG HIGH CHOLESTEROL PATIENTS

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Objective: Given rising healthcare costs, the aim of the current study was to determine the humanistic and economic impact of cost-cutting behaviors for patients diagnosed with high cholesterol. Methods: Data from the 2010 US National Health and Wellness Survey were used. Demographics, comorbidities, and cost-cutting behaviors were assessed for all respondents. Health-related quality of life (using the SF-12v2), absenteeism and presenteeism (using the WPAI questionnaire), and resource use (number of emergency room visits, hospitalizations, and physician visits in the past six months) were also measured. Results: A total of 28.6% patients (N=21,424) reported a diagnosis of high cholesterol. Most patients were male (55.1%) and white (83.5%) with an average age of 58.4 years (SD=13.3). Most patients (68.1%) reported engaging in a least one cost-cutting behavior. The most frequent behaviors included asking for generic alternatives (29.8%), buying prescriptions multiple months at a time (25.5%), and asking for samples (23.1%). A number of patients also reported not filling their prescriptions (9.7%) and cutting medications in half (9.4%) to save on costs. After controlling for demographic and patient characteristics, the number of cost-cutting behaviors was associated with significantly worse physical (b=-0.96, p<.05) and mental (b=-1.08, p<.05) summary scores and with worse health state utilities (b=-0.02, p<.05). The number of cost-cutting behaviors was also significantly associated with direct (b=508.7, p<.05) and indirect costs (b=1300.9, p<.05). Each additional cost-cutting behavior was associated with an additional $1301 per patient per year of lost work productivity and an additional $509 per patient per year of societal healthcare costs (physician visits, hospitalizations, and emergency room visits). Conclusions: The results suggest that moving to an increasingly cost-shifting environment may result in more patients engaging in cost-cutting behaviors, which can result in worse outcomes and higher societal costs. Improved access may help to alleviate this burden among high cholesterol patients.

M-233

965 – ETHICS AND POLICY IN HTA: IMPLICATIONS OF PATIENT CHARACTERISTICS TRUMPING HTA - THE EXAMPLE OF MORBID OBESITY IN SPINAL FUSION

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An initial Health Technology Assessment generally combines consideration of clinical improvement vs. cost for a particular technology or procedure. As HTA has become an accepted and commonly utilized health services instrument, researchers have begun to drill down the data to a more detailed level. This provides the opportunity to identify patient subgroup characteristics which may be of sufficient influence to subvert the general principles and clinical indicators defined in the original health technology assessment. However, this raises a new set of issues concerning the ethics of using subgroup characteristics to influence treatment decisions - particularly the potential to deny care. An example of a patient subgroup characteristic which can trump the original Health Technology Assessment is morbid obesity in spinal fusion. Multiple studies have shown that patients with simple obesity (Class I BMI 30-34.9, Class II BMI 35-39.9) generally have similar outcomes to non-obese patients except a slightly higher rate of infection (0.6% vs. 5.5%). However, surveys of grossly obese (Class III BMI ≥40) patients having spinal fusion have shown a $24,000 increased average cost (28% higher) for the index surgery and a 97% higher in-hospital complication rate. Such findings have profound implications for the decision making processes of surgeons, insurance companies, health economists and governments. Questions of cost and societal health are only one consideration. Ultimately, the medical system will have to address difficult ethical and policy issues pitting the rights of an individual patient to receive the benefits of care (despite higher cost and complications) vs. what policy criteria result in a net benefit for society as a whole.

M-234

669 – ZEBRA CROSSING! REVEWEING HTA IN AFRICA FROM 1990'S-2010

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Introduction: South Africa has undertaken a number of HTA activities in the last decade through publication of a policy framework on HTA (2000), establishment of a steering-committee and a regulatory-framework under the National Health Act and proposed medical device regulations. However, not enough evaluations have been done to establish their impacts with health policy and service delivery in the public sector. The current study focuses on impact evaluation of HTA activities by a) investigating the value-chain of HTA activities in heath delivery services and b) exploring motives, enablers and barriers for HTA implementation in South Africa Objectives: To assess the current state of implementation of HTA in South Africa Methods: Qualitative study design was used which involved interview of a convenient sample of practitioners and experts from public hospitals, DoH and Universities (n=22). Findings: Participants believed key role-players are DoH, Health professionals and Health managers and academic institutions. They believe that main motivation of establishment of HTA is to achieve better quality health services through evidence based decision-making. Example of good practices and their relevance and effectiveness particularly in a local setting are important enablers. Availability of trained human-resources and lack of understanding of HTA processes and its usefulness and impact on improvement of health-care are major barriers. Recently DoH has appointed a senior manager. Three Universities (UCT, Wits & Pretoria) have established academic programme in HTA/HTM to build capacity. These graduates are expected to be the backbone of HTA and Health Systems' Management in future. South Africa is currently in the process of introduction of comprehensive NHI. HTA can play a significant role in improving the efficiency of Health system. Conclusions: The above findings suggest that there is both political and academic interest in South Africa classifying it as a converging country where time might be ripe for scaling up HTA.

M-235

463 – HELPING INSTITUTIONALISE EVIDENCE-INFORMED HEALTHCARE POLICY MAKING IN LOW- AND MIDDLE-INCOME COUNTRIES: THE WORK OF NICE INTERNATIONAL

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Faced with a growing number of available medical technologies, drugs and procedures on the one hand; and finite resources on the other, healthcare policy makers are increasingly looking for innovative and legitimate ways to make decisions which ensure the greatest possible return on investment of their healthcare budgets. Governments in many richer countries such as the UK, Germany and Australia have well-established bodies to inform such decisions. However, with more funding available for health, a shift from communicable to non-communicable diseases, and an increasingly active civil society viewing basic healthcare as a right, explicit decisions surrounding the fair and equitable use of resources are becoming equally important in low- and middle-income countries (LMICs). In response, governments in LMICs are increasingly looking for advice on strengthening their capacity for making decisions on how to ensure fair and equitable access to healthcare. for the past ten years NICE has been providing guidance to the UK's National Health Service on clinically and cost effective care, based on the best available evidence and incorporating value judgements from wider society. It is now working with colleagues from other agencies around the world to support policy makers in LMICs faced with similar challenges, through its not-for-profit consultancy division, NICE International Since 2008 NICE International has provided technical and institutional support to a number of Ministries of Health, including those of Turkey, Jordan, Georgia, India and China through capacity-building, hand-on training and practical projects. This poster presentation will outline some of the major achievements of NICE international's work to date, and highlight lessons and implications for policy makers wishing to develop and strengthen evidence-based policy making institutions; as well as lessons for those with greater experience wishing to pass on advice to others.

M-236

488 – ISSUES OF HEALTH TECHNOLOGY DEVELOPMENT IN KAZAKHSTAN

Dmitriy Tereshkevich, Humans Health Institute, Kazakhstan

In Kazakhstan funding for health care organizations has been provided by different types: by own estimation of medical organization with limitation of state budget line, by medical insurance and on the modern stage by payment for the treated case from the state budget calculated with medico-economic protocol. Due to the lack of private fixed capital stock it was difficult to develop private health institutions that were represented mainly by small private practices, laboratories, mini - clinics. Weak private sector development in medicine has led to a lack of competition and lower quality health care services. The patient was not able to select hospitals and treatment, specialist, pharmaceutical product. The Government annually pays huge sums to medical institutions but their service is getting worse. And only at this stage, due to economic growth, increasing solvency we have a movement of private capital, domestic and foreign into national health system and the development of market relations, development of highly specialized medical care, use of expensive new medical technologies including in public and private clinics. Nevertheless, in public clinics with modern equipment and highly qualified specialists is difficult to get a quote for treatment. In this case Kazakhstan have developed system of informal payments to doctors and support privileged patients in medicine. There is a double payment to health care worker. It is confirmed by studies of the World Bank in Kazakhstan. The Government make every effort to resolve the situation. But the real terms of reforming the system are measured for decades, because it includes the reform of medical education. But medical assistance is needed today. Development of the system of informing of patient and his relatives, patient voices, patient laws and the promotion of free competition in the medical services market in Kazakhstan are very important.

M-237

863 – VACCINATION IN CENTRAL EUROPEAN COUNTRIES – SEARCHING FOR THE MECHANISM TO ACCELERATE PATIENTS' ACCESS TO MODERN PROPHYLAXIS

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Background: Despite the growing number of innovative prophylactic technologies on the market in recent years, their availability for patients is low and diversified across European countries. Objectives: To identify solutions which could effectively accelerate patients' access to modern vaccination. To set legislative and organizational regulations against Systems' Efficiency Indicators (SEI) in Czech Republic (CZ), Hungary (HU), Poland (PL) and Slovakia (SL). METHODS: Surveys of legislation and market data followed by discussions with country representatives have been carried out. Five variables determining vaccines' availability for patients were identified: obligatory status, public budget engagement, purchase mechanism, co-payment level, administration issues. Access to Vaccines Mechanism (A2VM) for each analyzed vaccine was described as a combination of options for all mentioned variables. SEI based on numbers of delivered doses (regardless of manufacturer) and birth cohort was calculated and expressed in Dose/Person for Pneumococcal, Rotavirus, Human Papillomavirus (HPV) vaccines (2010 Survey; Eurostat Database) FINDINGS: Availability of Pneumococcal vaccines in CZ,SL and HU is significantly higher than in PL, 3.49;2.97;2.28 and 0.79 Dose/Person respectively. The HPV vaccines' coverage is the highest in HU (1.08-1.45 depending on data) followed by CZ, whereas in SL and PL does not exceed 0.25 Dose/Person. The Rotavirus vaccines' coverage is comparable, up to 0.4 Dose/Person (PL and HU on the leading positions). In HU 6 A2VM were identified comparing with 4 A2VM for other countries. Reimbursement mechanism (co-payment possibility) exists in HU,CZ,SL, with direct access to refunded vaccines in GP practices in CZ. Private insurance mechanism enhances the system performance in SL and CZ. Conclusions: Public payer may not afford to finance free of charge, universal access to modern vaccination in the time of financial uncertainty. Diversity of A2VM (co-payment, supplementary insurance) can stimulate assimilation of innovations being beneficial from individual and population health perspectives.

M-238

197 – LIVING DONOR TRANSPLANT, THE RIGHT TO PHYSICAL AND MENTAL INTEGRITY AND THE LIABILITY OF THE STATE

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Background: Organ transplantation has emerged as the last therapy in vital organs failure. Indeed, it is a human right; a corollary of the right to life. The role of inter vivos transplantation has become larger, due to ineffective catchment policies, which usually are unable to meet public needs. Discussion: It is known that the right to life and dignity are inalienable and integrate the minimum existential core of the human person. Hence, health law embodies the normative protection of physical and mental integrity of human beings. That way, organ transplantation can be defined as inseparable part of the right to life. In which concerns kidney transplantation, it is known by medical literature that inter vivos and post mortem procedures have provided similar outcomes. Therefore, the World-Health Organization (WHO) suggests that inter vivos donation may be held secondarily. In fact, living donation only takes place because both donor and recipient are unable to choose freely, due to the imminent risk of death caused by the absence of cadaveric organ catchment. The manifestation of the will, therefore, is mediated by fear and pain. As well as patients have the right to transplantation; every other person has the right not to suffer from unnecessary mental or physical mutilation, in a donation procedure that could potentially be avoided by effective health policies. Conclusions: There is evidence that changes in transplantation policies may increase post mortem surgeries. Hence, a proper public policy should focus on cadaveric transplantation, considering living donation only in cases recommended by medical evidence. Actually, Brazilian policies have not reached the expected protection to its populations, as suggested by WHO. Therefore, the unwarranted physical and mental violation of living donor's integrity may lead to the liability of the State.

M-239

6 – OCCUPATIONAL HEALTH SERVICES APPROPRIATE FOR WORKERS IN MANUFACTURING INDUSTRIES

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Objectives: The study tried to conduct risk assessment for organic solvents in a printing industry; and to propose control measures for possible environmental pollution from industries and occupational illnesses of manufacturing workers. Methods: The study was conducted in a printing industry with about 400 employees and in a highly populated community. Monitoring of ambient air for various organic solvents was done using detector tubes, sampling pumps and charcoal tubes. Monitoring of health of workers based on clinic records was conducted. Findings: The industry as the target area uses solvents such as Ethyl Acetate (EAC), Methyl Ethyl Ketone (MEK), Ethanol, and Isopropyl Alcohol (IPA) for printing and lamination of plastics. Ambient concentration in the work area indicated the following measurements which were all above the thresholds limit value (TLV) set by OSHA. The results showed that workers were exposed to high concentrations of solvents that may cause adverse health effect such as respiratory and skin problems. The study recommended use of methods and tools in monitoring chemical exposures of workers in industries, as well as the use of health technologies appropriate for medical surveillance of occupational diseases among workers. In addition to chest x-rays is the adoption of pulmonary function test. In addition to complete blood count is the inclusion of metabolite testing of urine, blood, and other biologic samples for affectation of organs specific to chemicals used in industries such as toluene, EAC, MEK, and IPA. Conclusion: The regular health monitoring and technologies used in occupational health services do not capture the real health risk of the workers. Health methodologies and technologies should consider the hazards to which workers are exposed to, tand the health vulnerabilities of this special group of individual- the manufacturing workers. Keywords: occupational health services, chemical monitoring, industrial hazards, health of workers and employees

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M-240

431 – TELEGENÉTICA – ON-LINE GENETIC DIAGNOSIS

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The data of the National Mortality System (SIM) shows that in the last decade, the congenital anomalies are the second leading cause of infant death in some Brazilian cities. This phenomenon occurs because the improvement of health promotes a decreased rate of death from infectious diseases and malnutrition, and the congenital defects play a crucial role in the epidemiological scenario. The Brazilian Society of Clinical Genetics has 135 members, of whom 122 are medical geneticists. Almost all of these medical geneticists are linked to universities and state capitals, so that's why the most part of the Brazilian children who born with congenital anomalies, in other words, 3-5% of all newborns are discharged from the hospital without a medical genetic opinion about the etiology of condition. Some of these congenital anomalies may cause death in case of absence of specific diagnosis and early treatment. The main example is the inborn error of the metabolism that in case of absence of specific treatment may lead to death or to leave irreversible sequelae. The objective of this project was to approach doctors of maternities with medical geneticists to determine the cause of congenital anomalies and thus provide early treatment and to reduce the infant mortality. Besides providing genetic counseling for families of these children. The methodology used in the developing of the project was to use local resources: 1. Managers of Health Systems; 2. Experts in Clinical Genetics. The result was the development of an online platform where neonatologists have access to genetic counseling. The platform has internationally standardized signs and symptoms that favor the identification of the reason by consulting the datas and providing a genetic diagnosis.

M-241

494 – CEBRIM/CFF'S CONTRIBUTION TO THE RATIONAL USE OF DRUGS IN BRAZIL

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Background: The World Health Organization (WHO) views medicines information centers (MICs) as key resources for promoting the rational use of drugs and health technologies. To this end, MICs respond to questions sent by health professionals, publish newsletters, participate in pharmacy and therapeutics committees, and engage in continuing education activities, among others actions. Objectives: To describe the activities conducted by the Brazilian Drug Information Center (Cebrim/CFF) in 2009-2010 for promoting the rational use of drugs. MATERIAL AND METHODS: Based on the center's executive reports of 2009-2010 and additional archived documents, a list was compiled of Cebrim/CFF's activities which can contribute to the rational use of drugs. RESULTS: In 2009-2010, Cebrim/CFF responded to 953 requests (reactive information), issued five technical reports and 13 opinions, and published eight editions of the newsletter Farmacoterapêutica. As a permanent member of the Technical Multidisciplinary Committee for Updates to the Brazilian Essential Drug List (Comare), the center participated in 18 meetings, having prepared seven opinions for Rename 2010, one group analysis for the 2012 edition, and the update to the 2010 edition of the National Therapeutic Formulary (FTN). In the field of continuing education, it has participated in the organization a course for pharmacists in the area of pharmaceutical care, which provided training to 205 professionals in 2009 and enrolled another 73 in 2010, in addition to training four professionals and providing supervised internship to eight pharmacy students. In that period, Cebrim/CFF translated the booklet Counselling, Concordance, and Communication: Innovative Education for Pharmacists. Conclusion: Despite the absence of studies to assess the impact of its actions, Cebrim/CFF has pursued activities capable of promoting the rational use of drugs and, consequently, better patient care and optimized use of financial resources.

M-242

495 – ADHERENCE TO DRUG THERAPY AMONG PATIENTS WITH SCHIZOPHRENIA IN ALOÂNDIA, GOIÁS, BRAZIL

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Background: Schizophrenia comprises a group of mental disorders shaped by biological, psychological and social factors. Its treatment requires involvement of healthcare professionals, family members, and the patient as well, since successful treatment depends on adherence. This study evaluated adherence to drug therapy by patients with schizophrenia treated at a public outpatient clinic in Aloândia, in Goiás State, Brazil. Method: A specially developed questionnaire addressing the Medication Adherence Scale and socioeconomic profiles was administered to all patients with schizophrenia. In the case of those incapable of self-care, their caregivers were interviewed. Microsoft Excel software was employed for descriptive statistical analysis. Results: The questionnaires were administered in July 2010. Of the 18 schizophrenic patients assisted at the clinic, one was excluded for refusing to be interviewed; 29% (N = 10) were in age range of 40 to 60 years; 53% (N = 9) had less than eight years of formal education; 82% (N = 14) did not work; 40% (N = 7) did not practice any leisure activities; 53% (N = 9) reported forgetting to take the prescribed medication at the designated times; 58.82% (N = 10) reported discontinuing the medication when feeling unwell; 52.94% (N = 9) said their thoughts did not become clearer with medication; 41.18% (N = 7) reported feeling fatigued or slow upon taking the medication. The drugs most commonly prescribed were haloperidol and chlorpromazine. Conclusions: Despite the small number of patients, which limits the possibility of extrapolating data, the study is valuable as a validation tool. The findings suggest that adherence issues may be related to poor education and adverse effects of drugs. Approaches based on multidisciplinary teamwork and guidance are expected to improve adherence rates.

M-243

496 – A NEW ONLINE QUESTION-AND-ANSWER SYSTEM TO SUPPORT DAILY ACTIVITIES AT A DRUG INFORMATION CENTER

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Background: A regular task of a drug information service is to receive and answer drug information requests so as to improve the rational use of these products. Drug information services require functional tools to support this daily activity. Objective: To describe the software specificities of and characterize the queries placed from 2009 to 2010 to a new online drug information system especially developed for the Brazilian Drug Information Center (Cebrim/CFF). Method: The study was based on data on software features and on the questions and answers dealt with. Results: The new system was built on two previously existing versions and allows users to enter requests and data directly. Pharmacists at Cebrim/CFF then conduct database searches and enter their responses, which are subsequently sent to users. The system 184.22 a accumulated 4354 questions and answers from 2001 to 2010 (mean, 435.4 year). The most requested topics during this period were related to drug indications (13.9%), adverse reactions (9.9%), stability (7.7%), and identification (7.6%). Most users were pharmacists (74.7%). In the 2009-2010 period, 3463 users were recorded. Conclusion: Thanks to the new system, Cebrim/CFF's question-and answer-service has been made more user-friendly, while data have become more accessible, improving the service's quality assurance process.

M-244

455 – INSERTING THE EQUITY COMPONENT TO THE PRIORITY SETTING PROCESS FOR RESEARCH ON HEALTH TECHNOLOGY ASSESSMENT (HTA): CHALLENGES OF 3D MATRIX

Erika Barbosa Camargo, Brazilian Ministry of Health, Brazil; Luci Fabiane Scheffer Moraes, Brazilian Ministry of Health, Brazil; Marge Tenório, Brazilian Ministry of Health, Brazil; Fernanda Laranjeira, Brazilian Ministry of Health, Brazil

In the priority setting process, the use of scientific evidence is an important tool to promote appropriate allocation of resources. To set priority in health research the 2D Combined Approach Matrix (CAM) has been used as an important device. The 2D CAM considers only two dimensions: public health and institutional. The public health dimension consists in five elements: the magnitude of a health problem, determinants, knowledge level in relation to interventions, profitability and cash flows. The institutional dimension is composed of four elements: the individual, domestic and the community, the health sector, other sectors, and governance. In 2009 a new axle emerged and the matrix has acquired a new dimension becoming a 3D CAM. The new dimension is the equity that is still under an experimental fase and is intended to elucidate the correlation between poverty, powerlessness and social injustice, and may include categories such as gender, poverty, disability, religion, education or race. In the HTA research field, the equity dimension, often, goes toward the tradition of including new technologies, often costly for the benefit of a few. Consider this dimension in research for rational use of resources in health means a paradigm change, with the possibility of including in the research list priorities technologies before set aside such as those for neglected and tropical diseases, among others. Setting research priority in the HTA field is a huge challenge that low and middle income countries need to overcome to overpass the gap between the emergence of new technologies for health needs and the steady budget constraint. So the equity component is critical and should be considered. It is now urgent that priority setting in the HTA field must consider the deference's in order to determine their own basis for national researches to elucidate the gaps in HTA.

M-245

466 – DECENTRALIZED RESEARCH FUNDING: SCENARIO IN BRAZIL IN THE HEALTH TECHNOLOGY ASSESSMENT (HTA) AND HEALTH ECONOMICS FIELD

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Backgroud: The Research Program for the Brazilian Public Health System (PPSUS) is a decentralized type of research funding available in the states that aims to contribute to reduce regional inequalities in the science, technology and innovation in health field. PPSUS fostered among others research on HTA in order to support the evaluation and incorporation of technologies process in the Brazilian Public Health System (SUS) as a solution or reduction of the population health problems. Objective: To analyze the profile of the research funded by the PPSUS modality by the Brazilian Ministry of Health in the HTA an health economics research agenda during 2002-2009. Method: Data collection of public calls for proposals in the Shared Management of Science and Technology in Health field collected in the database of the Brazilian Ministry of Health available on the website (www.pesquisasaude.saude.gov.br / bdgdecit) and analyzed in January 2011. Results: The HTA and heath economics research agenda received a U$ 2.519.204,09 to fund 42 projects in 21 public calls for proposals launched between 2002 and 2009. The main themes searched were: 1) the health technology life cycle, 2) HTA and health economics studies applied to public health policy, 3) strategies to structure and sustainability for HTA and health economics and 4) political economy in health. The largest number of funding occurred in 2009 where 21 projects were hired throughout the different regions of Brazil: the south, the southeast, the northeast and the Midwest. Conclusion: the research contributed to strengthening the HTA field at regional and very local levels in Brazil in its different units of the federation, for the services and the SUS management. This initiative reflects the importance of research to develop scientific and technical capacity in local level in the HTA a Health economics field.

M-246

470 – THE BRAZILIAN EXPERIENCE IN THE PARTICIPATORY CONSTRUCTION OF NATIONAL GUIDELINES FOR BIOREPOSITORIES AND BIOBANKS

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Objective: Build a participatory way, with researchers, managers and social control, a proposal of National Guidelines for Biorepositories and Biobanks of Human Biological Material in Research based on the principles of social responsibility, solidarity, respect for people, beneficence, justice and precautionary. Method: The Coordination of Bioethics and Research Ethics of Decit/MH prioritized actions for the establishment of technical, ethical and legal standards to collection, storage and use of human biological material for research: basement on the current literature; participation in global discussions on the subject; identification of national institutions had biorepositories and/or biobanks of different types of biological sample and formation of a group of researchers, the National Health Surveillance Agency, and as an observer, the National Commission on Research Ethics for develop National guidelines for biorepositories and biobanks of human biological material with the purpose of research. Results: preparatory meetings showed that the theme was relevant to the present moment, and its components have demonstrated adherence to the preparation of guidelines. Participation in international conferences showed that Brazil was in the same state of the art that other countries and consolidated the aspects that should be addressed in this document. The proposed guideline was a public consultation in May 2010 and received 229 contributions. Conclusion: The document was sent to approval by Ministry of Health and publication in the Official Gazette of Brazil and, subsequently, the decision the board of directors of the Unified Health System.

M-247

508 – UPDATING PROCESS OF THE NATIONAL PRIORITIES AGENDA ON HEALTH RESEARCH (NPAHR) FOR TECHNOLOGY ASSESSMENT (HTA) AND HEALTH ECONOMICS: THE BRAZILIAN EXPERIENCE

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In 2004 the National Priorities Agenda on Health Research (NPAHR) was published with 24 sub-agendas that guided the actions of research funding the Brazilian Ministry of Health (MoH) and the state and county levels of the Public Health System (SUS). After six years of building NPAHR (2004), MoH started its update in order to allow that the health research priorities are aligned with the SUS needs. The methodology for the process development counted with working groups (WGs) composed by researchers and skilled managers, preferably those who where involved in creating the first edition of the NPAHR. The activities of the WGs were mainly made on line with the support from a research coordinator. In the Health Technology Assessment (HTA) and the Health Economics sub-agendas the themes that composed it originally were maintained. However, all subjects had in someway changes, additions and deletion of research lines. The update of the HTA sub-agenda resulted in the indication from the following list of priorities such as: the evaluation of efficacy and effectiveness of health technologies and economic evaluation of health technologies, criteria for equitable allocation of resources; management models in health; economic evaluation of high-cost drugs for the incorporation in SUS; studies on the mechanisms/processes for decision making regarding the incorporation of health technologies in the public and private sector; risk assessment and safety in the use of health technologies; technological horizon scanning; competitiveness and the prospection for technological innovations, according to SUS needs. The review in the research agenda for the HTA theme is of fundamental importance to advance the Science, Technology and Innovation field in Brazil, considering that new technologies can impact in the economic and social contexts. Nevertheless, we emphasize the importance of horizon scanning as a strategic component for innovation.

M-248

831 – HEALTH TECHNOLOGY ASSESSMENT AND HEALTH ECONOMICS SCIENTIFIC PRODUCTION: SOME INDICATORS

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Introduction: The level of scientific activities may be mapped through information metric studies allied to information organization methods in order to assess science and to set research policies, signifying priority areas for funding. Bibliographic databases records analyses permit mapping with data collection and resource economies, emphasizing the importance of information resources. Objective: To understand the scientific activity output through published scientific articles indexed with «Health Technology Assessment» and «Health Economics», corresponding to the 14th chapter of the 24 sub-agendas of the National Agenda of Priorities in Health Research (ANPPS) of the Brazilian Ministry of Health. The 14th sub-agenda feature topics such as innovation, acquisition, use and obsolescence of health technology and as economic evaluation or cost analysis in healthcare. Method: We analyzed a sample of records indexed in the LILACS database after it was reformatted specifically for this purpose. We selected 37 journal titles in health sciences published between 2003 and 2007. All the 7603 articles of the sample were compared with the indexed terms in the 14th sub-agenda of ANPPS. Thematic analysis was performed to depict related production situation and its evolution. Key issues or keywords in these articles were also reviewed. Results: During the period studied, there were a total of 266 articles related to the 14th ANPPS sub-agenda, 3.5% of the total number of articles were indexed with «Health Technology Assessment» and «Health Economics» or included related content, showing a slight annual growth of number of published articles. Conclusions and discussion: Although the ANPPS represents the National Health Research Policy, the 14th ANPPS sub-agenda themes are not rated among the most searched topics. This situation may be related to education, information and technology problems in Brazil. Health Technology research is, thus, a target for greater incentives.

M-249

904 – THE BRAZILIAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT (REBRATS): THE NATS-HC/FMUSP DEVELOPMENT AND HTA ACTIVITIES

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Introduction The Health Technology Assessment Commission of the Clinics Hospital of the University of São Paulo Medical School, NATS-HC/FMUSP, begun at the Heart Institute-HC/FMUSP in April 2003 and in April 2008 was formalized for the whole HC; aiming to assist the HC / FMUSP's administration in the appraisal, development, standardization and surveillance of health technology, HT, studying effectiveness, efficiency and economic aspects, as well as anticipating and forecasting of new technologies, techniques and equipments. In October 2010, the NATS-HC/FMUSP won a grant from the Health Ministry to implement one of its 24 Hospital Centers for Healthcare Technology Assessment (NATS) and participate on the Brazilian Network for Health Technology Assessment (REBRATS). Methods Since NATS-HC/FMUSP's inception a structured HTA instrument was adapted from the international Mini-HTA/DACCEHTA, a similar instrument to the Brazilian Health Ministry's REBRATS Technical Appraisals guidelines. Assessments and activities continued including systematic reviews and specified HT clinical and economic assessments, either for HT in demand to be incorporated at the HC/FMUSP or the ones required from the National Health System (SUS). Results To date the NATS-HC/FMUSP has succeeded to formalize 92 members in 5 specialized Working Groups (WG): Scientific Evidence; Medical Equipments; Laboratory Medical devices and in vitro Reagents; Nursing, Surgical and Generic Consumables; Prosthesis, Ortheses and Special Materials; Devices and Consumables for Nutritional Therapy; Hospital related Clothings; Corporative Informatics and Printings; and is working very hard to enhance liaison and HTA production at the 8 main HC's Institutes, including thousands of health professionals and researchers. The NATS-HC/FMUSP has produced 251 systematic reviews, 34 economic assessments, 7 guidelines, all disseminated in the local website and published in peer-review periodicals, as well as 83 technical internal reports to the superior HC's Administration. Conclusion REBRATS's participation has stimulated NATS-HC/FMUSP and improved the dissemination strategy. Increased HTA scientific and evidence-based production is ongoing.

M-250

835 – IMPACT OF IMPLANTABLE SINGLE CHAMBER CARDIOVERTER DEFIBRILLATORS PULSE GENERATOR REPLACEMENT TIME ON COST-EFFECTIVENESS ANALYSIS

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Introduction: Service life of implantable cardioverter defibrillators (ICDs) is a major determinant for cost-effectiveness (CE) healthcare program assessments and has a significant impact on patients' health, costs and policy decisions. Objective: Post market surveillance of pulse generator replacement time for patients' implanted single chamber cardioverter defibrillators. Methods: From a selection of 148 patients without bradycardia required stimulation and implanted with single chamber cardioverter defibrillators of the Heart Institute-InCor-HC/FMUSP's 755 ICDs implants follow-up cohort: Nine patients migrated and were followed elsewhere, 25 died and 5 had a cardiac transplantation; resulting in 109 study subjects. Cox regression, Log-Rank test of differences between independent significant strata of primary and secondary indication, ICD manufacturer, intensity of ventricular pacing and of concomitant use of anti-arrhythmic drugs and Kaplan-Meier actuarial survival analysis were performed. Results: There were a majority of male patients, 82, 3:1 male: female ratio; particularly with ischemic heart diseases, 33 patients; average of 55 years of age (range: 16-78) and of 45 months length follow-up. Kaplan-Meier curves

demonstrated an average of 64 months length until pulse generator replacement was required, a median of 70 months (in 50% of the patients), with a maximum of 111.25 months; and this is significantly modified by the concomitant use of anti-arrhythmic drugs (p=0,004). Cox model negatively correlates beta-blockers and amiodarone use, reducing pulse generator survival to the 45 months median (p=0,006) comparative to median 73 months until replacement without use of anti-arrhythmic drugs (p=0,009). Conclusion: The median of 70 months time until replacement implantable single chamber cardioverter defibrillators pulse generator is superior to CE current used case-base estimates and is significantly reduced by concomitant requirements of anti-arrhythmic drugs, emphasizing necessity of stratified assessments based on evolving clinical conditions in this domain.

M-251

875 – MEDICAL DEVICES POST-MARKET SURVEILLANCE IMPROVEMENT: LEARNING FROM TECHNICAL COMPLAINTS AND CASE REPORTS

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Introduction: Active medical devices intended for life support, depending on energy may fail due to inadequate battery surveillance or purchasing criteria, causing life-threatening events. Objective: Proposed techno-surveillance, purchase and use guidance for batteries used in active and life support medical devices. Problem Presentation - A Case Report A temporary pacemaker (TPM), with new battery installed, was sent to InCor-HC/FMUSP Pacemaker Clinic's clinical engineering with a failure report, after only two hours of use. Engineer's sequential service tests showed TPM working without problem during 12 consecutive hours, confirming premature battery depletion. Samples of 5 new (same 6LR61 9V alkaline TPM batteries recommended by manufacturers) testing investigation demonstrated: one of these batteries had partial wear, two had dimensions beyond the specification, one didn't presented expiry date labeled. The recalled supplier replaced batteries with appropriated quality. NEW ROUTINE The InCor-HC/FMUSP Pacemaker Clinic modified bid edictal purchase requirements include: manufacturer's ISO 9000 and 14000 certification; the results of electric performance tests with and without charge of new batteries and after 12 months of shelf at room temperature (MIL-STD 105E); durability tests results, service output, for 620ohms, 270ohms and 180ohms (IEC) loads; electrolyte leakage tests of discharge under usual characteristic conditions, short circuit and abusive characteristics; storage and distribution practices certification; batteries chemical composition &limits compliance statement according to Art.6/CONAMA Resolution Nb.257:30/06/1999 and indicating how they implement it (ecological practices); to provide one battery charge test device at each one hundred batteries purchased; nurse's training sessions to test each battery before use on TPM or devices intended to support life. Conclusion: Technical surveillance measures for control and regulation of batteries intended to be used in medical devices and hospital equipments, especially those for life support, need to be established in the Brazilian healthcare system.

M-252

459 – EVALUATION OF THE INSTITUTE FOR SCIENCE, INNOVATION AND TECHNOLOGY IN HEALTH (INCT-CITECS) PERFORMANCE

Fabiana Raynal Floriano, CITECS/UFBA, Brazil; Marcelle de Oliveira Cardoso, CITECS/UFBA, Brazil; Luis Eugênio Portela Fernandes de Souza, ISC/UFBA, Brazil; Maurício Lima Barreto, ISC/UFBA, Brazil; Sebastião Loureiro, ISC/UFBA, Brazil; Rosana Aquino Guimarães Pereira, ISC/UFBA, Brazil

The INCT-Citecs is one of the National Institutes of Science and Technology built on the initiative of the Ministry of Science and Technology of Brazil. It consists of health research groups and aims to contribute to improving the population's health through the development of research, knowledge transfer and training of personnel in the area of economic and technological assessment and innovation. Significant investment has been made, mainly with public resources, to consolidate INCT, including Citecs. Therefore, it is important to evaluate them, making sure that their goals are being achieved. Objective: To evaluate the performance of the INCT-Citecs, implemented in 2009. Method: a matrix was prepared with 75 indicators grouped into four categories, namely: 1 - Strengthening of the network; 2 - Research 3 - Knowledge transfer to society, and 4 - Training of personnel. This matrix was filled with information obtained through interviews with the coordinators of the 14 research groups that make up the INCT-Citecs. Results: Preliminary analysis suggests that, after the Citecs, on the one hand, there were (1) increased collaboration among research groups, with the development of new projects and the increase of scientific publications, (2) more national and international partnerships. On the other hand, the activities of (3) knowledge transfer and (4) training were not intensified. Complete analysis will be presented at HTAi 2011. Conclusion: The evaluation showed that the constitution of the Citecs has strengthened research activities, through intensified collaboration, but has been unable to increase knowledge transfer and personnel training. Considering that research is the core activity of the groups and that knowledge transfer is a new practice, these results are not surprising. The lifetime of the Institute, just over a year, probably have not been enough to produce results in those more innovative activities.

M-253

464 – PROFILE OF USERS AND THE PRACTICES OF SEEKING HEALTH INFORMATION ON THE INTERNET

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The creation of the internet greatly facilitated access to information and it also collaborated with its mass production in a variety of sources. However, the user may be exposed to many dubious and unreliable information that has a commercial interest as its ultimate purpose (Lopes, 2004). When it comes to information regarding health, that process represents a big risk for professionals and consumers, since both may be unaware of rules on the identification of quality standards in pages available on the internet. Filtering quality information about health is a confusing and difficult task due to the increasing speed of sites and lack of control with which the information has been accumulated (Jadad, Gagliardi, 1998). Several experts have shown that most of the information available on line about diseases and treatments are inconsistent, incomplete and inadequate (Gagliardi, Jadad, 2002; Oermann, 2003; Bedell, Agrawal, Petersen, 2004). In this presentation or poster, literature data will be contrasted with findings obtained in a research conducted at UNIFESP by the authors. In the research 1,750 internet users reported, through an electronic questionnaire (found at https://spreadsheets.google.com/viewform?formkey=dC1YcEVCU3NvSzE4VVQ0SnhBanp1Ymc6MA), how they usually make their search about health information. They also answered questions about the confidence gained from the instruction obtained in many different sites, behaviors adopted during and after the search for content and others that will also be presented.

M-254

872 – HOSPITAL MEDICINE IMPLEMENTATION IN A MEDIUM SIZED PUBLIC HOSPITAL: SUSTAINABLE SERVICE EXPANSION AND QUALITY IMPROVEMENT

Andre Wajner, Hospital Getulio Vargas, RS, Brazil; Fernando Starosta de Waldemar, Hospital Getulio Vargas, RS, Brazil; Anderson Donelli da Silveira, Hospital Getulio Vargas, RS, Brazil; Angelise Martins, Hospital Getulio Vargas, RS, Brazil; Juarez Verba, Hospital Getulio Vargas, RS, Brazil

In the United States, Hospital Medicine (HM) has grown to be the largest field of medical practice, adopted by most hospitals. It has been shown to reduce length of stay and total hospital costs. This technology has helped to increase hospitals inpatient capacity and reduce its emergency systems overload. In Brazil, however, very few initiatives are known. In 2010 Hospital Getúlio Vargas implemented a HM service with 60 beds. Seven hospitalists with Internal Medicine training and a strong evidence-based medicine background where hired. They were responsible for the daily medical care of all clinical patients and had also administrative duties. Objectives: To report the first year results of one of the first HM services dedicated to public inpatient care in Brazil. Methods: Clinical and administrative data from all patients admitted between January and December 2010 were prospective collected and reviewed. Findings: There where 3843 admissions. Length of stay (los) was 7.1 ± 6.6 days (d). Median los was 5d (IQ25-75) 3-9d. Mortality rate was 7%. The 2 main diagnostic related groups were: infectious diseases (43%) and cardiovascular diseases (22%). In contrast with the previous year there was an increase in inpatient volume from 3563 to 3843 in 2010, or 7.86%. Hospital related revenue rose from R$2.918.536 to R$3.590.645, or 23%. There were 22% less deaths. Conclusions: The new technology implementation was considered very successful. There was a significant return on investment, even considering physician payment raise. We were able to increase the number of admissions without increasing the number of available beds. There was also an improvement of the quality of the medical care provided by the institution, as measured by different quality indicators and reduction of hospital deaths. We believe HM promises quality improvement and economic sustainability for the Brazilian hospital system, notably associated with public hospital care.

M-255

592 – DISEASE BURDEN IN BRAZIL AND HEALTH TECHNOLOGY ASSESSMENT: A RETROSPECTIVE OF FOUR YEARS OF FINANCED PROJECTS

Flavia Tavares S Elias, Departament of Science and Technology MoH, Brazil; Christine N S Koury, Departament of Science and Technology MoH, Brazil

Background: Defining health technology assessment priorities has been a challenge for the Department of Science and Technology. Since 2007 the adopted strategy has been to apply prioritization criteria (epidemiologic relevance, services/policy relevance, state of the art, operational feasibility and social demand) for demands from technical areas on acquisition from the Commission for Health Technology Incorporation at the Ministry of Health. However, evaluation demands do not always correspond to health needs. Objective: To analyze the relationship between projects financed from 2007 to 2010 and disease burdens in Brazil. Methods: systematization of the summaries from financed projects through searches in the information www.saude.gov.br/rebrats and http://pesquisasaude.saude.gov.br/bdgdecit/ and categorization according to the twenty sub-groups of diseases and injuries of disease burden research in Brazil (SHARMM ET al, 1998). Results: 152 HTA projects were financed through competitive research bids between 2007 and 2010. Of these, 23% (35/ 152) are applying to the twenty main causes of loss of life years by premature death or incapacitation (Dalys). The first three largest Dalys, equal to 15% – diabetes, coronary ischemia, acute myocardial infarction, angina, cerebral infarction and e AVC – corresponded to 11% of the (16/152) projects. Conclusion: the percentage found allows for the questioning of the prioritization starting point where the criteria are applied to subjects sellected due to external influence and pressure from the market and not necessarily based on the needs impacting the population's health. Uniting the two dimensions, while also taking into account the strategic innovations in order to prioritize and finance assessment, will be important for health systems sustainability.

M-256

932 – THE INTRODUCTION OF INNOVATIVE & MINIMALLY INVASIVE MEDICAL DEVICES INTO THE CLINICAL PRACTICE: THE LIMIT OF THE ITALIAN FUNDING DRG SYSTEM. THE CASE OF ENDOVASCULAR DEVICES

Francesco Scarpa, W.L. Gore & Associati - Medical, Italy

Italian National Healthcare Service is public (tax-funded) and managed by Regional's Health Authorities. Hospital procedures are reimbursed with global budget and DRG System. The tariff system currently in use for DRG is based on national standards that can be modified by each region according to local needs. Starting from 2010 all regions are using the Grouper software CMS24th revision (USAFY2007) and the ICD–9–CM (2007) for diagnosis & procedures codes. DRG tariffs include reimbursement for all resources used during the process of care including equipment, implantable medical devices, personnel, drugs and hospitalization costs. On jeopardized basis an extra payment is recognized for some implantable medical devices. Due to the old version of the DRG System in use (CMS24th version; ICD-9-CM2007) and the total lack of updating mechanism of the system, the utilization of innovative and minimally invasive medical devices may not be properly recognized by the system: --With regard to ICD-9-CM, the lack of specific procedure-codes could imply inappropriate coding resulting with the same DRG's and tariffs for open, endovascular, percutaneous or laparoscopic surgery approaches. Not rare is the case that no difference in DRG and tariffs are recognized to the use of the implantable devices. --Higher tariffs for longer hospital stay versus lower tariffs for day surgery treatments penalize the minimally invasive approaches that, using innovative medical devise, should permit to treat the patients minimizing the hospital resource consumption and maximizing patient QOL. --The cost-restraint could limit the utilization of innovative/minimally invasive medical devices by the physicians, influencing the natural evolutions of the clinical practice. Case histories in the endovascular sector indicate easy advices to improve the situation: --Adoption of the last available version of ICD and DRG system --Introduction of regular update process for coding and tariffs --Introduction of extra payment for medical devices & innivative technologies able to reduce patient's LOS

M-257

664 – BENCHMARKING TIME AND PROCESS IN HTA AND DECISION MAKING

Franz Pichler, Centre for Innovation in Regulatory Science, United Kingdom

The CIRS project intends to establish a benchmarking programme of HTA and decision-making agencies for the purpose of enabling participating agencies to compare their processes with those of other agencies. A systematic process mapping methodology has been developed, based upon national regulatory and reimbursement systems, for the purpose of identifying common milestones. In partnership with participating agencies, milestone definitions and data collection methodology is currently being developed. This presentation will demonstrate how this project can build on previous experience of benchmarking international regulatory agencies and will explore how systematic benchmarking can i) promote process improvement, ii) improve comparative understanding of the similarities and differences in healthcare systems and iii) facilitate best practice.

M-258

388 – SURVEY ON THE CURRENT SITUATION OF QUALITY POLICY IMPLEMENTATION FOR MONGOLIAN HEALTH CARE DELIVERY

Ganchimeg Gombosuren, None, Mongolia; Tsevegdoo Dariimaa, None, Mongolia

Background: Mongolian health sectoral quality management has been developed since 1998 for over 10 years and health care quality improvement programme and legal documents concerning to its quality have been implemented approved by orders of Minister of Health. Background of this survey is to conduct surveys and analysis on health care quality policy implementation, study the current situation, determine the pressing issues and determine needs and requirements based on the evidence. Goal: To study health care quality policy implementation and pressing issues and develop recommendations on them. Research methods: The survey has been done in group and individual interviews based on quality survey methodology and it has been confirmed through introducing with documents and materials. Outcomes: The report and recommendations on quality policy implementation and determining pressing issues have been written. Quality management implementation will be improved through defining health care quality policy implementation and pressing issues. Conclusions 1. Implementation of quality programmes and orders is not sufficient, and there is a lack of feedback and provision of total quality management. 2. Staff recruitment of quality department is inadequate, they fulfill many functions and these reasons influence in quality activities negatively. 3. Most quality departments do not have quality improvement programme, quality continuous training programme is not well-organized. 4. There is a lack of safety documents for medical staff and customers, understanding on safety of medical staff is low. 5. All hospitals regularize activity to take comments and suggestions of customers and service providers, but feedback and activity according to suggestions are not regular. 6. Hospitals have shortages on providing internal and oblique monitoring methodology of health care, their coherence, feedback and eliminating infringements is insufficient. 7. There are no any laws on health care quality and strategic action plans at the national level. 8. Management on health care quality is insufficient. Recommendations developed on the base of that survey

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M-259

756 – EUROPEAN COUNTRIES WITH SMALL POPULATIONS CANNOT OBTAIN APPRECIABLE PRICE REDUCTIONS OR GENERICS: FACT OR FICTION?

Kristina Garuoliene, Faculty of Medicine, Vilnius University, National Health Insurance Fund, Lithuania; Jolanta Gulbinovic, Faculty of Medicine, Vilnius University, Lithuania; Brian Godman, Division of Clinical Pharmacology, Karolinska Institutet, Sweden; Bjorn Wettermark, Division of Clinical Pharmacology, Karolinska Institutet, Medical Knowledge Centre, Stockholm County, Sweden; Alan Haycox, Prescribing Research Group, Liverpool University, United Kingdom

Background: Recent publications have suggested smaller European countries have difficulties negotiating low prices for drugs including generics; as a result, limiting the potential to enhance prescribing efficiency as more standards lose their patent. Objective Assess whether this happens in practice for European countries with smaller populations. Method: Principally an observational study involving all ambulatory care patients within the compulsory health insurance system in Lithuania across four drug classes between 2001 and 2009. Utilisation measured in DDDs and prices as reimbursed expenditure/ DDD. In addition, description of generic pricing policies and their impact among selected European countries based on recently published papers by the co-authors. Findings: Appreciable reduction in reimbursed expenditure/ DDD for generics and originators in each drug class in Lithuania, e.g. 56% reduction for generic omeprazole, 83% reduction for generic simvastatin and 92% reduction for generic fluoxetine, helped by implementation of external reference pricing in 2004. This despite appreciably lower utilisation of PPIs, statins and anti-depressants in Lithuania versus Western European countries. Recent reforms have also resulted in high volume generics in Norway reimbursed at only 15% of pre-patent loss originator prices, with reimbursed expenditure/ DDD for high volume generics in Sweden at only 4 to 13% of originator prices following mandatory substitution. Reimbursed expenditure/ DDD for generic omeprazole in 2007 was higher in France, Germany and Italy than Lithuania, Norway and Sweden, with similar patterns for generic simvastatin. Conclusion: European countries with smaller populations can obtain appreciable reductions for generics vs. originators. As a result, provide examples to help conserve resources as well as help address concerns about the ability to continue providing comprehensive and equitable healthcare.

M-260

759 – CARE NEEDED WHEN EVALUATING THE IMPACT OF HEALTH POLICIES USING DIFFERENT DATABASES

Kristina Garuoliene, National Health Insurance Fund, Faculty of Medicine, Vilnius University, Lithuania; Jolanta Gulbinovic, Faculty of Medicine, Vilnius University, Lithuania; Brian Godman, Division of Clinical Pharmacology, Karolinska Institutet, Sweden; Björn Wettermark, Division of Clinical Pharmacology, Karolinska Institutet, Sweden

Background: EuroMedStat highlighted greater utilisation of statins across Europe when analysing commercial (IMS) vs. administrative databases – up to +55%; median + 15%. Highest differences where prescribing restrictions and patient co-payments. Recent pan-EU studies shown very low utilisation of PPIs and statins in Lithuania vs. Western European countries (2001 to 2007/8), with statin utilisation appearing lower than recent publication using commercial database for 2005 to 2007 (Kadusevicius et al – IJTAHC 2009; 25:419-24). Objective: Ascertain the extent of differences between database studies during 2005 to 2007 to provide future guidance for researchers, reviewers and health policy personnel. Methodology: Observational drug utilisation study assessing DDDs for statins between 2005 and 2007 in the Lithuanian Compulsory Health Insurance Database (NHIF) versus Soft Dent database (commercial software company recording OTC, reimbursed and purchased prescriptions vs. just reimbursed for administrative database). Both converted to 2010 DDDs for comparisons. Findings: 3 to 4 fold difference in utilisation rates for the statins between administrative and commercial databases (Soft Dent), e.g. DDD/TIDs were 2.7, 3.0 and 4.4 for Soft Dent database 2005 to 2007 vs. only 0.6, 0.7 and 0.8 respectively for NHIF database. Potential reasons include statins only reimbursed for 6 months post AMI with first prescription via cardiologist (monitored using patient databases) otherwise 100% co-payment. Restrictions recently relaxed for generic statins; however, co-payment still 20%. Conclusions: The differences are appreciably larger than those documented in the EuroMedStat project. Consequently, knowledge of the content of each database and associated reforms essential when comparing reimbursed utilisation rates within and across countries to avoid false impressions. Next step will involve comparing NHIF and IMS databases for statins and other classes (PPIs, ACEIs/ARBs, antidepressants) to see whether similar differences.

M-261

168 - PUBLIC HEALTH MANAGEMENT IN SMALL MUNICIPALITIES WITH LOW MUNICIPAL HUMAN DEVELOPMENT INDEX (HDI-M)

Gerson Luis Schwab, Pontifícia Universidade Católica do Paraná – PUCPR, Brazil

This is an exploratory cross-sectional study with a qualitative and quantitative approach. It refers specifically to public health management in six small municipalities with low HDI-M in the state of Paraná, Brazil, in the catchment's area of the 21st. Health District. The objective was to analyze the process of managing health in those cities and to identify facilities and difficulties encountered by the manager, his (her) profile and self-assessment; also, to analyze the application of financial resources and accountability for managers based on the Annual Management Report (AMR). Data collection was conducted by interviews, where the subjects were the municipal health managers. The main findings suggest an aspiration for changes in municipal management of health. Managers resented the lack of specific training to face the reality of decentralization and were unanimous in stating their desire to improve services for customers. As for AMR, they were presented in an unstructured and confused manner, without helping health planning, what would be its main function. They were still a mere instrument of accountability, in the narrowest productivity-driven sense. It was possible to demonstrate that there is no relationship between the achievements of goals in ealth upon with the amount of financial resources invested in each municipality. It can be concluded that the forms of managerial decisions must evolve to interdisciplinary teams, with social control not only acting in supervison, but mainly in developing the planning of public health. This would allow higher resolution and universal and equitable services to justify the final stage of the process of decentralization of the Health System.

M-262

867 – THE ROLE OF THE HEALTH TEAM IN THE CARE OF CHRONIC PATIENTS ON PRIMARY CARE

Giselle Cavalcante de Oliveira, Universidade Estadual do Ceará, Brazil; Patricia da Silva Taddeo, Universidade Estadual do Ceará, Brazil; Kilma Wanderley Lopes Gomes, Universidade Estadual do Ceará, Brazil; Martha Suellen de Lacerda Miranda, Universidade Estadual do Ceará, Brazil; Andrea Caprara, Universidade Estadual do Ceará, Brazil

The prepared health team is an integrant part of a strengthened primary care, which considerably improves the continuity of care to patients with chronic diseases. The high prevalence rate of chronic diseases affects the health systems because of the high cost, since they cause disability to patients and families, affecting the quality of life of people. This study aims to know how the care management of patients with chronic diseases takes place by the family health teams in the Brazilian primary care (Unified Health System – SUS), besides allowing a reflection by the health teams regarding the primary care for patients with chronic diseases. The research is a bibliographical review by the means of the searching for indexed articles in the Medline databases, Scielo and documents of the Brazilian Ministry of Health, by using the keywords: “care”, “chronic disease” and “primary care”, from 1994 (first year of implementation of the Family Health Program in Brazil) to 2010. Studies show that it is important and necessary that the teams be prepared to receive these patients and promote better conditions for survival. It was considered innovative to assemble a multidisciplinary team, which adopts a dialogic, reflective methodology to address issues related to health promotion, disease prevention and treatment of patients with chronic diseases and their families, besides enhancing and stimulating the formation of the bond between team and group. On the other hand, other results show that workers alienated from the process of care production in a doctor-centered, procedure-driven model will hardly consider themselves as makers of health acts, having great difficulty to realize their full potential as caregivers. Through reflection and previous instrumentation of those teams on the contents of health, family and interdisciplinary approach, significant changes in the quality of primary health care in Brazil are enabled.

M-263

248 – ACHIEVEMENTS AND CHALLENGES AFTER A 10-YEAR EXPERIENCE OF A HOSPITAL-BASED HTA PROGRAM IN A THIRD LEVEL PEDIATRIC HOSPITAL IN ARGENTINA

Graciela Demirdjian, Hospital de Pediatria Garrahan, Argentina

In 2001 an HTA program was initiated at our hospital, a national pediatric referral center with 500 beds and a self-managed budget. Its main goal was to promote a rational and evidence-based technologic development through multiple strategies including HTA reports for management advice regarding incorporation or acquisition, clinical practice guidelines for healthcare professionals, capacity building in clinical effectiveness and technical support for health services research. This is the first and only existing hospital-based HTA unit in the public setting in Argentina. Up to date, the program has produced over 20 technology assessment reports and economic evaluations of a broad range of health technologies comprising drugs, medical devices and equipment, and organizational issues. It has also coordinated and supervised the elaboration and implementation of 10 pediatric practice guidelines by local multidisciplinary teams. The HTA unit promotes and actively participates in utilization studies and monitoring activities in collaboration with our Pharmacy and Medical Technology departments. It has proactively encouraged primary clinical research in areas of insufficient evidence and directly coached health services research protocols aimed at the assessment of the clinical, organizational and economic impact of local attention programs and quality improvement strategies. In the last 5 years, 200 healthcare professionals have completed a one-year course on clinical effectiveness, constituting a vital human resource basis for future developments. We describe our working scheme and methodology, present some of the most significant results achieved by our HTA program after these first 10-year experience, and discuss some of the unresolved issues and future challenges. Our experience shows that an HTA program is both feasible and useful in a public setting hospital of a developing country. Diffusion of these strategies in scientific meetings and collaboration through regional networks can promote hospital-based HTA, facilitate evidence-based decision-making and generate considerable potential savings in healthcare budgets.

M-264

234 – HTA AND DEVELOPMENT OF A SUSTAINABLE HEALTH CARE SYSTEM – INTRODUCING A PROGRAM FOR COLORECTAL CANCER SCREENING IN NORWAY

Hege Wang, Norwegian Knowledge Centre for the Health Services, Norway; Ånen Ringard, Norwegian Knowledge Centre for the Health Services, Norway; Berit Mørland, Norwegian Knowledge Centre for the Health Services, Norway

The National Council for Quality Improvement and Priority Setting in Health Care (NC) is an advisory body responsible for providing recommendations on quality improvement and priority setting issues to the Norwegian health care system. It is also responsible for giving advice about the introduction of new technologies and public health programs, like national screening programs. The members of the council represent central, regional and local health authorities, health care providers, institutions of higher education, and NGOs. The incidence of colorectal cancer (CRC) is increasing in Norway, and in 2008 CRC was the second most frequent cancer. The case that was put forward to the NC was whether organized colorectal screening should be implemented in Norway. If yes, what would be the preferred screening technology? A comprehensive knowledge base was considered by the NC. This included a HTA report addressing the effect of screening on mortality and incidence rate of colorectal cancer. Additional documentation was provided on international recommendations, experiences from other countries, pros and cons of screening and cost-effectiveness. The NC concluded that screening reduces mortality from CRC, and that both screening with faecal occult blood test (FOBT) and with flexible sigmoidoscopy are effective technologies. The broad discussions also focused on possible negative effects of screening such as false positive or negative tests. Concerns regarding the limited capacity of coloscopy in Norway were also raised. The council recommended FOBT colorectal screening to be introduced as a limited pilot project. The need for giving balanced information to the invitees was underlined, as well as organizing a prospective evaluation from the outset of the screening project. The recommendations have been followed up by the Ministry, and the pilot project will be launched in 2011.

M-265

879 – POST-MARKETING SURVEILLANCE OF HEALTH TECHNOLOGIES: THE ROLE OF RISK MANAGEMENT

Helaine Carneiro Capucho, Hospital of the Faculty of Medicine at Ribeirao Preto, University of Sao Paulo, Brazil; Maria Eulalia Lessa do Valle Dallora, Hospital of the Faculty of Medicine at Ribeirao Preto, University of Sao Paulo, Brazil

Objective: To demonstrate the importance of the Risk Management service (RMS) of a teaching hospital, member of the Brazilian Networks of Sentinel Hospitals and Health Technology Assessment (REBRATS) for phase IV (post-marketing surveillance) studies of health technologies (HT). Methods: The interventions made by the RMS from notifications of problems related to the HT were evaluated in the time period of 2007-2010. Results: During the study period we received 3,424 notifications related to the HT (534 in 2007, 732 in 2008, 811 in 2009 and 1,347 in 2010). It is possible to observe a constant increase in notifications, which resulted from the culture of this hospital for monitoring the HT incorporated by the Institution. Those notifications considered relevant for a possible lack of security from the HT (94%) were referred to Anvisa and to the holder of record of this HT in Brazil, helping the first in post-marketing surveillance and the second to make improvements in their products. To increase patient safety during the use of HT in the hospital, the RMS made interventions such as: the publishing of 89 alerts for monitoring the HT with suspected failures and 16 reports that contained guidelines on handling HT; 38 product lots interdictions; 33 failures of specific brands to avoid further acquisitions; and changes in internal processes. Conclusion: The post-marketing surveillance conducted in this hospital is important for the safety of patients, also aiding the Pharmacy and Therapeutics Committee and the Center for the Evaluation of HT to revise the products standardized by them. Besides the hospital, the surveillance serves the users of the Brazilian health system, because information provided to Anvisa can help them in market regulation and in the review of the technologies already incorporated by the Ministry of Health and, additionally, in assessing the necessity of incorporating new technologies.

M-266
693 – AUDIT MANAGEMENT AND HEALTH AND APPLICATION TOOL PHARMACOECONOMIC

Henry Pablo Lopes Campos e Reis, Unimed Fortaleza, Brazil; Saulo Rodrigo Lucas Ribeiro, Unimed Fortaleza, Brazil; Maria Liana de Magalhães Nascimento, Unimed Fortaleza, Brazil; Joel Bezerra Vieira, Unimed Fortaleza, Brazil; Jussara Barbosa de Freitas, Unimed Fortaleza, Brazil; Ursula Dourado Barsi, Unimed Fortaleza, Brazil; Antonio Eliezer Arrais Mota Filho, Unimed Fortaleza, Brazil; José Luciano Leitão de Alencar, Unimed Fortaleza, Brazil

Introduction: The Pharmacoeconomics can be defined as the application of economic knowledge in Science and Health's mission is to ensure audit quality and efficiency in care. Objetivos: To report the application of pharmacoeconomics as a tool management strategy in a provider of health plans. Metodologia: The methods of cost reduction and cost-effectiveness were applied to the multidisciplinary audit from 2009 Audit Pharmaceuticals in analyzing technology assessments and definitions of protocols: 1) Use of an infusion pump Equipo (BIC) 2) Optimizing the use of antifungal agents, 3) Stewardship Strategy for the rational use of antimicrobials; 4) Payment of antineoplastic agents miligramagem; 5) Change the administration of adjuvant antineoplastic Home care for himself. The analysis was from the perspective of Provider Health care costs were derived from the product table Unimed Fortaleza / Brasíndice (issue 706). 4.Economic: 1) After reviewing the literature, rejected the payment of BIC catheter for administration of antibiotics, regulating the macro gear drops and simple adjustment to infusional time, saving R $ 182,391.65 (2009), 2) whereas anidulafungin and caspofungin are antifungal with efficacy, safety, and similar outcomes for cost-minimization, it was suggested the use of anidulafungin, saving R $ 49,104.02 (Janeiro-Julho/2010) 3) The strategies of antimicrobial stewardship rationalization led economy R $ 131,795.01 in Intensive Care Units (Janeiro-Abril/2010) 4) After studying physical and chemical stability and microbial widened the list of cytostatics with payment by miligramagem for 14 performances, saving R $ 2,066,573, 31 (2009), 5) With the feasibility study of structure and processes in the partner network for the unit itself was agreed modification of 05 drugs to support chemotherapy for Home Care, saving R $ 569,072.95 (2009). Conclusão: The incorporation of pharmacoeconomic tool in the practice of management in health insurance seems to be a viable mechanism and fundamental financial sustainability Provider of Health Plans.

M-267
818 – EVALUATION OF WORLDWIDE RESPONSE TO PROMOTE RESPONSIBLE FOOD MARKETING TO CHILDREN

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Objective: The prevalence of childhood obesity in Singapore has increased over the past two decades. With increasing evidence linking food marketing to childhood obesity, health agencies are calling for international action to promote responsible food marketing to children. A review of the worldwide response was conducted to evaluate the impact and feasibility for implementation in Singapore. Methods: A systemic literature review was conducted on MEDLINE and 3 other databases, focusing on existing international reviews between 1987 and 2006 on the extent of food marketing to children and the scope of relevant regulatory responses. Additional grey literature and policy statements published between 2003 and 2010 were identified by searching key websites and direct contact with other organisations. The systematic reviews and interpretation of evidence in major policy statements were further evaluated by stakeholders (policymakers, clinicians, health promotion experts, nutritionists, and media agencies). Findings: The responses were classified into 3 categories: Legislation, Self-regulation and Industry Pledges. Legislative responses varied from hard regulations (Sweden) to specific restrictions (South Korea). There was no common definition of the age limit, which ranged from 12 to 21 years. Institution of self-regulating codes of conduct was the most common response worldwide. However, most countries faced difficulties in monitoring and enforcement as well as industry resistance. Multi-national food and beverage companies in Australia, Canada, U.S, Thailand, and the E.U. have voluntarily committed to responsible food advertising to children with promising results. Such pledges, however, did not cover all forms of marketing. Media literacy was found to complement the above measures. Conclusion: Singapore, like most countries, adopts a self-regulatory approach towards food marketing. The responses highlight the need to actively engage the industry in order to enforce our policies. We will continue this process of evidence-gathering, review and stakeholder discussion to develop appropriate multi-sectoral approaches in this area.

M-268

502 – ACCESS WITH EVIDENCE GENERATION FOR SURGICAL TREATMENT OF HIV-ASSOCIATED FACIAL LIPOATROPHY IN SPAIN

Carlos Alberto Sanchez-Piedra, Healthcare Technology Evaluation Agency, Spain; Jesus Gonzalez-Enriquez, Healthcare Technology Evaluation Agency, Spain; Iñaki Imaz Iglesias, Healthcare Technology Evaluation Agency, Spain; Antonio Sarria-Santamera, Healthcare Technology Evaluation Agency, Spain

Background: Facial lipoatrophy is a stigmatizing feature of HIV-related lipodystrophy. The AIDS National Plan asked for the inclusion of surgical treatment of facial lipoatrophy for HIV-AIDS patients in the benefit package of the Spanish National Health System. Due to uncertainties about its safety and effectiveness in the long term, Spanish Ministry of Health decided to allow access to this intervention under specific requirements with public funding from the "Cohesion Fund" (Royal Decree published on March 2010). Methods: A prospective study to evaluate the long-term safety and effectiveness of surgical treatment of HIV-associated facial lipoatrophy was proposed. The study design and final protocol was elaborated by an Experts Committee. HIV patients with moderate to severe facial lipoathophy, asking for treatment and giving informed consent, are considered for inclusion. Surgeons perform the treatment under ambulatory or short hospitalization basis. The protocol includes follow-up visits at 1, 12, 18 and 24 months. A web application is available for recording of previous clinical data, surgical intervention and follow-up data (adverse events, lipoathophy grade, pacient subjective assessment, QoL and photographs). The study started in March 2010 and will last three years. Results: Twenty-one hospitals from 11 autonomous regions are involved. Until December 2010 a total of 541 patients have been included, and 359 patients have completed the treatment with the fillers considered in the protocol. A 43.8% of the patients showed a grade III of severity in facial lipoatrophy pre-treatment. A 47.3% of the patients have been treated with biodegradable fillers. No serious adverse events have been reported. Discussion: Access with evidence generation can be a useful tool in health technology assessement, as a mechanism to cover doubtful interventions before taking final decisions. This procedure allows access to new interventions with specific requirements (clinical indication, training, research protocol) and facilitates the development of new evidences.

M-269

803 – MAPPING EFFORTS IN THE HEALTH TECHNOLOGY ASSESSMENT (HTA) FIELD IN BRAZIL, 2004-2010

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Introduction: Health Technology Assessment (HTA) activities were introduced in Brazil in the 1980s, and have increased in the academic setting more recently. In the country, the main stakeholders involved in the regulation process and life cycle follow-up of health technologies are the Ministry of Health, the National Agency for Sanitary Surveillance (ANVISA), and the National Agency for Supplementary Health (ANS). Objectives: Mapping HTA studies funded by the Brazilian Ministry of Health between 2004 and 2010, and assessing the perception of the major stakeholders involved. Methods: The Brazilian Ministry of Health's health research tool was applied for mapping the HTA studies. The perception of stakeholders was obtained through interviews focused on questions concerning the growth and investment in the HTA field, actions performed, HTA priorities and main limitations observed. Results: The Brazilian Ministry of Health funded 217 projects and invested more than 12 million dollars in HTA research between 2004 and 2010. The studies were mainly economic evaluations and systematic reviews. There has been growth in the investment in the area, exemplified by human resources training and information dissemination through different bulletins. All stakeholders interviewed underlined the difficulty on prioritizing studies, recognizing the emphasis on high cost and high complexity technologies. Limitations pointed out include the lack of agreement between managers and technical teams, the need for quick answers, and the need for HTA at the moment of registering the technology in the country. Conclusions: HTA also needs to focus on low and middle complexity technologies, and verifications are necessary along their life cycle. Agreement between managers and technical teams need to be pursued. Moreover, it is necessary to invest in the collection of primary data, and to improve information dissemination.

M-270

303 – DEVELOPMENT AND PROOF OF CONCEPT OF SOFTWARE FOR HOSPITAL HEALTH TECHNOLOGY ASSESSMENT

Irene C. Morilla Bachs, Fundacio Clinic per la Recerca Biomedica, Spain; Laura Sampietro-Colom, Hospital Clinic, Spain; Santiago Gutierrez-Moreno, Fundacio Clinic per la Recerca Biomedica, Spain

Objective: Development and proof of concept of a software aimed to prioritize competing new Health Technologies (HTs) after their assessment using the mini-HTA tool. Methods: Two layer value/risk software was developed based on the mini-HTA. First layer included 12 mini-HTA variables classified in two dimensions, value (safety, clinical benefit, patient impact, cost-effectiveness, evidence quality, innovativeness) and risk (staff, space and process of care impact, incremental costs, net cost, investment effort). Weights given to these variables were obtained from a survey among stakeholders (National, Regional and local). Second layer included information on how the new HT compares with available comparator as regards the mentioned 12 variables, coded as high, equal or low. An algorithm combining first (weights) and second (multipliers) layers was developed, to obtain a value/risk plot. For the proof of concept, the results from the assessment of three new HTs (Surgical Robot, Platelet Rich Plasma, Deep Brain Stimulation) were introduced in the software. Findings: There were not statistical differences in the weights given to the 12 variables among stakeholders. Therefore, median weights considering all the stakeholder groups were introduced in the first layer of the software. The dot plot generated after the proof of concept showed a good discriminative power among the three HTs assessed (surgical robot, platelet rich plasma for total hip replacement and deep brain stimulation for Parkinson), showing that deep brain stimulation is the most valuable and less risky HT to introduce in the hospital. Conclusions: The software developed here allows a robust and straightforward comparison of very different competing HTs; making easier for hospital decision-makers to prioritize investments under fixed budgets.

M-271

918 – AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT IN POLAND (AOTM) – ANALYSIS OF TYPE AND IMPLICATION OF RECOMMENDATIONS TO REIMBURSEMENT DECISION

Magdalena Wladysiuk, HTA Consulting, Cracow, Poland, Poland; Iwona Skrzekowska Baran, Novo Nordisk Pharma, Poland; Agata Schubert, Novo Nordisk Pharma, Poland; Beata Lisiecka, HTA Consulting, Cracow, Poland, Poland

Objectives: To evaluate impact of recommendations of Agency for Health Technology Assessment in Poland on reimbursement decision making process and trends of changes in 2006-2010. Methods: All published by AOTM recommendations from 2006 up to 10.2010 were analysed under: type of technology (drug, diagnostics methods, rehabilitation and others), type of recommendations (unconditional, conditional, mix conditional financing, negative, change in financing, removal), population, specialization, type of service, type of justification. The reimbursement decision were compared with consistency with the type recommendation (also number of them). Results: Until the end of 10.2010, 250 technologies were assessed and 95 of them received negative recommendations (37% of total number). Unconditional recommendations composed 20% and conditional ones (with mix) 25% for drugs. At the end of 2009 only 34 and in 2010 only 13 have been included on the reimbursement list. 25 non drug technologies have been assessed and only 32% have negative recommendations. Unconditional recommendations composed 40% and conditional ones (with mix) 16% for non drug technologies. 81% of all recommendations were connected with adults and mostly in oncology, neurology and psychiatry. From 100 negative recommendations 26% of them were justified due to safety issues and 30% of them due to credibility of HTA analysis. Conclusion: Based on the analysis of number and type of recommendation during the last few years AOTM has increase capability and create feasible system of value judgment. There is still no indication from Ministry of Health when and how the positive assessed technologies could actually be included on the country's reimbursement list or therapeutic programs. There is discontent in Poland especially over the slow pace of access to the most modern cancer and diabetes treatments compared with other countries.

M-272

745 – A RAPID REVIEW OF PATIENT PERSPECTIVES ON OPHTHALMOLOGY SERVICES USING PEER-REVIEWED LITERATURE AND PERSONAL BLOGS

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Background: We conducted a rapid review of selected ophthalmology services, including patient perspectives, in order to support decision-making for disinvestment from, and/or refinement of descriptors for, publicly funded items. Objective: To explore the utility of, potential for, and barriers to, the inclusion of patient perspectives in a rapid review of current publicly funded medical services. Methods: User-community views related to seven ophthalmology services, including cataract surgery, eye injections and retinal photocoagulation, were sourced from peer-reviewed literature and personal weblogs. For cataract surgery, we also collected media articles and community responses relating to proposed policy changes to reduce public funding. Unsuccessful attempts were made to conduct interviews with patients undergoing relevant procedures. We compared findings for user-community views with findings from mini-HTA reviews and guideline concordance conducted for these items. Results: Peer-reviewed journal articles (n=62) and blogs from 54 bloggers in 7 different countries were included. Journal articles focused on quantitative outcome measures including pain scores and patient satisfaction surveys. Findings in the blogs usually supported existing quantitative data but provided contextual rich detail and in some cases highlighted additional issues. However, often the data appeared more relevant to development of clinical practice guidelines rather than disinvestment or descriptor decision-making. Conclusions: Within the restrictions of government-sponsored HTA and the tight timelines imposed, empirical research to gather community perspectives is difficult. Integrated findings from peer-reviewed literature and weblogs can provide insight into patient perspectives on existing technology use and raise key questions for further research but the utility of this information for disinvestment decision-making and refinement of item descriptors may be limited. Patient perspectives on existing health technologies are important for improving patient satisfaction and the quality and sustainability of health services and also flags to policy-makers whether particular disinvestment or refinement decisions are likely to prove unpopular with the community.

M-273

450 – FINANCING HEALTH SYSTEM AND REDUCING INEQUALITIES

Janice Dornelles de Castro, Universidade Federal do Rio Grande do Sul, Brazil; Maria Lecticia Pelegrini, Universidade Federal do Rio Grande do Sul, Brazil

The per capita income was a country's economic development most important indicator; nevertheless, there are different beliefs about the better way to evaluate development. There are also the need to consider ensuring basic social needs of articulating the sustainable economic growth with equity and social justice. The understanding that health sector can create economic development, motivates this study, which is seeking to verify the Health System financing policy capacity to reduce inequalities in health through the relationship between the variation in per capita spending on health and the variation of IDESE, which is an synthetic index that measures the degree of development of the municipalities of the State of Rio Grande do Sul – Brazil, the period analyzed was 2001 – 2005. Data used were from IBGE (Population and Consumer Price Index Expanded-IPCA); DATASUS (Public Budgeting Information System Health – Siops); Foundation of Economics and Statistics/FEE (IDESE). Data processing was performed by calculating variation rate in expenses for each municipality, as well as, the variation of IDESE in the same period. Then, the municipalities were aggregated into quartis according to the percentage of spending on health. The results showed that municipalities with the biggest expenses in the period were the ones with greater IDESE in the beginning, 2001. The average value of IDESE in each quartile, improved little in the period, regardless the level of expense. Some municipalities had negative increment of IDESE (28.6%), worsening their condition over the period and precisely in these cases, the average percapita expenses were higher, with a significance level of 5%. There were small changes in each quartile from 2001 to 2005. The difference in the percentage of health spending has grown in various regions of the State, highlighting the differences within other social indicators. The central region gained greater spending growth; the northern

M-274

451 – ECONOMIC DEVELOPMENT THE PRIMARY CARE CONTRIBUTION

Alice Diefenbach, Universidade Federal do Rio Grande do Sul, Brazil; Janice Dornelles de Castro, Universidade Federal do Rio Grande do Sul, Brazil

The health sector's contribution to the achievement of development has been the subject of research. The goal is to evaluate how large is the capacity of a program for Primary Care – for the Family Health Strategy- to promote positive changes in indicators that influence the conditions of welfare and thus promote development. Municipalities with population of up to five thousand inhabitants have been selected and created two groups: Group I consists of municipalities with the ESF covering 70% or more of the population. Group II are the ones with less than 70% coverage. The analysis was based on the period of one year before, until one after the implementation of ESF, years 2003 to 2005. The variables used are: Idese - Health, infant mortality, GDP per capita, municipal income taxes and transfers SUS /Primary Care. It was expected to be proportionally higher incidence of positive change of variables in those counties where the ESF coverage was high, 70% or more of the population, supporting the idea that the health sector through its policies has the capacity to promote development with improving economic indicators representing the welfare of society. Through the analyzed data, improvement in indicators of both groups has been observed. Notwithstanding, on average, the growth of indexes has been lower within the group with coverage of less than 70%. This suggests the relevance of primary health measures with high coverage of population when it comes to changes in health indicators.

M-275

458 – SAFETY ANALYSIS OF CHEMOTHERAPY UNITS IN MEXICO: A FIVE-HOSPITAL STUDY

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Safety procedures and design characteristics in chemotherapy units in Mexico are not regulated and very few studies have been carried out on these subjects. In order to evaluate this situation, chemotherapy units at five different hospitals were studied. These are third level hospitals that belong to the National Institutes of Health, the Social Security Institute and a private hospital (the main hospital of a 17 hospital group), which constitute a representative sample of highly specialized institutions that apply chemotherapy. Prior to the study, a series of minimal safety characteristics were established, based on published literature. Several different aspects were analyzed: Use of biological safety cabinets and appropriate preparation areas, personnel safety practices, and personnel training among other factors. Although there was a wide variation among the different hospitals, none of the institutions under study obtained more than 80% of the minimal safety standards that were proposed, and most of the problems were common to several of the institutions. As a result, it was found that the most important problems dealt with the design and layout of the chemotherapy units. Compliance with personnel protection equipment and safety procedures were also significantly lacking. Use of safety cabinets was widespread but the placement and design of the surrounding areas were not ideal, and personnel training was in general adequate but could be improved. These results allow us to have a good understanding as to what the main deficiencies in these chemotherapy units are and lead us to propose the nationwide adoption of uniform and compulsory safety procedures.

M-276

476 – COMPARING SMC AND NICE GUIDANCE ON NEW MEDICINES: TIMELINES AND RECOMMENDATIONS, AND THE COST OF CONSULTATION

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Objective: To compare the outcomes and timelines of technology appraisals of new drugs between the National Institute for Health and Clinical Excellence and Scottish Medicines Consortium, before and after the introduction of the "single technology appraisal system by NICE. Methods: All medications appraised, were assessed for differences in outcome or timescale. In the event of re-assessment, final decisions were included. Timings were from marketing authorisation to final decision. NICE appraisals were further analysed by single technology appraisal (STA) and multiple technology appraisals (MTA). Findings: 140 medications were appraised by both organisations. The same outcome was reached in 99 drugs (70.7%), similar ones but with different restrictions in 27 (19.3%), and a different outcome in 14 (10 %). 90.1% of medications were recommended with or without restriction by NICE and 80.4% by SMC. For all medications, the average times for appraisals was 8.7 months for SMC, and 22.9 months for NICE (18.3 months for STAs and 25.1 months for MTAs). For the same medications, NICE appraisals took on average 17.3 months longer (8.2 months for STAs and 19.8 months for MTAs). For cancer medications, SMC took on average 9.8 months compared to 22.4 months for NICE. For cancer-related appraisals, STAs took longer than MTAs (24.15 months and 21.4 months respectively). A significant part of the difference reflected the more extensive consultations by NICE. Discussion: Despite the different approaches between SMC and NICE, the same outcome was reached in 70% of medications. Both NICE and SMC recommend most medications, with or without restriction (90% and 80% respectively). NICE appraisals take longer than SMC, due to the different appraisal systems. The STA system has quickened the time to guidance, except for cancer drugs. The NICE timelines may reflect the "cost of consultation".

M-277

~~597 – EVALUATION OF PROGRAMS AND PROJECTS OF HEALTH AS A TOOL FOR IMPROVING THE EFFECTIVE USE OF~~ RESOURCES IN THE HEALTH SECTOR

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The evaluation of social programs and projects has several concepts. In the theoretical studies and practical experiences, evaluative research incorporates both scientific and technical references, but is distinct from the notion of academic research. In Brazil and worldwide, the health evaluation has incorporated evaluative methodologies derived from social programs and projects. However, in the health, new conceptions of assessment has not been incorporated so full, since they focus, priority, products and results. The General Coordination of Public Health Research of the Department of Science and Technology (Decit) of the Ministry of Health of Brazil adopted a strategy for Monitoring and Evaluation - M & E of researches financed through the National Fomentation. This strategy aims to ensure a smooth process of socialization and monitoring of results / products achieved, and its incorporation into intervention approaches in health problems. Three mechanisms are used for M & E: the issue of technical and scientific reports (partial and final) and financial implementation, monitoring visits and seminars for monitoring and evaluation. From 2004 to 2010 were conducted 14 visits, 05 monitoring seminars and 17 final seminars, in a total of 308 projects evaluated. In contemporary Brazilian society, approaches that involve, through shares and stakeholders, are the key in the health assessment and self- assessments, and in which they interact evaluators and evaluated, individuals and institutions, products and processes are tools that can potentially contribute to improving the effective use of resources in the health sector. In this sense, Decit provides, in seminaries for monitoring and evaluation, plural spaces for discussion, sharing and agreement, involving the participation of State Departments of Health, technical areas of MS nationally responsible for the thematic, Decit, the National Council for Scientific and Technological Development (CNPq), consultants ad hoc and experts on topics of research.

M-278

568 – APPLYING THE CONCEPT OF' USE WITH EVIDENCE DEVELOPMENT' TO NEW TECHNOLOGIES IN ORTHOPAEDIC SURGERY: THE CASE OF HIP RESURFACING ARTHROPLASTY IN DENMARK

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Background: Hip resurfacing arthroplasty (HRA) was identified by the Danish Horizon Scanning System as a potentially important emerging technology in 2006, but in need of long-term follow-up results of safety and effectiveness. The main advantage of HRA included increased mobility during rehabilitation, which was deemed relevant for younger patients. In Autumn 2010, HRA was withdrawn from the market due to safety problems. Objective: To describe and analyse the role of HTA in the process of generating and interpreting the evidence to support decision making on HRA in Denmark. Methods: Literature review on the safety and effectiveness of HRA in the period of 2006-2010. Analysis of policy documents of the National Board of Health, and the Danish Orthopaedic Society (DOS), supplemented with information from (medical) newswires, and interviews with stakeholders. Results: The Horizon Scan recommended to initiate and await results from RCTs comparing HRA with total hip arthroplasty (THA). This was endorsed by the DOS. Consequently, the National Board of Health recommended hospitals to only use HRA in the context of protocolized care to enable comparative effectiveness research. The board also financed an RCT as part of a comprehensive HTA. In 2010, a publication based on Scandinavian registries, including the Danish HTA results, concluded that 2-year results did not support continued use of HRA. The DOS recommended a 5-year monitoring programme for patients that had received HRA. Conclusion and discussion: The case shows that Horizon Scanning was essential in raising awareness in policy and practice about the uncertainty surrounding this promising technology, and thus an essential first step in a structure for use with evidence development. Furthermore, the possibility of financing HTA at the governmental level, and the availability of registries managed by clinical societies are necessary conditions for evidence generation of technologies Key-words: use with evidence development, new surgical technology

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M-279

142 – RESOLVABILITY AND EFFECTIVENESS OF REFERENCE AND COUNTER-REFERENCE TO USERS ENDODONTICALLY TREATED

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The work is a result of a survey that aimed to determine the resolving capacity of two health services in Rio de Janeiro used for reference and cross-reference users for root canal treatment (endodontics) of your teeth. This approach allowed us to evaluate the resolution of the accumulated through the structuring of medium complexity services, organized according to principles of hierarchy and regionality of the Unified Health System The reference to endodontics aims to streamline the service by providing greater coverage by avoiding a subsequent extraction of these teeth for lack of choice of the patient. Data were collected in the unit of primary source and medium complexity referenced. Using the quantitative aspect, the evaluation was made by the reported number of cases resolved on the number of cases treated, and the criterion for measuring the number of clients will be forwarded. The sample included 106 patients in the trial period between May 2007 and February 2009. The variables used were: date of reference date of completion of root canal treatment, date of completion of the channel (cross-reference date) and date of the final restoration of the tooth. The outcomes of reference was 54% and completion of the final restoration of the tooth was 82%. The main reason for not performing in endodontics was not the scheduling of users representing 60%. The user also appears to be responsible for not making treatment or abandonment due to shortages, accounting for 18.5%. The results indicate that there should be further consideration in structuring a system of reference and cross-reference that makes the integration of primary care service with the highest level of complexity in order to meet the health needs of the population, especially with regard to scheduling.

M-280

921 – MANAGEMENT MODELS TO PATIENTS WITH CHRONIC DISEASES THE LEVEL PRIMARY CARE: A LITERATURE REVIEW

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Chronic diseases began to occupy the leading causes of morbidity and mortality in Brazil and worldwide. On the other hand, people with chronic diseases require care over time, access, qualification in care, and participation in their treatment plan. Through the Family Health Strategy (Estratégia Saúde da Família), Brazil has been implementing a health system focused on social equity, that is, co-responsibility between population and health sector. Other countries have developed the Chronic Care Model (CCM), which consists of six components: community resources; health organizations; support for self-care; team organization; support for decision making; and information systems. This work aims to reflect on care models for people with chronic diseases. This is a bibliographical review realized on indexed databases and documents of the Brazilian Ministry of Health. The reviewed studies that were selected address: care management; care models; chronic diseases; and professional-patient relationship. Countries that have developed the CCM were successful in obtaining: the involvement of professionals, patients and managers; the patient's recognition as a subject capable of taking responsibility to take care of their own health; the encouragement to the development of autonomy; their participation in the process of adherence to treatment and health promotion and prevention practices; qualification of professionals through training, second opinions and following of guidelines; and the use of an information system to monitor exams, medications, visits, complications, scheduling, evaluation and planning actions. Considerations: The CCM is a model that can be adapted to different social contexts, developed or developing countries, which enables the involvement of professionals, managers and patients in the care management in order to qualify the health care, adding value to the needs of people.

M-281

626 – BARRIERS IN FACILITATION OF NATIONAL STRATEGIES FOR CONTINUOUS DEVELOPMENT AND SUSTAINABILITY OF HTA IN EUROPE

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Study performed under EUnetHTA JA 2010-2012 project. Objective: The objective of the study was to investigate the current experience, stage of development, needs, scopes and outcomes with emphasis put on factors limiting establishment and performance of Health Technology Assessment (HTA) organizations all over the Europe. Methods: Cross-sectional study by means of a semi-structured questionnaire of HTA organizations was carried out. Standard descriptive analyses were conducted to characterize the responders' organizations and response rate. The content of open-ended questions was analyzed for each question separately. For other kinds of questions, distribution of responses as numerical and percentage rates was calculated. The barriers against the process of HTA organization establishment and performing the ordinary HTA activities were identified and rated using 0-5 Likert scale. The MS Office Excel program was used to perform analysis of data. Results: Answered surveys from 21 European countries were received. Overall response rate was 36.3%. Main identified barriers against establishment of HTA organization were: Funding, Gathering trained staff and Reaching political interest. Mean results for all responders relating to above mentioned barriers were 2.7; 2.6; and 2.5 respectively. The same main barriers were identified against performing ordinary HTA activities by the organization with mean results for all responders 2.1; 2.0 and 1.7 respectively. Subgroup analysis showed similar results in the HTA-doers group, but slightly different among organizations that are not performing HTA activities yet (HTA non-doers). HTA non-doers indicated: Gathering staff, Funding and Agreement with stakeholders as main barriers against establishment of HTA organizations with mean results 3.8; 3.7, and 2.8 respectively. Conclusion: The study has identified main difficulties against establishment of HTA organizations and performing ordinary HTA activities in European settings. It revealed that identified barriers were similar among all responders. To identify sources of this barriers further investigation should be performed.

M-282

789 – IMPLANTATION OF THE NUCLEUS OF HEALTH TECHNOLOGY ASSESSMENT (NATS) IN THE UNIVERSITY HOSPITAL JOÃO DE BARROS BARRETO IN BELÉM – PARÁ

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Introduction: The health system has suffered the impact caused by the increase of expenses in health, where particularly, the growing innovation and technological use have had a main role, hence, the non systematized incorporation and the inadequate use of technologies imply not only risks for the users, but also they commit the effectiveness of the health system. In this context, the Health Technology Assessment (ATS) constitutes a wide investigation process of the emerging or already existent clinical, economical and social consequences of technologies use in health, from the research and development to the obsolescence, whose main objective is help the the health managers in the decision making as for the incorporation of technologies.Objective: To describe the implantation of the Nucleus of Health Technology Assessment (NATS). Methodology: Report of experience about the implantation of the NATS in the University Hospital João de Barros Barreto.Results/Conclusions: The implantation of the Nucleus of Health Technology Assessment in the University Hospital João de Barros Barreto had as strategy the preparation of a workshop to the professionals that would be part of the interprofessional team of NATS, and courses of PTC to the other professionals of the hospital community. Among other actions, we highlight the Elaboration of PTC for the incorporation of new technologies, for instance the Adenosina Deaminase's test in Pleural Tuberculosis's diagnosis, and the accuracy of the D-dimer test in the diagnosis of Deep Vein Thrombosis and Pulmonary Embolism. We believe that the existent technological diversity and the search of appropriate criteria for its use, are factors of which it is indispensable the application of PTC, as well as, the preparation of training courses in the area of ATS, with a permanent education activity to the professionals in the hospital scope, mainly to the of assistance of public health of the region.

M-283

662 – COMPARATIVE COST-EFFECTIVENESS ANALYSIS (CEA) AMONG DIFFERENT RENAL REPLACEMENT TECHNIQUES

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Introduction: The"Institution" is the agency financing in Uruguay the treatment of the three renal replacement techniques (RRT): kidney transplantation (TxR), peritoneal dialysis (PD) and hemodialysis (HD). No previous studies have been performed in Uruguay. Objectives: Assess and compare the magnitude of expenses and cost-effectiveness among the RRTs, also in the context of the national health expenses and in relation of gross domestic product. Methodology: Retrospective cohort study of the three techniques in year 2005 incidents patients. The "end point" studied was death for dialysis and graft survival for TxR. All healthcare costs were estimated in US dollars per patient, per year and per technique by information provided by the "Institution". A Kaplan Meier Survival Analysis and mean cost-effectiveness ratio analysis were made. Subpopulations waiting for TxR in this period were compared to transplantation patients. Results: 612 patients were included: 471 in HD, 109 with TxR and 32 in PD. Mean age at admission was 43,8 years for TxR, 59,8 for PD and 61,1 for HD. Patients with TxR had a significant lower mean age ($p < 0,00001$). The survival probability (P(s)) for HD at years 1, 3 and 5 was 87,5%, 72,6% and 57,8% respectively. The P(s) in PD was 84,4%, 74,6% and 67,1% . The P(s) for the graft in TxR was 96,3%, 95,1% and 80,5%. The mean cost-effectiveness ratio at years 1, 3 and 5 for HD of 221,3; 745,1 ; 1536,8 respectively; for PD 172,5 ; 585,5 ; 1084; for TxR 210,8; 67,3 ; 69,5 and patients waiting for TxR 194; 195 ; 213 . Conclusions: This is the first comparative CEA by different RRT in Uruguay. In the first year, PD has the best mean cost-effectiveness ratio while in years 3 and 5; TxR widely surpasses the other techniques.

M-284
928 – RADIOTHERAPY EQUIPMENT: CHANGES IN THE LAST 10 YEARS IN URUGUAY

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Introduction: Radiotherapy (RT) is prescribed to about 40% of malignant tumors, a major cause of morbidity in Uruguay, with over 13000 new patients diagnosed annually. Assessment surveys of RT units by the Ministry of Public Health (MPH) begun in 2001. In this presentation we describe survey findings until 2010. Objective: To describe current RT equipment status and its changes within the last 10 years. Method: Retrospective study. Data sources (MPH): 2001 Radiotherapy Units Assessment, 2004 and 2007 Medical Technology Census-Department of Medical Technology and 2010 Radiotherapy Equipment Survey. Questionnaires included source type, manufacture year, health sub-sector, and geographic location among several items; all were completed by RT professionals. Results: Linear Accelerator (LA) units surveyed: 3 in 2001, 6 in 2004, 7 in 2007 and 10 in 2010; of them 3 were high energy (HE) and bought entirely new (2 in 2001 and 1 in 2004). Geographic location in 2001 was null outside the capital city (Montevideo), and progressed to 3 in 2010. In 2001, one of them was manufactured over 10 years earlier; in 2010 there were seven over 10 years old. Cobalt Units (CU) surveyed: 11 in 2001, 9 in 2004, 8 in 2007 and 3 in 2010. Geographic location: 3 were located outside Montevideo in 2001, and one in 2010. There was no new CU purchased, and already in 2001 all had over 10 years of manufacture. Considering both types of teletherapy, number of units varied between 13 and 16 throughout the decade. Conclusions: There was a shift in technology, with an increase in LE/LA and a decrease in CU throughout the decade, with incorporation of HE/LA. Acquisitions of equipment were primarily recycled units. Presence outside the capital city of the country increased.

M-285
246 – SYSTEMIC REVIEW OF PSYCHOSOCIAL PROTECTIVE FACTORS OF HEALTH IN CHILDREN

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Introduction: protective factors include circumstances, characteristics, conditions and attributes that facilitate the aim of integral health in children. The psychosocial protective dimensions are the base for the development of a healthy life for children and must be studied in detail, to evaluate which ones have protective function. Objective: Resume the evidence of psychosocial constructs that protect health in children from 6 to 12 years old. Methods: A detail search was done in generic and specialized databases and in meta searchers. Inclusion criteria were language Spanish, English and Portuguese, published between 1999 and 2010.The search was performed between august and November of 2010. Results: We found 22 articles, 1 of them was a systemic review, 10 expert opinion and 9 descriptive articles. The systematized factors were grouped in 3 categories and we found 30 constructs that correspond to individual characteristics, 34 related to familiar context and 11 to communitary environment. Conclusion: The family, which is the social base for the development of affection and learning, contains the majority of protective factors in children. Protective factors are the result of several and complexes processes that interact each other. These factors should be studied in detail to be able to generate health politics related to the promotion of health in children.

M-286

795 – DIGITAL INCLUSION OF COMMUNITY HEALTH AGENTS IN BRAZIL: NEW WAYS OF NETWORK LEARNING

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Despite the many digital inclusion initiatives taking place in Brazil, the number of those excluded from the social technological process is still considerable. This is especially true for professionals from the Family Health Strategy teams (ESF), and even more so for the 1,162 Community Health Agents (ACS) working in the healthcare regions of the Federal District Health Secretariat. These agents have been in the digital inclusion process since 2007, and their needs include: intersecting health Information, Education, and Communication (IEC), adding new communication and information technology, and producing materials for managing information and knowledge in the basic healthcare network. The purpose of the Digital Inclusion Project for agents in Brazil is to: a) describe the health information and communication literacy process for agents, with a focus on content production, reception, mediation, and the social applicability of knowledge production; b) analyze the application of inclusion activities in the regular use of palmtops by agents; and c) evaluate how subjects from a sample group of health agents, community members, and managers using technology, whether directly or indirectly, perceive the results of information and knowledge management. Method: Qualitative study anchored on the results of action research conducted throughout the Health Administrative Regions of the Federal District in Brazil. This 20-month research project is being conducted using a sample of 1,162 professionals involved both directly and indirectly in projects, and that represent regional health councils, communities assisted by community health agents, and managers. Community representatives are selected by health agents during family visits using a casual (random) approach. KEY WORDS: information technology, knowledge management, health communication, health technology assessment.

M-287

334 – NEEDS ASSESSMENT OF SEVERE CHRONIC MENTAL DISORDERS PATIENTS TREATED IN PSYCHOSOCIAL HEALTHCARE SERVICES IN SÃO PAULO, BRAZIL

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Introduction: Psychosocial healthcare services (Centros de Atenção Psicossocial, CAPS) are the principal kind of mental health services established by the Ministry of Health Mental Health Policy in Brazil, and focus their care actions on adults, children, and adolescents with severe mental conditions and substance abuse. The priority of CAPS for adult care is to provide care to patients with severe chronic mental disorders in their community on non-intensive, semi-intensive or an intensive basis. Few studies in Brazil tried to assess the needs of these patients related to living conditions, routine tasks, social relationships and disabilities associated with their psychiatric illness. These studies can be very important for service planning and for the establishment of treatment goals. The aim of this research was to study those needs in patients intensively treated in 21 CAPS in São Paulo, Brazil, in 2007. Methods: Intensively treated patients were interviewed by trained researchers to obtain information about socio-demographic characteristics, symptoms, number of hospitalizations, activities at CAPS and use of health and community services. Needs were assessed using The Camberwell Assessment of Needs (CAN). Results: Three hundred and seventy three patients had their necessities evaluated, of whom 215 (57.6%) were men. Mean age of participants was 41.2 years (s.d: 12.6), 201 (53.9%) met the ICD-10 criteria for schizophrenia, and only 80 (21.4%) had no psychiatric hospitalizations. Daytime activities (91.4%), company (88.5%) and transport (67.6%) were the most frequent requirements. Patients related that they received satisfactory formal help provided by their health service center for daytime activities and company needs but no formal orientation for accommodation arrangements, sexual expression or money. Conclusions: Although patients related that they have received adequate formal help for some of their main needs, it was possible to identify other domains of their lives which health services could take actions to provide.

M-288

11 – IMPACT OF EDUCATIONAL INTERVENTION ON THE PROCESS OF CASE MANAGEMENT OF ACUTE RESPIRATORY TRACT INFECTION AT COMMUNITY PHARMACIES IN PAKISTAN

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Objective: To assess the impact of training of dispensers on the process of case management of ARI at community pharmacies in Islamabad, Pakistan. Method An educational intervention was designed to improve the case management for ARI at community pharmacies in Pakistan. Representatives of chemist and druggist association, drug inspectors, academia, drug sellers and community pharmacist were involved. The focus, targets, contents and format of intervention was designed after a series of discussions with the above mentioned stakeholders. The training workshop included presentations, video clips and group tasks. Sixty pharmacies of Islamabad were randomly selected from the list of pharmacies and were divided into two groups i.e. control and intervention. The targeted group of intervention was dispensers working at these community pharmacies. Dispensers were contacted through formal letter inviting for training and followed on phone for the confirmation of participation After four weeks of training a letter along with a small poster and a sample of standard drug label was sent to the participants of training and were reminded of the request to share the information with colleagues. Post intervention data was collected after two months of training. Findings It was observed that while treating ARI at community in 30 % of the cases weight of the patient, 46.7 % of the cases history of medication and 23.3 % of the cases medical history was asked from the patients after training. An increase in referral from 10 % to 40 % was seen in case of ARI after training. An increase in communication of correct dose and frequency ranging from 55.6 % to 100 % and 37% to 72.2 % was observed after training. Conclusion History taking was found better and the patients were communicated with correct dose, frequency, use and side effects for ARI after training.

M-289

395 – NEW AND EMERGING TECHNOLOGIES FOR THE TREATMENT OF VISCERAL LEISHMANIASIS IN BRAZIL: CURRENT STATUS AND FUTURE PROSPECTS

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Background: An early warning systems, or horizon scanning systems, may relevantly affect the prevention, diagnosis and treatment of neglected diseases, for instance Visceral Leishmaniasis (VL), which is endemic in Brazil. N-methyl-glucamine, a pentavalent antimonial, currently is, and has been for over 60 years, the primary line of treatment recommended by the Brazilian Ministry of Health. This medication is toxic, yet not always effective, and often provokes adverse side effects. Objective: Attempt to identify new and emerging VL treatment technologies. Methods: A comprehensive review of drug-based VL treatments was conducted using the IMS Health database, where technologies in a variety of life cycles were identified. The present study focused on recently launched and phase III technologies. Additional information on the effectiveness of these medications was obtained from many outside sources. Findings: Three VL medications in stages I and II, one in stage III and three other commercially available therapies were identified. Studies concerning Paromomycin, a stage III injectable therapy that was registered in India in 2006, have shown that 94.6% of VL patients were cured safely and effectively. Regarding commercially available technologies, three new drugs were identified: Liposomal Amphotericin B, Miltefosine and Sodium Stibogluconate, the latter two being unavailable in Brazil. Due to its high cost, Liposomal Amphotericin B represents the last line of treatment available in Brazil, despite offering greater effectiveness and lower toxicity. Miltefosine is the first effective oral VL treatment and Sodium Stibogluconate belongs to the family of pentavalent antimonials. Conclusion: In Brazil, many of the latest therapies are expensive and unviable as primary treatment options. This study demonstrated that injectable Paromomycin may represent a viable alternative to N-methyl-glucamine in terms of safety, effectiveness and cost (estimated at US$ 10-15/patient). Further studies should be performed to comprehensively evaluate all VL treatment options.

M-290

621 – BRAIN INJURY REHABILITATION - A HEALTH TECHNOLOGY ASSESSMENT

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Objective: To investigate how patient and relatives experience acquired brain injury. The literature review aims to advice how rehabilitations services can be improved in the perspective of the patients and relatives. Methods: a systematic literature review 2000 -2010 Results: The review describe acquired brain injury as a sudden interruption on many levels in activity and daily living where brain function is different from before. The literature shows that establishing new ways of managing daily life is a difficult tasks requiring substantial energy. As a whole the changes places persons with acquired brain injury in a vulnerable situation both on short and long term. The assessment finds that transitions between institutions are considered especially challenging. Furthermore, to find relevant rehabilitation services is a problem. Patients and relatives benefit from professional case managers with relevant competencies. Besides, studies underpins that the patients need to be active involved in therapeutic and educational approaches that promote the persons motivation, autonomy and self-image of being able to master his or her life situation better. Employment and leisure activities are thought to play a key role in regaining status and self respect. Several studies show that patients need support for a very long time to be able to function in the labour market. Conclusion: To reach the aim of brain injury rehabilitation in the perspective of attaining independence and self-determination requires a structured and long term focus on how to incorporate and collaborate with this group of patients. The group of persons with acquired brain injury is heterogeneous and has a variety of different needs, which easily can be ignored without a qualified professional involvement and a relevant health organisation of the rehabilitations services.

M-291

399 – EFFECTIVENESS OF ADDICTION TREATMENT OF CRACK IN PRIMARY HEALTH CARE: SEARCH IN DATABASES

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In Brazil, there was an increased use of crack, making it a public health problem. The Primary Health Care (PHC) is responsible for organizing health care for the population, their families and community. So, it plays an important role in relation to treatment, harm reduction and coordination of care for drug users. Despite the magnitude of the problem, evaluation of the effectiveness of interventions for the treatment of crack addiction and harm reduction in the APS is little discussed. This study aims to present the search of the literature on the effectiveness of treatment of crack addiction in the APS. We conducted a literature review on the following databases: Cochrane, PubMed, Lilacs, Medline and Scielo between December 2010 and January 2011. The words used for the search were: crack, crack cocaine, crack and primary health care. In Lilacs used the term crack, getting 74 results, 6 selected. In Pubmed, was found, using the terms crack and primary care and crack and treatment and primary care, crack cocaine treatment and primary health care, respectively, 51, 36 and 18 results, none of which was selected. In Cochrane, using the term crack, 177 results were obtained, and selected one controlled trial. In Medline, between 1997 and 2010, there were 19 selected results and one study was found by using the terms addictive behavior and crack. In Scielo, the term crack was used, getting 128 results, with 1 being selected. No studies were identified regarding the effectiveness of treatment for addiction to crack in the APS. Few studies about treatment of crack addiction have been found and most of them had compromised quality.

M-292

503 – MIND THE GAP: STRESSING THE DIFFERENCES BETWEEN NATIONAL AND INTERNATIONAL PERFORMANCE INDICATORS

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Objectives: The main objective of this paper is to perform a comparative study of the performance indicators used in Brazilian and international benchmarking reference models. The study starts with a single indicator, the caesarean rate, common to the majority of Brazilian and international performance systems. By carrying out a comparison, it is possible to identify the main differences regarding the chosen indicator among the evaluated systems. Methods: To analyze the differences in the methods applied to calculate hospital quality indicators, this study analyses the caesarean rate. This rate is present in international systems (AHRQ - http://www.ahrq.gov/), PATH - http://www.pathqualityproject.eu/)) as well as in three of the main Brazilian systems (CQH - http://www.cqh.org.br/, SIPAGEH - http://www.projeto.unisinos.br/sipageh/ and PROAHSA http://www.hcnet.usp.br/proahsa/). The data collection will be performed through secondary sources. This method provides the base to establish an effective methodology and a guide to define a benchmarking program in Brazil. Findings: The caesarean rate is one of the indicators most often used in performance assessment systems. For this indicator, extremely low rates may reflect limited access to health care. Conversely, extremely high rates may reflect a misuse of the care procedure. The actual rates may vary according to the case-mix which considers the complexity of clinical conditions. Conclusions: Healthcare quality assessment and improvement continues to be one of the most important issues for government agencies, professional organizations, insurance companies, users and others. Both in Brazil and abroad there are differences among healthcare quality assessment systems. One of the challenges is to ensure that the Brazilian systems are comparable with the international ones. Currently, several Brazilian healthcare quality assessment systems do not explicitly specify all of the constraints involved in their indicator´s calculus method. This lack of detail makes such a comparison difficult, if not impossible, in terms of methodologies and benchmarking.

M-293

438 – SUSTAINABILITY OF TUBERCULOSIS CONTROL SERVICES: A SYSTEMATIC REVIEW

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The implementation of public policies, strengthening of social control and the quest for sustainability of Tuberculosis (TB) control actions has not been sufficient to eradicate the disease. Viewed as a complex process, sustainability is characterized as an emerging issue and defined as the ability to keep a program or service at a level that can provide prevention and treatment of a particular health problem. The work aims to lift the state of the art of publications on this subject nationally and internationally. To that end, we conducted a search in three databases (PubMed, CINAHL and LILACS), using descriptors indexed and unindexed. As inclusion criteria was established that the articles need to be published since 2005. Were found, in total, 1661 publications on the subject, and these became a pre-selection of 32 respecting the inclusion criteria. Later, they were read in full and 14 were selected, being 11 international and 3 national. To classify them according to evidence level, it ranged between V (a systematic review of qualitative or descriptive studies), VI (descriptive or qualitative study) and VII (consensus or opinion) and, generally, addressed sustainability as an emerging issue as and as a crucial event for the strengthening and maintenance of health services and programs. Thus, was verified the completion of a few studies nationally, which is characterized as a bias, considering that sustainability is a topic that has gained notoriety. We suggest to conduct studies on the subject in order to understand this event and subsequent adaptation of health services to it, especially regarding to the maintenance of TB control actions.

M-294

263 - SHARING INFORMATION REGARDING CANCER SCREENING BASED ON INTERESTS OF DIFFERENT TARGET GROUPS

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Objectives: To develop targeted leaflets regarding cancer screening guidelines that take into account the knowledge required by different target groups. Methods: Desirable information for cancer screening was collected among the public committee by the KJ method (problem-solving mode developed by the Japanese ethnologist Jiro Kawakita) before development of the leaflet and was used to develop the basic content plan. This basic information was reclassified, and the final versions of the leaflets for the following groups were compared: cervical cancer screening targeted at 20-years-old subjects (first group); cervical cancer screening targeted at subjects aged 30 years and older (second group); and colorectal cancer screening targeted at subjects aged 40 years and older (third group). Results: Common interests among the three groups included targeting cancer and screening methods. Although the KJ method revealed that the first group expected broad information, in the final version of the leaflet, only basic information regarding participation in cancer screening programs remained. The final versions in group 2 and 3 were similar to the first interest in an actual plan to participate in a screening program, including details of the screening methods, as well as physical and financial burden expected. Treatment information was initially desirable by all groups, but this information was excluded, since asymptomatic persons who participate in screening are far from treatment. Although information regarding the harm of cancer screening was initially included according to the results of the KJ methods in the second and third groups, the first group did not expect it. Conclusions: A targeted leaflet is a powerful tool to share knowledge regarding cancer screening. We must understand the expectations of different target groups and prepare appropriate leaflets that support the decision to take part in cancer screening.

M-295

310 – THE EFFECTIVENESS OF CARDIAC RESYNCHRONIZATION THERAPY IN THE BRAZILIAN PUBLIC HEALTH SYSTEM (2002-2007)

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Background: The impact of cardiac resynchronization therapy (CRT) in the public health system of developing countries is unknown. Randomized controlled trials have thus far demonstrated the beneficial effects of CRT in advanced heart failure, despite their relatively short follow-up. The observational data, in turn, are of great importance for estimating whether survival benefits are sustained over the long-term. In this context, the aim of this study was to evaluate, in clinical practice, the effectiveness of CRT in the Brazilian Public Health System from 2002 to 2007. Methods: Probabilistic record linkage approach was used to find a cohort of 3525 patients undergoing CRT in the Brazilian Hospital Admission Forms and Mortality Information System. Kaplan-Meier survival curves were plotted and log-rank test was utilized to compare the curves. Cox regression model was applied to evaluate predictors of survival and hazard ratio (HR) was presented with 95% CI. Results: Mean age of patients at implant was 60±13 years, 34% were female. The majority were CRT alone (79.7%) with smaller proportions of CRT-D (20.3%). Mean follow-up period was 2.8 years. At 1 and 5 years, overall survivals were 80% (95% CI 79.4-80.8) and 55.6% (95% CI 54.6-56.6), respectively, and were better in women ($p<0.0001$ by log-rank). Overall survivals of CRT alone and CRT-D were not statistically different in this group of patients ($p=0,237$ by log-rank). Age in decades (HR,1.04; 95% CI 1.00-1.09; $p=0.037$), sex (HR,1.42; 95% CI 1.26-1.60; $p<0.0001$) and year of implant ($p=0.053$) formed the final model of Cox regression. Conclusions: Favorable long-term survival was observed over the years, suggesting improvement in the quality of the Brazilian public health care of patients with advanced heart failure with CRT. Male sex and increasing age in decades were significant predictors of decreased survival in this cohort.

M-296

702 – EFFECT OF TEMPERATURE AND STORAGE CONDITIONS ON THE INSULIN STABILITY MARKETED IN SUS AND RELATIONSHIP WITH THE VARIATION OF BLOOD GLUCOSE IN VIVO

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The aim of this study was to evaluate the stability of the insulin distributed in the SUS in different storage conditions and relate to patients blood glucose levels. The assay of insulin was validated by spectroscopy / UV through linearity, precision, accuracy, robustness and specificity. The study used thermostability room temperature and refrigerated at 0 to 15 days. The calculation for the validity period of chemical kinetics followed. The blood 80 patients was collected at home for in vivo tests at 0, 15 and 30 days after opening the bottle. All were given glucose levels and glycosylated hemoglobin A1C fraction. The validation results r2 was greater than 0999. The method proved to be precise and accurate (CV 0.4%) and recovery rate (99.99%), even when subjected to robust change detection (wavelength), pH and solvent suppliers. The specificity, evaluation of placebo samples showed no interference in the analysis of insulin. The period of validity in refrigerated conditions, was obtained the reaction of zero order and first order for the room temperature. Thus, the T90% values were 27.1 and 42.3 days respectively, stating that the temperature influences the life of the product. The results of the patients showed a fluctuating glucose levels varied significantly between time zero, 15 and 30 days (115 ± 18 mg / dl, 173.5 ± 23 mg / dl and 160 ± 15 mg / dl respectively). The glycosylated hemoglobin values were stable with values close to 7%. A significant increase in glucose levels after 15 days of opening the bottle of insulin, which may be related to the reduced stability of the same or because of their misuse as it is dispensed by the SUS pharmacy insulin Novolin N ® under the suspension form.

M-297

529 – DISTANCE EDUCATION TECHNOLOGY FOR COMMUNICATION BETWEEN NURSES AND BLIND PEOPLE

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Introduction: Distance Education (DE) is a teaching-learning process that occurs reciprocally between teachers and students. This process is facilitated by technology use for communication to occur between people in different physical environments and at different times. Communication is human beings' ability to express their ideas, thoughts, feelings and emotions. The communication process can occur in two ways: verbal and non-verbal. The verbal way can be observed through writing and speech. Non-verbal communication covers body gestures, behaviors etc. AIMS: To train students-nurses regarding communication contents through DE: permit integration between nurses' previous knowledge and experiences; permit learning a new communication model to blind patients. Method: Experimental, education technology development research, ongoing at the Health Communication Laboratory of the Nursing Department at the Federal University of Ceará. The course will be applied to a group of 25 nurses through DE, starting in March 2011. Then, the students will hold consultations will blind people, which will be recorded and assessed at the end of the course. Results: The nurses are expected to gain training through the course. Thus, they can attend to blind people during nursing consultations according to communication model and assess their behavior and attitudes towards communication with the blind during the consultation. Conclusion: The use of distance education helps nurses to learn about verbal and non-verbal communication and its use with the blind through this innovative didactical method, as communication is fundamental for quality care.

M- 298

199 – THE EVIDENCE-BASED MEDICINE AS A SAFETY PARAMETER FOR THE JUDICIALIZATION OF HEALTH POLICIES

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Background: In Brazil and other countries, the judiciary branch plays an active role in health policies, due to the phenomenon called judicial activism or judicialization of health. Aim: To establish useful parameters to support the judicial power in cases involving health policies and drugs. Discussion: It is known that scientific evidence is associated with a lower rate of errors. Though, it is expected that legal practitioners recognize evidence as a basis for decision-making. However, one of the greatest challenges on implementing this premise is the broad discretion held by the judges, as there is no hierarchy of legal evidence (Principle of free persuasion of the judge). The Brazilian Cochrane Center, from the experience gained in tackling the issue, believes it is possible to establish three precepts, which would ensure that judicialization of health policies could be conducted safely. Conclusion: First of all, when the object of the lawsuit reveals a high level of scientific evidence, the judicial intervention will be legitimate. The inertia of the government, in such situations, can be characterized as faut du service, legitimizing judicial mediation. In the other hand, it there is no available evidence, the judiciary branch may, as a rule, dismiss the case. However, in such situations, the judge can conduct an extensive analysis of the peculiarities of the case, trough the performance of forensic expertise. Finally, if there is scientific evidence that points against the intervention, the judicialization of health policies may cause damage to the collective and the individuals health. By ignoring evidence, the Judiciary Branch will be denying the constitutional right to health; though, for reasons unrelated to science, believes to be guarantying it.

M-299

81 – INEQUITY ON THE PROFILE OF ORAL CANCER PATIENTES ASSISTED AT A HIGH COMPLEXITY ONCOLOGY CENTER IN CURITIBA-PARANÁ, FROM 1999 TO 2008

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Objective: To analyze the inequity on the profile of oral cancer patients assisted at the High Complexity Oncology Center (CACON) in the Erasto Gaertner Hospital (HEG) during the time period between 1999 and 2008. Method: quantitative, with a cross-in database with records of 1,434 people suffering from oral cancer. Included were people whose disease falls within the International Classification of Diseases (ICD – 10) classification of oral cancer: C00, C01, C02, C03, C04, C05 and C06. The outcome endpoint was the staging of the illness at the moment of hospital admittance. The data was systematized and submitted to frequency distribution analysis, utilizing the non-parametric U Mann-Whitney and Kruskal-Wallis. Results: The study population was 82.2% male, 93% caucasian, mean age 58 years. The majority (63.2%) was resident in Curitiba and its metropolitan area, the remainder from the interior of the State of Parana and Santa Catarina northwest. 37.5% of cases registered so with stages III and IV. Inequity in relation to the disease stage were observed by gender ($p = 0.001$), family income ($p = 0.00$), topography of the lesion ($p = 0.00$), survival ($p = 0.001$) and associated risk factors ($p = 0.00$). Conclusions: The results indicate a polarization in the distribution of mouth cancer, reaching the most vulnerable groups. There is need for qualified service primary health care strategies that support health promotion, prevention and specific treatment in early stages of oral cancer disease.

M-300

677 – ESTIMATING THE COVERAGE AND THE ADHERENCE OF WOMEN TO THE CERVICAL CANCER SCREENING PROGRAMME OF THE RIO DE JANEIRO STATE

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The Brazilian cervical cancer screening programme uses the Cervical Cancer Information System (SISCOLO) to monitor its performance. However, the adopted indicators are built on the production of Pap smear tests which limites the scope of the evaluation. This study aimed to estimate the coverage of the target population (between 25 to 59 years old) and the women adherence to the programme of the Rio de Janeiro State. The probabilistic record linkage based on Fellegi-Sunter method was applied to the SISCOLO database from July 2006 to June 2009 in order to estimate the number of women attending the programme. Out of 2,030,074 tests, 1,477,147 women were found. This allowed to estimate the total programme coverage of 0.10, while in the target population, representing 70.7% of the total women, the annual coverages were 0.13, 0.12 and 0.12 respectively in the period. Regarding the adherence of woman to the programme, 74.4% were identified in only one of the three-year period. For women identified in two years of the period, 13.2% were identified consecutively and 7.9% non consecutively. Besides, 4.5% were identified in all of the three years. Among the identified women, 4.2% presented a positive test result for cellular atypia in the Pap smear test. Taking into account the first year, out of 638,324 women identified, 30,562 (4.8%) presented a positive test result. Out of those, 42.3% did not return for examining in the next two years. The 7,626 remaining women were followed up in the next years, and 20.0% presented a persistent positive test result in the second year, 10.0% in the third year and 3.6% in all the three years. The findings pointed out an estimated coverage below the annual target of 0.30, failures in the follow up and women with persistent positive test results in the three-year period.

M-301

869 – USE OF GASTRIC LAVAGE IN THE DIAGNOSIS OF CHILDHOOD PULMONARY TUBERCULOSIS: A SYSTEMATIC REVIEW

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Objective: To analyze standardization of gastric lavage protocols in the diagnosis of pulmonary tuberculosis in children. Methods: A systematic review was conducted for the period between 1968 and 2010 in the following databases: LILACS, SCIELO and MEDLINE. The search strategy included the following terms: “gastric lavage and tuberculosis” or “gastric washing and tuberculosis” with the restriction of “children aged up to 15 years;” “gastric lavage and tuberculosis and childhood” or “gastric washing and tuberculosis and childhood.” There were retrieved 82 articles and their analysis was based on information on the gastric lavage protocol for the diagnosis of pulmonary tuberculosis in children: preparation of children and fasting; time of gastric aspiration; aspiration of gastric residues; total volume of aspirate; solution used for aspiration of gastric contents; decontaminant solution; buffer solution; and time for forwarding samples to the laboratory. After a thorough analysis, 15 articles were selected. Results: Only two articles detailed the whole procedure with information about amount of gastric aspirate; aspiration before or after solution injection; solution used for gastric aspiration and buffer solution used. However; no article reported the wait time between specimen collection and laboratory processing. These results showed, still, the inconsistencies of gastric lavage protocols. Conclusions: Although gastric lavage is a secondary diagnostic approach used only in special cases that did not reach the diagnostic scoring as recommended by the Brazilian Ministry of Health, there is a need to standardize gastric lavage protocols for the diagnosis of pulmonary tuberculosis in children.

M-302

190 – INTERVENTIONS IN THE SCHOOL ENVIRONMENT IN ORDER TO REDUCE OBESITY: A SYSTEMATIC REVIEW OF THE BANK OF THESIS FROM THE HIGHER EDUCATION PERSONNEL IMPROVEMENT COORDINATION (CAPES)

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A systematic review of literature on studies about interventions in schools environment in Brazil aiming the reduction of obesity and life changes habits in schools was done. Thesis and dissertations published in the Higher Education Personnel Improvement Coordination (CAPES) from 1987 to September 2010 were investigated. The studies were selected based on the reading and analysis of their titles and summaries, to perform a quality analysis based on the Downs & Black (1998) protocol. From the 107 thesis and dissertations selected, 48 duplicated studies and 53 that did not fit the criteria of selection were excluded. The analysis of the 6 remaining studies demonstrated that the intervention period varied from 4 months to 3 years. It was also observed in 4 out of the 6 studies the applied intervention was on nutritional education. The 2 others investigated the encouragement of physical activity and the increase of milk consumption. Positive results regarding the nutritional education in schools were found in 2 studies, whereas the others found no significant changes after intervention, suggesting the need of longer run interventions. It was not possible to combine studies in a meta-analysis due to methodological diversity of the same. We concluded that there are few intervention studies conducted in Brazil within the Graduate Programs and CAPES and there is the need to expand interest in the subject, given the importance of the topic. Lasting longer interventions and the monitoring of outcomes are necessary to evaluate the effectiveness of these actions. It is also suggested the relocation of the CAPES Thesis Database searching system, combining key words in between and guiding institutions to provide the studies in order to facilitate access to information.

M-303

57 – USE OF AN INTERACTIVE MULTIMEDIA APPLICATION AS A SUPPORT FOR TEACHING MAMMARY SEMIOLOGY

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Teaching techniques must be dynamic and, indeed, have been in constant progress. Recently, and quite aggressively, new features implementing the technology of information have been used in medical education. However, the scarcity of resources and its applicability in gynecology teaching is notorious. The objectives were: a) the development of an application for the teaching of breast semiology using computational resources, b) make it available on the World Wide Web (Internet), c) measure the learning of students who interacted with the application. To perform the test and evaluate its potential application in medical education, students from different institutions of medical education were invited. During 45 days 313 hits were made, but only 95 users responded the entire questionnaire. The theme chosen was breast semiology, presented in two distinct ways. The students, at random, could choose a conventional lecture made available through video and was allowed to interact in a linear manner with the material, or choose a multimedia application, with a nonlinear interaction. There was also the possibility of access to both forms of presentation, which was done by 34 users. The evaluation was composed of twenty (20) multiple choice questions, and at the end a Likert scale, to check the usefulness of the application, should be answered. The results showed that users who used only the conventional lecture (CL) had worse performance compared to users who used the multimedia application (MA). Accordingly, users who used both the resources got higher grades when compared to the group of students who used only the multimedia application, respectively (CL = 15.4, MA = 17.5, CL + MA = 17.9, $p < 0.0001$). Given the evidence presented, it is concluded that the use of multimedia application favored learning and the retention of knowledge for students.

M-304
151 – IMAGE PROCESSING SOFTWARE IN THE DETECTION OF CERVICAL CANCER

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Preventive gynecological exam consists of an exfoliative cytology associated with a colposcopy. The colposcopy provides magnified images of the cervix, allowing the identification of patterns of chromia and vascular changes. The cervical mucosa is better seen and highlighted by the methodology that employs the use of substances that promote tissue instant reactions, such as 2.5% acetic acid and iodine solution (Schiller test). The use of images in medicine is considered an important resource in medical diagnostics. The subjectivity of interpretation, the expansion of programming resources and development of specific software, together with the creation of hardware with greater processing capacity, favored the emergence of new techniques to help professionals in the manipulation of images. Thus, this work will be directed to implementation of techniques for digital colposcopic image processing, based on classic algorithms to directly assist the detecting of, although discrete, cervical epithelial abnormalities. The identification of reliable evidence for the assumption of a classification process, among which is the calculation of the area, their length, shape, color, borders, with other possibilities that the observer thinks it's necessary, determine the improvement of the sensitivity, specificity and accuracy in the interpretation of various images from the cervixcolposcopy. Significant regions of 56 colposcopic images were processed, being 30 normal and 26 with distinctive epithelial alterations, according to the report of a specialist. The system helped to identify 96% of the lesions on colposcopic images after application of the pre-processing technique. About 36% of these images showed some kind of noise after segmentation. Importantly, in the images that were analyzed without the pre-processing technique, only 69% of the epithelial lesions were detected, with 31% of false negatives, resulting in very high percentages of error for a screening system for cervical cancer.

M-305
705 – HEALTH CARE MANAGEMENT PROCESS IMPROVEMENT: CENTRAL SUPPLY AND STERILIZATION CASE STUDY IN A PUBLIC TEACHING TERTIARY HOSPITAL

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Introduction: For the past 25 years, sterilization processing was decentralized requiring complex procedures throughout the hospital increasing workload, limiting capacity and equipments obsolescence was imminent. The IC-HC/FMUSP has 976 beds performing 28,800 surgeries yearly, in 43 operating rooms. Yearly, the Supply and Processing Department – CME – warranted sterilization of 516,000 packs. In March 2009, upon Direction's decision to centralize sterilization processing a project was designed to improve quality control, re-design sterilization processing physical areas, as well as integrate new technologies. Methods: An interdisciplinary Project responsible team was designated. Project Server® aided to sub-divide into: Physical sub-project (including pre-accreditation hospital self-assessment, market research, demand versus productivity study) and Process (CME change to interim location, operating procedure standards review, operational training). Results The architectonic renovation project encompassed rational use of newly incorporated technologies and heightens 80% demand expansion, unidirectional flow, as well as comfort and ergonomics, i.e., appropriated illumination and furniture, ambient temperature and thermodesinfectors and sterilizers automatic robotic charging system. The new CME won a 707 m² area and US$ 1.56 million

physical renovation. Three companies presented proposals, the decision was analyzed consumption, productivity and safety criteria. The new CME has 03 efficient steam sterilizers (instead of the old 08 ones), 04 thermodesinfectors (instead of the old 03), 01 low temperature steam with formaldehyde hybrid sterilizer, 01 cart washer machine and 01 hydrogen peroxide plasma sterilizer. New equipments added US$ 1.21 million costs. Nurses were involved throughout the process, reviewed procedure standards and engaged in operational trainings. Conclusion: Innovative CME centralization required renovation during 18 months and had costs over US$ 3 million including traceability system. Technological upgrade to the automatic robotic system provides resources optimization. Timely, the new CME complies with Best Hospital Practices standards and has won 80% productivity efficiency, ensuring quality and safety of services provided.

M-306
288 – MOBETRON 1000 (MOBILE ELECTRON BEAM SYSTEM)

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Objective: Widespread implementation of intraoperative radiotherapy (IORT) programs is hindered by logistics involved in transporting patients from operating room to the radiation oncology department for treatment. This technology review aims to assess safety, effectiveness and cost effectiveness of Mobetron, a mobile electron beam system for IORT that can be used in existing operating rooms with reduced shielding requirements and logistics. Methods: A systematic review was conducted by searching scientific databases which include Pubmed, Proquest, EBSCO Host, Medline, CINAHL, Science Direct, Cochrane Database of Systematic Reviews, HTA databases, Horizon scanning databases and FDA website. Relevant literature were critically appraised and graded according to US/Canadian Preventive Services Task Force. The review was peer reviewed by external experts. Findings: There was limited evidence on the effectiveness and safety of Mobetron® 1000 for intraoperative radiotherapy. However, there was no evidence on the cost effectiveness. This device has obtained FDA approval. Limitations of the device include; the maximum energy level of 12 MeV makes Mobetron® 1000 unsuitable to be used for gross residual tumours. It cannot be used in unshielded operating room if the workload exceeds four patients per week. Conclusion: In view of the limited evidence, Mobetron® 1000 can be used for research purpose to provide more quality evidence.

M-307

838 – PHARMACOGENETICS AND HEALTH ECONOMICS OF CYP19A1 IN POSTMENOPAUSAL BREAST-CANCER WOMEN TREATED WITH AROMATASE INHIBITORS

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Breast cancer is a global public health burden with more than one million new cases diagnosed annually. Endocrine therapy (ET) is an important component of adjuvant therapy in postmenopausal women with hormone receptor positive breast cancer. Aromatase inhibitors (AI) are the preferred modality of ET when compared with tamoxifen (T), despite higher costs. But some pharmaco-economics studies had shown that might be a substantial economic burden on society with relative small benefits. Target markers for a subset of patients who might preferentially benefit from AI than T need to be identified to best optimize the benefit of these drugs. The aromatase gene has been resequenced and functional genomics have been performed on the identified nonsynonymous coding single nucleotide polymorphisms showing significant decreases in levels of activity. These findings are consistent with a hypothesis that genetic variation in the CYP19 gene might be important in the activity of aromatase inhibitors. In this work, we will analyze the effect of the single nucleotide polymorphisms (SNPs) rs4646 (C/A) located at the 3'-untranslated region (3'-UTR) of CYP19A1 gene, on 5-year disease-free survival (DFS) or overall survival (OS), and the effect of TTTAn (rs60271534) on aromatase inhibitor-associated arthralgia (AIAA) (a common and often debilitating symptom in breast cancer survivors). After that, we will develop a Markov model to determine whether rs4646 genotyping in AIs user women are cost-efectiveness for maximized DFS and OS and to explore the impact of TTTAn (rs60271534) and its frequency on AIAA. Our study aims to reveal whether the polymorphisms rs4646 and TTTAn (rs60271534) may be useful tools to guide the indication for aromatase inhibitors in postmenopausal women with to reduce the musculoskeletal adverse effects, as well as disease-free survival in a cost-effective way.

M-308

953 – CONTENT VALIDITY OF THE QUALITY OF LIFE SCALE FOR PATIENTS WITH WORK-RELATED MUSCULOSKELETAL DISORDERS (QOL-WMSD SCALE)

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Background: This work is the second part of an in progress research which is supported by the Brazilian Network for Health Technology Assessment (REBRATS) whose the main objective is to develop, validate, and standardize the Quality of Life Scale for Patients with Work-related Musculoskeletal Disorders (QoL-WMSD) to the Brazilian context. Methods: We interviewed fourteen patients participating in a support group constituted by individuals with WMSD. Patients were asked to say what quality of life means to them. From these responses, we found the descriptors and dimensions linked to the quality of life construct. The findings of the content analysis were gathered with a systematic literature review by searching a wide range of medical and psychological journals. Descriptors and dimensions pertaining to other quality of life measures were also investigated with the goal of finding specific and general characteristics that could contribute to developing the QoL-WMSD Scale. Findings: The set of 72 descriptors was organized into 4 dimensions: 1) Physical Aspects, which include the sub dimensions Mobility and Locomotion, Pain and Discomfort, and Independence; 2) Occupational Aspects that involve the sub dimensions Chance of Disability, Financial Difficulties, and Stability and Security; 3) Psychological Aspects; and 4) Social Aspects, which include the sub dimensions Leisure and Social Support. An additional sub-scale was developed to evaluate general aspects of quality of life that were potentially affected by the specific WMSD. Conclusions: From these dimensions, the items will be investigated in a five-point Likert scale distributed in two sub-scales. The first sub-scale will explore the intensity of some aspects of quality of life before acquiring a work-related musculoskeletal disorder, and the second sub-scale will ask for these aspects during the WMSD. Dimensions, descriptors and items of the QoL-WMSD Scale will be presented as a result of the content validity process.

M-309

652 – VACCINE SELF SUFFICIENCY AND ADJUVANTS

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Brazil provides free influenza vaccines for those >:60 years. A production plant for influenza, now begining production, was planned for 20 million doses/year and must cope with: increase of older people. Evidence that school children is the source of influenza virus to families. AH1 virus infects young adults, small children and pregnant women populatin living in the North-NE of Brazil we vaccinated each year in April after the peak of flu is gone. Our own developent of a whole viral vaccione, has an yield 2 tp 7 times larger than split vaccine, and by maintaining intra-viral, more conserved antigens, protect against related strains. Development of new whole cell pertussis vaccine, obtained by removl of LPS allows Butantan to convert LPS to monophosphoryl lipid A, a powerfull adjuvant, which bind to TR4, stimulating thymocytes to increase immune response, without inflamatory reactions. 10 ug of MPLA (yearly capacity 20 Kg) was shown to be a powerful adjuvant, combined with other, reducing as tested in volunteers, 3-4 fold influenze vaccine antigen. Northern Hemisphere seazonal vaccine is going to be produced at the time when the plant is idle. Additional ongoing project shows that MPLA is a adjuvnt for a recombinant Leishmania vaccine, developed by IDR, and if protective, will control the disease in humansm by dog vaccination. Recombinant Hep B vaccine left about ten million unprotected adults, tht woud not respond to the usual vaccine. The use of MPLA seems abnle to decrease the amount of antigen for children, and immunize adults > 50 years. The use of MPLA is being tested with a candiate ovary tumor vaccine by Ludwig Foundation.

M-310

991 – INTERLEUKIN-12 IN CHILDREN WITH SEPSIS AND SEPTIC SHOCK

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Aims: To examine the behavior of interleukin-12 (IL-12) and verify whether it can be used to differentiate children with septic conditions. Methods: Septic children aged between 28 days and 14 years, prospectively enrolled from 01/2004 to 12/2005, were divided into sepsis (SG; n = 47) and septic shock (SSG; n = 43) groups. IL-12 was measured at admission (T0) and 12 hours later (T12). Disease severity was assessed by PRISM score. Results: IL-12 did not differentiate children with sepsis from those with septic shock at admission [SSG: 0.24 (0 – 226.4) = GS: 1.23(0 – 511.6); p=0.135] and T12 [SG:6.11 (0 – 230.5) = SSG: 1.32 (0 – 61.0); p=0.1239]. Comparing moments, it was not observed statistical difference for SG [SG- T0: 1.23 (0 – 511.6) = T 12h: 6.11 (0 – 230.5) - p= 0.075]. However, for SSG, IL-12 increased from T0 to T12 [SSG - T0: 0.24 (0 – 226.4) < T 12h: 1.32 (0 – 61.0) - p= 0.018]. The mean percentage agreement between clinical diagnosis and laboratory findings were 59.7% and 58.5% for SG and SSG, respectively without any statistical difference between groups and time points (p >0.05). There is no correlation between IL-12 at admission and PRISM score for both groups. Conclusion: IL-12 does not differentiate septic conditions and is not related with disease severity at admission. In septic shock patients it increases with time. Key words: interleukin-12, children; critical care; sepsis; septic shock

M-311

718 – DEVELOPMENT AND VALIDATION OF RISK SCORE TO HOSPITALIZED PATIENTS FOR CLINICAL PHARMACY RATIONALIZATION IN A HIGH COMPLEXITY HOSPITAL

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Introduction: The risk score development was based on drug related problems (DRP) literature. DRP is defined as a wind or circumstance involving drug therapy that actually or potentially interferes with desired health outcome. Among the DRPs are: drug interactions, medication errors and adverse reactions. Aim: To develop and validate an instrument for drug-related problems risk classification in hospitalized patients to rationalize clinical pharmacy services in a high complexity hospital Methods: Risk factors selected from literature to be included in the score were: number of drugs (polypharmacy, defined as concurrent use more than four drugs), high alert medication; use of total parenteral nutrition or tube; age (children and elderly); comorbidities and immunocompromised patients. We defined eight indicators with scores ranging from zero to four and the sum was categorized as high risk ≥ 9, moderate 5-8 and low ≤ 4. The interobserver agreement was assessed in a subsample using the Kappa statistical. The agreement with the other items was analyzed using McNemar test. Results: The score was applied to 1442 patients with 398 (27.6%) of them presenting high risk, 612 (42.4%) moderate risk and 432 (29.9%) low risk. The prevalence renal and/or hepatic problems was 50.2%, cardiac and/or pulmonary problems 61.5% and immunocompromised patients 52.6%. Regarding the number of drugs prescribed, the use of 0-5 drugs was verified in 68.8% of the patients with low score and the use of 11-15 drugs in 63.1% of the patients with high score.It was administered by two independent observers in 145, within 12 hours. The kappa coefficient was 0.89. The items of disagreement were number of medications (P = 0.04), use of potentially dangerous drug (P = 0.01). Conclusions: The instrument properly classified the degree of risk with good reproducibility, which allows us to evaluate the need of Clinical Pharmacist to inpatients monitoring.

M-312

936 – APPLYING ASSESSMENT IN TOOLS, PROCESSES AND PEOPLE IN HEALTHCARE ORGANIZATIONS

Leandro Zerbinatti, Fundação Atech, Brazil; Leila Mara Faccioli, Fundação Atech, Brazil

Solutions for health care providers are complex and involve expertise from various professions working in patient care without exposing him to unnecessary risk. In Systems Engineering, a complete solution consists of tools, processes and people. In the healthcare environment it could not be different. The information processing solutions to implement evidence-based medicine decision making are called critical information systems. The Capability Maturity Model Integration - CMMI is used to evaluate the maturity and capability to development systems process and also for the development of health information systems. Accreditation processes is a “method of assessment of institutional resources, voluntary, regular and reserve, which seeks to ensure the quality of care through the previously defined standards.” In Brazil, the main methods used for accreditation are “Organização Nacional de Acreditação - ONA, Joint Commission and Accreditation Canada. The methods used in evaluation and accreditation are interviews, investigations, evidence, documents, information systems that people use in the work process. A good solution in healthcare organization ensures the implementation of evidence-based medicine, using aspects of information technology, processes and health care professionals who turn to technology in an efficient process of care. Assessment and accreditation check the consistence of methods, models and standards set to ensure that the procedures, tools and people will improve the patient’s life. If the tools and defined, processes are efficient, professionals are trained to perform their activities; a constantly improving service is built.

M-313

522 – USE OF LONG-ACTING BRONCHODILATORS IN HOSPITALIZED PATIENTS WITH EXACERBATION OF COPD

Letícia Toss, Hospital de Clínicas de Porto Alegre, Brazil; Carolina Baltar Day, Hospital de Clínicas de Porto Alegre, Brazil; Maria Angélica Pires Ferreira, Hospital de Clínicas de Porto Alegre, Brazil

Introduction: The long-action beta-adrenergic agonists (LABA) have been increasingly used in hospitals for management of exacerbations of chronic obstructive pulmonary disease (COPD). There are few evidences on the efficacy and safety of these agents in this context. Objectives: To describe the profile of patients using formoterol during hospitalization for the treatment of COPD exacerbation, and compare it to those who received only short-acting bronchodilators; check if there are differences in the use of short-acting bronchodilators and in the occurrence of adverse effects related to bronchodilators. Material and methods: We collected and analyzed demographic, clinical and laboratory data of COPD patients hospitalized from January to July/2010. There were defined two groups: users of formoterol (FOR) and users of short-acting bronchodilators. Value of p<0,05 was considered significant. Results: In the FOR group (n = 63), 50.8% were women, with average age of 66 years, and 71.4% had COPD. Formoterol was used in association with salbutamol and/or ipratropium in 96.8% of cases and isolated in 2 (3.1%) cases. In the BCA group (n=33), 58.1% were women, with average age of 67 years, and 80.6% had COPD. Inhaled salbutamol in doses above 1600 mcg/day was used in 15 and 4 (23.8% versus 12.1%) patients in groups FOR and BCA, respectively; ipratropium in doses above 160 mg/day was used in 14 and 4 (22.2% versus 12.1%) in groups FOR and BCA. ECG changes occurred in 15,8% e 18,1%, and duration of hospitalization was 16 and 14 days in FOR and BCA groups respectively. Twelve cases of hypokalemia were observed in FOR group, versus 5 cases in BCA group. Conclusions: In most cases formoterol was used in association with high doses of short-acting bronchodilators. It is necessary to increase the sample for definitive conclusions.

M-314

844 – THE USE OF VIRTUAL LEARNING ENVIRONMENT TRAINING IN BASIC LIFE SUPPORT FOR PROFESSIONALS SYSTEM MOBILE EMERGENCY (SAMU-192): AN EXPERIMENT IN SUSTAINABILITY

Liliana Rodrigues do Amaral, Hospital Alemão Oswaldo Cruz, Brazil; Fabio Renato Espadaro, Hospital Alemão Oswaldo Cruz, Brazil; Sheila Wadih Sassine, Hospital Alemão Oswaldo Cruz, Brazil

The Virtual Learning Environment can be defined as the most advanced interface between user and computer; it allows interactions and experiences in an active and personal. This capability made the virtual learning environment becomes popular and used particularly in health, and employee training to emergencies. This teaching method allows an interactive and participatory, using clinical scenarios that replicate real-life experiences, enabling the greatest number of people with a lower cost. The aim of this paper was to use the virtual learning environment for the training of professionals in the Emergency (SAMU 192) in Basic Life Support, verifying adherence and aggregation of knowledge. The methodology was field research with a quantitative, descriptive and exploratory, and involved one hundred and fifty units of the SAMU 192 in Brazil, training of tutors of local school and method of assessing learning with pre-and post-tests. The results show the formation of three hundred local tutors in eight workshops held over the period February to September of 2010, with the aim of presenting a platform for education, evaluation methods and regulation of terms of activities. Until December 2010 had the full participation of ten thousand five hundred forty-two students, with one hundred percent compliance and aggregation of content. We conclude that the new method of distance learning using virtual learning platform, video classes and complementary activities, causes the student to be included in the digital environment, covering a larger number of people in a shorter time, reducing costs of operation and training allows the continuity of the standard programs in a sustainable way.

Tuesday Session, 28th June

T-001

189 – THE IMPACT OF HOME DENTAL CARE IN ELDERLY

Keila Cristina Rausch Pereira, Universidade Do Sul De Santa Catarina, Brazil

Through the aging process the human body undergoes several chances reducing functional capabilities. In this stage of changes there is more prevalence of chronic degenerative diseases. This process can be aggravated by the level of elderly dependency that put him in a situation of home care. With the difficulty or even the impossibility of displacement of the elderly with functional dependence for medical/dental care, oral health problems aggravated affecting the compromised quality of life of elderly. This study aimed to evaluate the impact of home dental care in the quality of life of bedridden elderly people in Tubarão, SC. For the sample, 25 elderly were selected in a home care situation registered at USB – Becker Clinic (Morro da Caixa neighborhood) – Tubarão. Before treatment, a questionnaire of self perception of oral health interference in quality of life, IODD, was applied. The initial porpoise of the research was achieve the basic attention procedures of care provided by SUS, but after evaluating their needs, a adaptation was necessary. Were realized 10 rebasing of total prosthesis, 7 restored teeth, and 15 prophylaxis held in elderly patients who had teeth. All the seniors and caregivers were educated about oral hygiene, oral and prostheses care. The average initial score of IODD was 30,96 in 56% of the sample, in a period longer than 3 mouths after the treatment, the average score was 8,48 in 28% of the sample. Providing more advanced procedures and in many places (home, hospitals …) into the system would facilitate the inclusion of the bedridden elderly that now a days find your selves without access of dental care services. The home dentistry should be thought as a strategy to assist the quality of life in elderly who are in home internment.

T-002

975 – SYSTEMATIC REVIEW OF PROGNOSTIC SIGNIFICANCE OF CHROMOSOME 18Q LOSS OF HETEROZYGOSITY IN COLORECTAL CANCER

Ko Ryeojin, Neca: National Evidence-Based Healthcare Collaborating Agency, Korea, Republic of; Lee Seonheui, Neca: National Evidence-Based Healthcare Collaborating Agency, Korea, Republic of; Kim Areum, Neca: National Evidence-Based Healthcare Collaborating Agency, Korea, Republic of; Kim Yeulhong, Department of Internal Medicine, Korea University, College of Medicine, Korea, Republic of; Jeong, Seung-Yong, Department of Surgery Seoul National University College of Medicine, Korea, Republic of; Lee In Kyu, Department of Surgery, College of Medicine, The Catholic University, Korea, Republic of; Seong Moon-Woo, Center for Clinical Services, National Cancer Center, Korea, Republic of

Objectives: To evaluate the prognostic significance of 18q Loss of Heterozygosity (LOH) in colorectal cancer patients. Methods: We conducted a systematic review of the literature searching the following databases: MEDLINE, EMBASE, the Cochrane Library and Eight domestic databases including KoreaMed. Cohort studies to assess 18q LOH using molecular methods by genotyping microsatellites markers in relations to survival outcomes were included. Two reviewers independently selected data in standardized form and assessed the methodological quality. Quality evaluation was performed by SIGN method. Results: Total 25 studies were included. The frequency of chromosome 18q LOH observed was 39.7-80.1% in colorectal cancer. The results of the relationship between chromosome 18q LOH and survival prognosis was inconsistent. The results of Fourteen studies provided suitable data for meta-analysis, and showed significantly worse overall survival in patients with 18q LOH (RR = 1.51, 95%CI 1.22-1.87, I2=64.1%, p=.001). However, there was significant evidence for heterogeneity between studies. This is thought to result in differences microsatellite marker choice on chromosome 18q, and thresholds required to determine LOH. Conclusions: There are contradictory results of relationship between chromosome 18q LOH and survival prognosis. Although, meta-analysis showed that colorectal cancer with 18q LOH have poorer prognosis, it is unclear to make generalization about the prognostic significance of 18q LOH, since there was heterogeneity of assessment methods and results. It would be necessary to make a consensus for these microsatellite markers to assess 18q LOH in colorectal cancer.

T-003

600 – GENERATING EMPOWERMENT IN HEALTH AMONG ROMA PEOPLE IN SWEDEN THROUGH WORK INTEGRATED LEARNING

Cristine Crondahl, University West, Sweden; Leena Eklund, University West, Sweden

In Sweden the Roma People live under worse conditions than the average, have worse health, do not have full access to health and social care, lack influence in the society and are powerless and poor in both social and economic terms. In order to overcome the oppressed situation and to become empowered the Roma need specific skills and competencies, which they may apply to a variety of health concerns. To tackle this issue a 2-year intervention financed by the European Social Fund was initiated. The idea is to strengthen the individual development, and to increase the possibilities of the Roma to take control over their own health and life situation through work integrated learning (WIL). Objective: To assess the effectiveness of WIL to empower the Roma participants in health matters and to cope with the oppression and discrimination. Methods: The data consists of qualitative interviews of the participants of the intervention as well as observational notes and were analyzed by qualitative content analysis. The study design is process evaluation including data collection before, during and after the intervention. Only the "before" data will be reported in the conference. The rest of the data will be collected and reported at a later stage of the intervention. Findings: The preliminary results show that the participants' self-esteem grew after the intervention start. Their attitude towards life became more positive and they reported to be able to better cope with stress and life events. Roma people's tendency to normalize their long-lasting oppressed situation was perceived as an obstacle. Conclusions: The preliminary results indicate that WIL is a worthwhile approach in strengthening the individual empowerment of Roma people and helping them cope with the ongoing health stressors in life. Further analysis of the data is presently under work and will be presented in the conference.

T-004

763 – SALUTOGENESIS AND EMPOWERMENT AS PROMINENT APPROACHES FOR A SUSTAINABLE HEALTH PROMOTION – SOME THEORETICAL COMPARISONS

Leena Eklund, University West, Sweden; Monica Eriksson, University West, Sweden

Extensive evidence proposes Antonovsky's salutogenic theory as a pathway to health promotion. The fundamental concept of salutogenesis is Sense of Coherence (SOC). Salutogenesis is defined as the process of movement towards the health-end of the health ease/dis-ease continuum. The aim of empowerment is to reduce inequity through a learning process and mobilize the uneducated for social action. Empowerment is defined as a process enabling the people to increase control over their health determinants. Empowerment still lacks a coherent theoretical basis. It is claimed that empowerment and SOC have much common and are sometimes overlapping. However, the relationship between these concepts has not been verified by research. Objectives: To compare the salutogenic theory with the empowerment concept and approach. Methods: Data consists of a worldwide systematic research synthesis (1992-2003) including 471 scientific publications and an on-going follow-up to 2010. The search was performed through PubMed, Libris, ISI, PsychInfo, Cinahl, Social Services Abstracts and Sociological Abstracts. The analysis was conducted by comparing selected indicators of both theories, such as approach, theoretical focus, definitions, orientation, key concepts, measurement instruments, outcomes and applicability. Findings: There are both similarities and differences between the concepts, which also somewhat overlap. Several unique and distinctive features for each concept were found. Salutogenesis is based on stress theories whereas empowerment has its roots in pedagogy and social psychology. Both concepts are process oriented. Empowerment can be seen as both means and an outcome whereas salutogenesis is a global life-orientation. Both concepts can be applied at the individual, group, health systems and societal levels. Both proved to be effective in promoting health. The two concepts differ when it comes to definitions and theoretical foundations. Conclusion: Both approaches are promising methods that can lead to improved health outcomes and are seen as viable public health strategies.

T-005

960 – ASSESSMENT OF PREVENTIVE AND THERAPEUTIC ALTERNATIVES RELATED TO OSTEOPOROTIC HIP FRACTURES IN ELDERLY WOMEN IN BRAZIL

Maria Dolores Santos da Purificação Nogueira, ANVISA, Brazil; Leticia Krauss Silva, Fundação Oswaldo Cruz, Brazil; Mariane Branco Alves, UFRJ, Brazil

The study focused on secondary prevention of osteoporotic hip fractures through screening with bone densitometry plus antiosteoporotic drugs, compared with the expectant alternative, for women ≥ 65 year old; both alternatives were complemented by hospital plus rehabilitative care for the corresponding hip fractures. Two decision analyses were elaborated to carry out the study: a) screening with bone densitometry and antiosteoporotic drugs compared with the expectant alternative; b) the most effective secondary prevention strategy, according to the first analysis (a), compared with the expectant strategy, both alternatives complemented by public hospital care, either average care or care delivered at the Brazilian National Institute of Traumatology and Orthopedics (INTO). Figures for adhesion/adherence and effects of antiosteoporotic drugs were obtained through the analysis of available randomized controlled trials. Brazilian hospital information system databases and national demographic data, as well as clinical data produced by a prospective study conducted at INTO, were used to provide figures related to hip fractures care and survival. First decision analysis showed that secondary prevention measures will have low effectiveness in preventing osteoporotic hip fractures in Brazil, that is, 5 prevented hip fractures by 1000 women admitted to the program, corresponding to less than 10% of the expectant alternative estimated fractures, for any of the available drugs. Sensitivity analyses were carried out regarding adherence and efficacy figures; no relevant change in results was found. The second decision analysis, taking into account hospital care, indicated also low effectiveness of secondary prevention, which accrued only 20.3/14.7 life years saved by 1000 women admitted to the program and attended at average public service/INTO service. These poor results were related to several shortcomings of the Brazilian public health system in facing emergency fractures in the elderly, which should be taken into account in decision making and by cost-effectiveness analyses related to osteoporotic fractures.

T-006

64 – DOSE-RESPONSE RELATIONSHIP OF INHALED CORTICOSTEROIDS IN CHILDREN WITH PERSISTENT ASTHMA: SYSTEMATIC REVIEW AND META-ANALYSIS OF BENEFITS AND HARMS

Linjie Zhang, Universidade Federal do Rio Grande, Brazil; Inge Axelsson, Ostersund Hospital, Ostersund, Sweden; Mei Chung, Tufts Medical Center, United States; Joseph Lau, Tufts Medical Center, United States

Objective: To assess dose-response relationship (benefits and harms) of inhaled corticosteroids (ICS) in children with persistent asthma. Methods: We conducted a systematic review and meta-analysis of randomized, controlled trials (RCTs) that compared two or more doses of ICS in children aged 3 to 18 year old with persistent asthma. MEDLINE® was searched for articles published between 1950 and August 2009. Main outcomes of our analyses include morning and evening PEF, FEV1, asthma symptom score, β2-agonist use, withdrawal due to lack of efficacy and adverse events. Meta-analyses were performed to compare moderate (300 to 400 µg/d) with low doses (≤200 µg/d beclomethasone-equivalent) of ICS. Results: Fourteen RCTs with 5768 asthmatic children that evaluated five ICS were included. The pooled standardized mean difference (SMD) from 6 trials showed a small but statistically significant increase of moderate over low doses in improving FEV1 (SMD 0.11, 95%CI 0.01-0.21) among children with mild to moderate asthma. There was no significant difference between two doses in terms of other efficacy outcomes. Local adverse events were uncommon and there was no evidence of dose-response relationship at low to moderate doses. Conclusions: Compared with low doses, moderate doses of ICS may not provide clinically relevant therapeutic advantage in children with mild to moderate persistent asthma. Additional RCTs are needed to clarify the dose-response relationship of ICS in persistent childhood asthma.

T-007

179 – EVALUATION OF RAPID TEST FOR ANTI-HCV DETECTION AMONG ORAL FLUID SAMPLES

Patricia Pais Martins, Fiocruz, Brazil; Helena Medina Cruz, Fiocruz, Brazil; Leticia de Paula Scalioni, Fiocruz, Brazil; Moyra Machado Portilho, Fiocruz, Brazil; Elisabeth Lampe, Fiocruz, Brazil; Livia Melo Villar, Fiocruz, Brazil

The accessibility of a very accurate, rapid, point-of-care test for hepatitis C virus (HCV) may be valuable in addressing the problem of under-diagnosis of HCV, by increasing opportunities for testing outside of traditional laboratory settings. In this work, a new HCV rapid test device (OraQuick® HCV rapid antibody test) was evaluated among oral fluid samples obtained from HCV suspect cases and health individuals and compared it to Enzyme Immunoassay (EIA) results among paired serum samples. Oral fluid samples are collected directly on a collection pad protruding from the device, before placing the device in a vial of pre-measured developer solution which transports the sample into the device and allows it to run. Alternatively, serum samples were obtained from all individuals and tested using a commercial EIA (HCV Ab, Radim). Reactive results by rapid test generate a reddish-purple line at the test zone. A second control line which detects human IgG ensures that the patient sample has been collected and has migrated beyond the test zone. Devices are interpreted between 20 and 40 minutes. In this study, 30 individuals gave paired serum and oral fluid samples, which 9 were anti-HCV reactive and 21 were anti-HCV negative by EIA and OraQuick ® HCV rapid antibody test. These results demonstrated 100% of sensitivity and specificity of OraQuick ® HCV test. OraQuick ® HCV test appears to provide sensitivity and specificity that is equal to laboratory-based tests and may increase testing opportunities due to its simplicity and flexibility. However further studies using a large number of paired serum and oral fluid samples from different population (acute and chronic HCV cases, drug users, individuals living in remote areas) will be studied to prove this hypothesis.

T-008

255 – THERAPIES FOR RARE DISEASES (RD): CHALLENGES IN ADOPTION AND ACCESS. IS THERE A ROLE FOR EVIDENCE-BASED MEDICINE?

Vanessa Teich, Medinsight-Evidências, Brazil; Camila Pepe, Medinsight-Evidências, Brazil; Luciana Clark, Medinsight-Evidências, Brazil; Carlos Ruchaud, Genzyme, Brazil; Elisa Sobreira, Genzyme, Brazil

Background: Rare Diseases (RD) are defined as those potentially fatal or chronically debilitating diseases that require combined efforts to be diagnosed and treated. Methods: we reviewed the literature and legislation of several countries in different continents to appraise which is the present status of drug incorporation and access for patients with RD and also if Evidence-based medicine has a role in improving the pace of change in this area. Results: we evaluated the RD legislation in the United States, Japan, Australia, European Union, Taiwan, Brazil, Colombia and Uruguay. Basically, most of the countries studied have some kind of legislation on RD that gives incentives such as market exclusivity and financing to the Pharmaceutical industries (PI) in order to accelerate the discoveries in the field. The revision of the literature concerning EBM and RD involved many topics such as methodological challenges, the need for patient registries, the importance of evidence overview, limitations of time, sample and outcomes in study designs and which are the best options and the limitations imposed on health technology assessment (HTA) for RD. Conclusion: RD are a special group of diseases with characteristics that may hinder the application of conventional HTA techniques. However, that does not preclude the search for the best available evidence and the best study design possible. As these are often very expensive therapies, they, at the same time, treat a very specific and reduced number of patients, so the correct evaluation of their impact is even more important for countries with an emerging economy and an universal health coverage, such as Brazil.

T-009

775 – GEFTINIB (G) VERSUS CONVENTIONAL CHEMOTHERAPY (CT) FOR THE 1ST LINE TREATMENT OF ADVANCED NON SMALL CELL LUNG CANCER (NSCLC) PATIENTS WITH EPIDERMAL GROWTH FACTOR RECEPTORS MUTATION (EGFRM): A SYSTEMATIC REVIEW (SR) AND META-ANALYSIS (MA)

Luciano Paladini, Evidencias, Brazil; Otavio Clark, Medinsight-Evidencias, Brazil; Tobias Engel, Evidencias, Brazil, Luciana Clark, Medinsight-Evidencias, Brazil

Objective: To perform a SR and MA in order to determine if, in NSCLC patients with EGFRm the use of G, an EGFRm inhibitor, is superior to conventional chemotherapy. Methods: First we searched many different databases in order to identify randomized controlled trials (RCTs) that have compared G against CT in the treatment of NSCLC. Searched databases were MEDLINE, CENTRAL, LILACS, EMBASE and Abstract of major meetings. All relevant studies were retrieved and the data analyzed with RevMan statistics package. End points of interest were: Overall Survival (OS), Progression Free Survival (PFS), Overall Response Rate (ORR), Complete Response (CR) and Toxicity. For time to event data, we calculated the hazard ratio (HR) by a fixed-effect model (inverse-variance method) and for dichotomous events we calculated the relative risk (RR). The statistical level of significance was set at 95%. Statistic heterogeneity was assessed through the I2 method. Results: Our search retrieved more than 400 studies, for of which 4 fit the inclusion criteria. All studies compared G against a combination of Platin CT. A total of 648 patients were included in these studies. The OS analysis showed a trend to favor G, but the analysis did not reach statistical significance (HR= 0.82; 95% CI 0.63 to 1.08; p=0.15; I2=15%). PFS significantly favored G (HR= 0.42; 95% CI 0.35 to 0.50; p<0.00001; I2=58%), as did the ORR (1.87; 95%CI 1.60 to 2.19; p<0.00001; I2=58%) and CR (5.60; 95%CI 1.0 to 31.4; p=0.05; I2=0%). Overall, G showed less Grade III/IV toxicity than CT. Conclusion: Geftinib is an effective 1st line treatment for NSCLC, with less toxicity and better PFS than conventional chemotherapy. More studies are needed to determine a possible advantage in overall survival.

T-010

776 – PLATIN COMPOUNDS (PC) PLUS TAXANES (T) AGAINST T ALONE FOR THE TREATMENT OF METASTATIC BREAST CANCER (MBC): A SYSTEMATIC REVIEW (SR) AND META-ANALYSIS (MA)

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Context: In the last years, the use of PC was incorporated to the treatment of MBC, combined to T, but the real effect of this combination was never adequately proved. Doubts about PC efficacy and toxicity are still lingering. Objective: To perform a SR/MA to determine if the addition of PC to T in the treatment of MBC is linked to clinical benefits. Methods: We searched different databases to identify randomized controlled trials (RCTs) that have compared PC+T against T in the treatment of MBC. Searched databases were MEDLINE, CENTRAL, LILACS, EMBASE and Abstract of major meetings. All relevant studies were retrieved and the data analyzed with RevMan statistics package. End points of interest were: Overall Survival (OS), Progression Free Survival (PFS), Overall Response Rate (ORR) and Toxicity. For time to event data, we calculated the hazard ratio (HR) by a fixed-effect model (inverse-variance method) and for dichotomous events we calculated the relative risk (RR). The statistical level of significance was set at 95%. Statistic heterogeneity was assessed through the I2 method. Results: Five RCTs with 1028 patients in total were included in the final analysis. Four used PC+ Paclitaxel and one used Docetaxel. No benefit in OS or RR was linked to the addition of PC to T: OS (HR= 1.01; 95%CI 0.80 to 1.28; p=0.94; I2=67%); ORR (RR = 0.96; 95%CI 0.86 to 1.08; p=0.52; I2=63%). Additional analysis performed to address this heterogeneity (random effects analysis) have not changed the results and diminished the heterogeneity. The PFS analysis showed a huge statistical heterogeneity (I2= 95%) that could not be explained with additional analysis, making inappropriate to poll the data. Toxicity was similar between groups. Conclusion: Adding platin compunds to taxanes for the treatment of metastatic breast cancer do not benefit patients in terms of survival or response.

T-011

577 – COST-EFFECTIVENESS EVALUATION OF THE HYDROGEL 2% PRODUCED IN PHARMACY COLLEGE TO TREATMENT AMBULATORY PATIENTS WITH LEG ULCERS

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Objective: This study aimed to evaluate the effectiveness of hydrogel 2% in patients with leg ulcers from the lesion and compare the cost of using hydrogel 2% with industrialized hydrogels available in the national fair. Method: This is a study of therapeutic intervention, prospective and non-controlled clinical trial. The sample consisted of 20 volunteers of both sexes who were followed during 90 days of treatment with the hydrogel 2% from February to October 2010. This study was submitted to Ethics Committee in Research of the University Hospital on advice CAAE: 0154.0.258.000-08. The costs were measured in the value of national currency (Real). Results: The results showed that 62 5% of volunteers were predominantly female, the average age ranged from 11.4 ± 60.5 years. The most prevalent tissue in the initial assessment was the yellow slough that averaged 3.75 ± 1.2 in the presence of the wound bed. In draft after 90 days of treatment with hydrogel 2%, was obtained important tissue changes to healing or to reduction area lesion (p = 0.0416). Granulation tissue began to prevail with an average of 3.12 ± 1.0, and also 25% of the volunteers had total healing (100% tissue epithelization). Regarding the analysis of costs treatment with hydrogel 2% stood out initially that the treatment of ulcers belonging to area 1 was higher than the second area of ulcers, and this variation of $ 114.40 to $ 393, 23 (mean = $ 227.55 and SD = 72). When compared with the industrialized hydrogels in its proportion of 100 grams, it was noted that the costs of treatments ranging from $ 107.26 and $ 300.63 (p = 0.0312). Conclusion: The hydrogel 2% masterfully manipulated in a pharmacy college is an alternative for the treatment of chronic wounds because it proved to be a cost-effective alternative

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T-012

748 – EFFICACY OF MYCOPHENOLATE MOFETIL IN COMPARISON WITH RAPAMYCIN INHIBITORS ON THE MAINTENANCE THERAPY FOR RENAL TRANSPLANTATION

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Immunosuppressive drugs are essential for maintenance therapy after renal transplantation because they reduce the incidence of acute rejections and prevent graft loss. The main group of drugs used in maintenance immunosuppressive therapy combines a calcineurin inhibitor, an antimetabolite agent, i.e. mycophenolate mofetil (MMF), and a corticosteroid. Another strategy used for this purpose is the substitution of the first two classes mentioned above for the rapamycin inhibitors, sirolimus (SIR) and everolimus (EVE). Thus, this study compared the efficacy of these inhibitors to antimetabolites. In order to achieve this we carried out a systematic review followed by a meta-analysis. The search strategy was applied to MEDLINE, LILACS and Cochrane Central Register of Controlled Trials and a handsearch to identify relevant studies. Two reviewers assessed studies for eligibility and quality independently. The criteria for inclusion were all Randomized Controlled Trials (RCTs) that compared these drugs during the maintenance treatment (> 6 months) in adult patients who underwent kidney transplantation only. RevMan was used for Data Analysis. Data of 12, 24, and 36 months were synthesized (random effects model) and the results expressed as a relative risk with 95% confidence interval. Six RCTs were included in total: three compared MMF vs. EVE (high dose and low dose) with a 12- and a 36-month follow-up; and three RCTs compared SRL vs. MMF with a 12- and a 24-month follow-up. We observed that acute rejection, graft and patients survival results showed no statistic significance for all comparisons and in all analyzed periods. Conclusions: there are few studies about this comparison; however it was shown that there is no statistically significant difference in the efficacy of these drugs. Thus, we suggest conducting a pharmacoeconomic analysis in order to support better decision-making. This study is being developed by the same research group.

T-013

519 – LASER TREATMENT FOR BENIGN PROSTATIC HYPERPLASIA: A SYSTEMATIC REVIEW

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Objective: To undertake a systematic review of the efficacy and safety of different laser techniques versus transurethral resection of the prostate (TURP). Method: A bibliographic search was conducted in February 2010 using pre-established inclusion and exclusion criteria and targeting the principal biomedical databases. We only included systematic reviews, meta-analyses of randomised controlled trials (RCTs), and RCTs that compared TURP to laser techniques. Results: Of the 495 studies retrieved, 29 met the selection criteria. Finally we included 5 systematic reviews and 5 RCTs that compared TURP to the following laser techniques, i.e., visual laser ablation (VLAP), contact laser prostatectomy (CLAP), interstitial laser coagulation (ILC), holmium laser ablation (HoLAP), holmium laser resection (HoLRP), holmium laser enucleation (HoLEP), potassium-titanyl-phosphate (KTP) and thulium laser resection (TmLRP), though in some cases only a single RCT had been conducted. In the case of the latest laser techniques, such as high-intensity diode (HiDi) or HPS 120-W laser, no published RCTs have been retrieved to date. Conclusions: The scientific evidence is very heterogeneous as regards methodological quality and variables studied. Laser techniques show an efficacy equivalent to that of TURP in the relief of symptoms, as measured by the International Prostate Symptom Score, maximal urinary flow rate and reduction in postvoid residual volume. With respect to incontinence and urinary retention, retrograde ejaculation, erectile function, percentage of reintervention and mortality, the safety of the latest laser techniques (HoLRP, HoLEP, KTP and TmLRP) is comparable to that of TURP. While in general no differences in adverse results were found, a less lost of blood in the most recent laser techniques over TURP was observed. In urinary catheterisation time and hospital stay, the latest laser techniques had a clear advantage over TURP. Intervention time was longer for laser techniques, particularly HoLEP, HoLAP, HoLRP and KTP.

T-014

587 – INGUINAL HERNIA LAPAROSCOPIC REPAIR IN A HEALTH MAINTENANCE ORGANIZATION, BRAZIL

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Introduction – A hernia is defined as a protrusion of tissue, structure or part of an organ through the muscle or membrane where it is normally inserted. It is estimated that 5% of the population will develop some type of abdominal hernia, and among them, the prevalence of inguinal hernias is 75%. Objectives – To evaluate whether the laparoscopic approach compared to open surgery, for inguinal hernia repair, is safer and more effective considering the outcomes assessed were recurrence, postoperative pain, hospital stay, return to daily activities, complication rate and costs. Methodology - We performed a search for studies involving patients with femoral and inguinal hernias repaired by laparoscopy compared to open surgery We retrieved information from Unimed Paraná`s system management, in its database, to contrast with the data found in scientific literature. Results - We included 7 systematic reviews with or without meta-analysis and economic evaluation. Studies have shown that there is no difference in hernia recurrence between laparoscopy repair and open technique. In terms of hospitalization the data are controversial. When the Unimed Paraná's data was analyzed, there weren't clinically significant differences in hospital stay. On the other hand, in the scientific literature, laparoscopy provided less postoperative pain and faster return to normal activities. However, there was a higher incidence of serious rare complications such as vascular and bladder lesions; as well longer operative time. In fact, the hernia repair's cost in Unimed PR System was significantly higher for video laparoscopy representing 2.2 times more expensive. (p <0.000). Conclusion - The decision to incorporate the laparoscopic technique as a routine therapy will depend on a balance between the benefits such as less postoperative pain and return earlier to usual activities; the higher risk of serious rare complications and 2.2 times higher cost than the open technique.

T-015

217 – ROUTINE USED OF ACETAMINOPHEN FOLLOWING CHILDHOOD IMMUNIZATION

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Introduction: Acetaminophen is very widely used as an antipyretic as well as analgesics because of its high efficacy and good safety profile. It is used to relieve mild to moderate pain and to reduce fever. In children, it is considered as a safer antipyretic compared to other drugs including in fever after receiving immunization. Even in many cases, acetaminophen is administered to relieve possible risk of high fever or febrile convulsions in children after routine infant vaccinations. However, there was a claime said that acetaminophen may reduce the immunogenicity of vaccine in children. Objective/AIM: The objective of the technology review was to assess the safety, efficacy or effectiveness and cost-effectiveness of routine used of acetaminophen following childhood immunization, either it's caused the vaccine to lost its effect or not. Methods: Literature review was conducted by searching a wide range of a few databases included PubMed, Ovid Medline (R) from 1990-2006 (EBM Reviews – Cochrane Databases of Systematic Reviews), National Horizon Scanning, and INAHTA regarding the effect of acetaminophen on childhood immunization. Those databases were covered a medical journal and paediatric journals for the topic of interest. Findings: Only one study was retrieved regarding the effect of acetaminophen on childhood immunization. The randomized controlled trial showed that the routine prophylactic use of acetaminophen may reduce the antibody response. No study was retrieved on the cost-effectiveness. Results and Conclusions: The acetaminophen can be used for fever treatment following vaccination. However routine prophylactic use of acetaminophen to prevent fever following vaccination is not advocated as there was only one evidence showing that such practice reduced the immunogenicity of the vaccine. More quality evidence is required to support the effect of acetaminophen in the immunogenicity of the vaccine such as multicentre randomized controlled trials (RCT). KEY WORDS: Acetaminophen, childhood, immunization and immunogenicity

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T-016

218 – SYRIJET MARK II: NEEDLELESS INJECTOR

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Introduction: Needleless system is a device which provides and alternative to needles for various procedures to minimize pain and reduce the risk of injury involving contaminated sharps. Needleless System is well known since the sixties in various fields including in dentistry. In addition to reduce pain, it claims to minimize needle prick injuries among health care practitioners. Objective/AIM: The objective of this technology review was to assess the safety, efficacy or effectiveness and cost-effectiveness of Syrijet Mark II: Needleless Injector in dentistry. Methods: Literature review was conducted by searching a wide range of a few databases included PubMed, Ovid Medline (R) from 1990-2006 (EBM Reviews – Cochcrane Databases of Systematic Reviews), Ovid Medline (R) from 1990-2006 (EBM Reviews – Cochcrane Databases of Controlled Trial), National Horizon Scanning, and INAHTA. There was no limit in the search. Findings: The search found two studies on efficacy and two studies on safety of Syrijet Mark II: Needleless Injector in the area of dentistry. There was also retrievable evidence on FDA approval for Syrijet Mark IV under 510(k) in 1979. However, there was no evidence on cost-effectiveness of Syrijet Mark II. Conclusions: The efficacy and safety of Syrijet Mark II: Needleless Injector in dentistry is inconclusive. More quality evidence is required to support the used of Syrijet Mark II in dentistry. Besides, the cost per unit versus effectiveness must be considered before using in routine practice. KEY WORDS: Needleless system, dentistry and Syrijet.

T-017

955 – SYSTEMATIC REVIEW OF CLINICAL RISK MANAGEMENT INTERVENTIONS FOR PREVENTION OF ADVERSE EVENTS IN HEALTH CARE ORGANIZATIONS

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Background: Patient safety has become a major global priority, leading to the generation of policies to encourage the implementation of systems for clinical risk management (SCRM) for the prevention of preventable adverse events in clinical settings. SCRM are multi-component systems that analyze adverse events or clinical process and have a structured prevention module in their methodology. Objective: In the context of health technology assessment (HTA), to determine the components and effectiveness of clinical risk management systems for the prevention of adverse events in health care facilities. Methods: We conducted a mixed systematic review with a quantitative component that identifies effectiveness outcomes and a qualitative component that identifies the steps and characteristics of each SCRM and how they work in their particular contexts. We used the methodology of the Cochrane Public Health Group and the Center Eppi with integration of the two components. Results: We included 25 studies for the quantitative component of effectiveness and identified 105 studies for the qualitative component of SCRM. We identified 7 SCRM reported in the literature (proactive and reactive). There are little, poor quality and contradictory evidence to measure the effectiveness of 4 SCRM. Comparative tables were created as a result of a meta-synthesis of information which shown the similarities and differences among them. Discussion: There is no evidence of high quality to identify which is the most effective SCRM for prevention of adverse events. There are several methodologies of SCRM that are systematic and reproducible that are allowed to be used in different contexts and hospital processes. Further research is needed with greater methodological rigor and further progress in methodologies for public health interventions.

T-018

159 – SOCIOECONOMIC ASPECTS AND ITS RELATION TO THE ORAL HEALTH OF RESIDENTS ON FIGUEIRINHA NEIGHBORHOOD IN XANGRI-LÁ CITY, RIO GRANDE DO SUL, BRAZIL

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Under the new provision of the Unified health System (SUS), by establishing the Family Health Strategy to guide its actions, according living conditions and needs of their users, this study aimed to make a survey about the oral health status of the Xangri-Lá,RS's Figueirinha neighborhood population. From the survey of the community's socioeconomic data, it was found that the population to be considered in the study is young, and has also the following characteristics: low incomes and low levels of education. The population lives with poor infrastructure conditions and without basic sewage. Referring to the population's oral conditions, it was found high occurrences of visible plaque (74.7 %), gingival bleeding (63.6 %) and elevated caries indexes, which depicts a profile of a poor community concerning health care and oral hygiene conditions. Young people showed a high number of decayed teeth and adults a big number of missing teeth. Thus, it can be concluded that this population requires public policies that include oral and general health curative, preventive and educational measures.

T-019

392 – CORTICOSTEROIDS FOR ACUTE VIRAL BRONCHIOLITIS IN INFANTS: A SYSTEMATIC REVIEW

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Autores: Santos MARC; Galvão MGA; Cunha ALA OBJECTIVE: to systematically collect evidence of the efficacy of systemic corticosteroids in infants with acute viral bronchiolitis. SEARCH STRATEGY: We searched MEDLINE (1966 to March 2010), EMBASE (1980 to March 2010), LILACS (1982 to March 2010), SKOPUS (1950 to March 2010), SCIELO (to March 2010), WEB OF SCIENCE (to March 2010), and the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library Issue 4, 2009). Selection Criteria: Randomized controlled trials studying the effect of systemic corticosteroids in children younger than two years of age with acute bronchiolitis were included. Our outcomes were: admissions by day 1 and 7 for outpatients, length of stay (LOS) and hospital readmissions. Data Collection And Analysis: Two reviewers independently selected the trials and assessed methodological quality using the Jadad 5-point scale. Disagreements were resolved by consensus. Data was processed using Cochrane Review Manager 5 software. Mean difference (MD) and risk ratios (RR) were calculated. MAIN RESULTS: twelve studies (2119 participants) met the inclusion criteria; with a median Jadad score of 5 (inter quartile range 3 to 5). Corticosteroids did not significantly reduce admission rates by day 1 or 7, when compared to placebo (RR: 0.91; 95% CI: 0.75, 1.11; and RR: 86; 95% CI: 0.70, 1.05; respectively). There was no benefit to LOS (MD: -0.06; 95% CI: -0.08, 0.67) nor to hospital readmission rates from day 2 to 10 and from day 10 to 30 (RR: 3.66; 95%IC: 0.43, 31.03; and RR: 0.41; 95% IC: 0.11, 1.53; respectively). Authors Conclusions: no effect of corticosteroids for acute bronchiolitis treatment was demonstrated in hospital admissions, length of hospital stay or hospital readmissions. The simultaneous use of corticosteroids and bronchodilators may have influenced the results. Future research should further investigate the efficacy, harms and applicability of this combined therapy.

T-020

905 – QUALITY OF LIFE TO PATIENTS WITH CHRONIC MYELOID LEUKEMIA

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Knowing the quality of life related to health hematologic patients is limited, especially when dealing with chronic myeloid leukemia. Despite the general recognition of the importance of quality of life related to patients health (HRQOL), relatively few studies have investigated this issue in hematologic patients (efficace et al, 2008). A review of HRQOL in leukemia suggests that patients generally have a good recovery, although lasting impacts are associated with more aggressive treatment (Redaelli et al., 2003). Bone marrow transplantation in chronic myeloid leukemia, in particular, is related to a reduction in long-term physical and social performance. In children, side effects of treatment for leukemia may have a greater short-term impact on HRQoL (LANDOL et al., 2006). Although the prognosis for children is relatively good physical and psychosocial impacts on HRQL may persist into adulthood (SPEECHLEY et al., 2006). Currently, four specific HRQL questionnaires for the study of Leukemia are validated and available: the FACT-Leu Suite FACIT; Life Ingredient Profile (LIP) and two modules of the EORTC QLQ suite, and the EORTC QLQ-CLL16 MRC / EORTC QLQ-LEU (Redaelli et al., 2003). But it was not translated or adapted into Portuguese. The MRC / EORTC QLQ-LEU was developed in 1996 by Watson and colleagues, to assess quality of life in the long term in patients with chronic myeloid leukemia. The MRC / EORTC-QLQ-LEU is a scale of 32 items with an emphasis on disease related symptoms, opportunistic infections, sensory impairment and functional status, as well as graft versus host syndrome. The QLQ-LEU distinguishes patients undergoing bone marrow transplants who underwent chemotherapy (Watson et al., 1996). This is probably the first national study that assesses symptoms, problems and quality of life in patients with chronic myeloid leukemia using questionnaires of HRQOL specific to this pathology. The CML patients complain that deserve attention, especially.

T-021

658 – BRAIN DEATH AND NURSING TECHNOLOGY FOR QUALITY OF CARE: AVAILABLE EVIDENCE IN BRAZIL IN AND THE WORLD SCIENTIFIC LITERATURE

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Introduction: The advent of organ transplantation enhances contemporaneity requirements for studies about the diagnosis of brain death and technologies related to nursing care. A synthesis of the published Brazilian scientific literature may help to ascertain basis to promote best practices or point to gaps in knowledge, denoting the need for further studies in this area. Objective: To assess published evidence for “Brain Death” and “quality of nursing care” technology in Brazil and in the worldwide scientific literature. Method: Descriptive and exploratory systematic review of published evidence, from 1980 to 2010. Studies were selected indexing descriptors “Brain Death” and “nursing”. For the Brazilian we used the Virtual Health Library (VHL) databases of the Regional Library in Medicine (BIREME) and for querying the worldwide scientific literature, we used the US National Library of Medicine (NLM)´s PubMed MEDLINE database. Results: There were 247 related abstracts in the BIREME VHL databases. NLM´s PubMed MEDLINE database presented 254 indexed abstracts. The highest proportion (92,3%) of the VHL studies did overlap with those found in the MEDLINE database. The 3 countries with the higher number of publications were the United States, Britain and Germany; with (6,07%) Brazilian studies. Most (15,74%) of the articles found were reviews of the literature. Fifty-four clinical trials and case reports were included. The various aspects of brain death, organ and tissue donation and transplantation were depicted. Nursing understanding of brain death definitions was positively correlated with the health professionals’ comfort level to perform tasks related to the potential donor. Conclusions: This review evidences the need to strength Brazilian healthcare system planning and publications level. The neurology and organs and tissues transplantation are domains where international databases are documenting patient’s follow-up. These publications are important to innovative sources, besides visibility and exchange of technological and scientific knowledge.

T-022

855 – THE NURSING CARE TECHNOLOGIES USED IN NEONATAL INTENSIVE CARE UNIT

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Introdution: The technologies commonly used in Neonatal Intensive Care – UTIN are modern gadgets defined as hard on technologies that restricts the care to humans. Objectives: This study aims to contextualize the use of lightweight technologies against the harsh environment of technologies in the UTIN. Method:This bibliographic study done in the Virtual Library in Health – VHL in SCIELO (Scientific Electronic Library Online), LILACS (Latin American and Caribbean literature in health sciences) and MEDLINE. In the first two bases used three descriptors in English: Technology in Health, Neonatal Intensive Care and Neonatal Nursing, already in the last base used the same descriptors in English-Portuguese. MEDLINE and LILACS databases using advanced form did not arise any article. After the selection of articles by reading the titles were read the summaries and deleted those that do not meet the aims of research. In SCIELO 246 articles were found using the descriptor Technologies in Health has 192 on the subject of health sciences and selected seven and three were excluded. With the descriptor Neonatal intensive Care were found 65 articles which were selected six and deleted two. Using subject descriptor Neonatal Intensive Care were found 45 articles and selected one. Results: During parsing of articles found, realized the concern of the authors in the use of lightweight technologies, however it was noted that the professionals appreciate more the use of harsh technologies in relation of relational technologies, justifying their need to ensure the survival of newborns at risk. Conclusions: It is concluded that the care being provided in a more human needs inserting technologies whether they are lightweight, soft-hard or hard, putting it on the same level of importance.

T-023

241 – INTERVENTIONS AIMING THE DECREASING OF OBESITY IN SCHOOL CHILDREN: A SYSTEMATIC REVIEW IN THE CARIBEEAN AND AMERICAN LATIN LITERATURE IN HEALTH SCIENCES (LILACS) ELECTRONIC DATABASE

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A systematic review in the electronic database LILACS searching for papers on interventions for reducing childhood obesity and health promotion in schools environment was done. Advanced form with key words related to the topic was used. A total of 1.120 references in Portuguese and Spanish was obtained. Title and abstract were read and 34 papers related to the proposed subject remained. From these, 5 were Master degree dissertations, 26 papers and 3 different ways of publication; 67,6% were nationals and 32,4% internationals. After the application of inclusion and exclusion pre-determined criteria, 6 papers were selected to be submitted to the quality analysis according to Downs and Black (1998) criteria. These papers were from Brazil (2), Chile (2), Peru (1) and Mexico (1). All of these 6 studies made anthropometric measures with different indexes and diagnosis standards and one of the then evaluated biochemical standard. Furthermore, 2 studies evaluated dietary intake. As for the sort of intervention 5 had some nutritional education program and from these, three of them also encouraged physical activity and one of them worked with the parents. Another study applied a breakfast program with the school children. The results showed success in the reduction of obesity in 3 studies. The 2 studies that also evaluated dietary intake even tough did not obtain positives results related to the reducing of obesity showed improvements related to dietary intake. Another study did not find different in the body mass indexes and biochemical standards. It was observed that there are a few number of studies on interventions for reducing obesity among school children in the LILACS. The majority of them are short-term which may jeopardize the results, thereby long-term studies in this topic should be encouraged in order to achieve better results on school children weight and body composition.

T-024

468 – SEXUALITY OF THE ADOLESCENTS AND YOUNG PEOPLE LIVING AT THE RIVERSIDE IN THE RURAL AREAS, AMAZONAS - BRAZIL: MISINFORMATION AND VULNERABILITY

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Objective: This study is about adolescents and young people living at the riverside in a rural area, Amazonas State/Brazil, with emphasis on theirs sexuality and reproductive health. Method: Using a standardized close questionnaire, it was realized a cross-sectional study. All the adolescents and young population of the chosen communities were invited to participate. The instrument had questions about leaving conditions, health, work, risks exposure, sexuality, use of drugs, among others. The statistical program used was the SPSS. It was studied the categorical data using the chi square test, with 5% of significance level. Results: The sample was comprised of 118 people, 50% of each gender, ages between 10 and 24 years old. It was observed that the riverside family is nuclear type and the participation of the children in the family productive process occurs before the 10 years of age. Among the participants, 52.7% of the girls and 47.3% of the boys had already begun sexual activity ($p<0.001$), 86.2% and 92.3%, respectively, declared that were using condoms (25.4% were always using them). Of the total sample, 97.3% did not know about double protection; 90% ignored about emergency contraception and 85.5% did not know how to get AIDS. Regarding environment, 70% of the participants did not know about deforestation; 88.2% did not know biodiversity and 89% ignored sustainable development. Conclusion: We concluded that, at the rural area in the Amazon Region, it is urgent the improvement of the adolescents and youth education, through the efficacy of the education system. It is also important to implement activities of health promotion, environmental care and citizenship activities. Key words: Adolescent, Youth, Health, Rural Area, Epidemiology, Life Style.

T-025

446 – CEFAZOLIN PROPHYLAXIS IN PATIENTS SUBMITTED TO BARIATRIC SURGERY

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The objective of this review is to analyze available scientific evidence in order to define whether the use of cefazolin prophylaxis reduces the risk of surgical site infection (SSI) in obese and morbidly obese patients submitted to bariatric surgery when compared to patients not receiving antibiotic prophylaxis. The search was conducted in the databases: Cochrane Library, Medline, Scielo and Lilacs. We focused systematic reviews or, in the absence of these, randomized clinical trials, clinical trials or observational studies, considering always the best evidence available. Mesh terms: bariatric surgery, gastric bypass, antibiotic prophylaxis, surgical wound infection, cefazolin, and free text, surgical site infection were used. Considering the low number of studies about this subject, no limits were applied. We retrieved and analyzed Spanish, Portuguese and English articles. Also references were searched in articles retrieved. Twenty four abstracts were retrieved and reviewed by two researches to evaluate the appropriateness. Preliminary analysis of the title and scope excluded three studies. According to the abstracts of the remaining 21 studies, sixteen were not adequate to the objective and the remaining five, four studies retrieved by Pubmed and one by both Lilacs and Scielo, were analyzed using a full text. Two additional studies were included after examining the references of these five studies. Among the four clinical studies, two had SSI as the outcome and only one was randomized. Surgical site infection was the outcome in three observational studies. Cefazolin remains the antimicrobial agent most commonly used for prophylaxis of SSI in bariatric surgery. However, there is a paucity of well conducted studies to support this use in the scientific literature. Related issues to be settled include not only the agent used but also dose and time of administration. This scenario provides the use of different antimicrobial agents in different regimens without consistent evidence.

T-026

341 – PROSTATE CANCER SCREENING THROUGH PROSTATE-SPECIFIC ANTIGEN (PSA) AND DIGITAL RECTAL EXAM (DRE)

Mariana Beatriz Pineda, Cenetec, Mexico

To advise decision makers on the appropriateness of devising a prostate cancer screening program employing PSA and DRE in asymptomatic males 50 to 69 years of age. In particular: to determine the effectiveness of such screening program in the reduction of population mortality. Conclusions and results Regarding the effectiveness of the screening program in the reduction of population mortality, we found no statistical significant evidence that a prostate cancer screening program employing PSA and DRE in asymptomatic males 50 to 69 years of age, would have an impact on the mortality rate from prostate cancer. The meta-analysis results favor slightly the intervention with a risk ratio of 0.94 [95%CI: 0.74 to 1.19]. Recommendations Due to the findings, suggesting that a prostate cancer screening program with PSA and DRE focused on 50 to 69 years of age males, would not have an impact on the mortality by prostate cancer, would represent a high budgetary impact and would expose patients to unnecessary risks, CENETEC does not recommend the implementation of the program.

T-027

505 – CLINICAL CONSIDERATION RELATED TO COCHLEAR IMPLANTS

Mariana Beatriz Pineda, Cenetec, Mexico

Mass screening of neonates has posed new questions on policy makers regarding the cochlear implant (CI). This work is aimed at raising awareness among decision makers on the effectiveness of the device in prelocutive and postlocutive patients; assessing the CI safety. Conclusions and results Cochlear implants have demonstrated to be effective in postlocutive children and adults; the results obtained in satisfaction of the patients as the gains in quality of life are significant for those who receive the implant and follow the rehabilitation process. In prelocutive children, better results are observed in those with an earlier implant (>3 years), but individual differences may be observed deriving from medical, rehabilitation and environmental factors. Methods A review of available literature was performed analyzing found articles in three independent groups: those focused to the clinical assessment, those related to economic assessment and those considering ethical, social and cultural aspects.

T-028

305 – CANCER EPIDEMIOLOGIC STUDIES INVOLVING DIFFERENT KINDS OF HOSPITALS IN BRAZIL: CHALLENGES AND PERSPECTIVES

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To estimate the five year global survival for patients with lung cancer or breast cancer, a retrospective cohort study has been carried out by request of the Ministry of Health in Brazil. Data has been collected in 11 hospitals, for patients that started their first treatment during 2003. These institutions were chosen by the Ministry of Health for their high quality in cancer care and quality of medical records. Five of them are private hospitals, classified as “Institutes of Excellency” by the government and 6 others are large hospitals linked to the Brazilian Public Health System, in three Brazilian states. The objective of this presentation is to report the challenges of such work that could be of guidance for those involved in similar research: 1. There is a lack of experience regarding collaborative research carried out in more than one institution, especially among private hospitals. Although all hospitals agreed to participate, the time between the initial acceptance of the study and indication of a local medical coordinator was, in average, six months. 2. Many Internal Review Boards are not used to deal with research projects that are not linked to a university or supported by the Pharmaceutical Industry and had difficulties to understand the scope of the project – which is another source for the delay in starting the research. 3. Medical information is kept differently at these institutions, with one or more methods being used, such as paper files, scanned copies of patient records or electronic records. Sometimes two or three systems had to be consulted to obtain all necessary information. 4. The quality of registration of patient information is very different in quantity and quality among hospitals, doctors and other caregivers. These challenges represent a learning process, leading to the development of new procedures for data search and management.

T-029

391 – RECENT EVIDENCE ON CORTICOSTEROIDS TREATMENT FOR ACUTE VIRAL BRONCHIOLITS: A SYSTEMATIC REVIEW

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Objective: to systematically review evidence of the efficacy of systemic corticosteroids in infants with acute viral bronchiolitis. Search Strategy: We searched MEDLINE (1966 to March 2010), EMBASE (1980 to March 2010), LILACS (1982 to March 2010), SKOPUS (1950 to March 2010), SCIELO (to March 2010) and WEB OF SCIENCE (to March 2010), the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library Issue 4, 2009). Selection Criteria: Randomized controlled trials studying the effect of short-term systemic corticosteroids in children younger than two years of age with acute bronchiolitis were included. The outcomes were: oxygen saturation (SaO2); respiratory rate and heart rate (HR) at 60 minutes and 3 to 6 hours for outpatient studies. Data Collection and Analysis: Two reviewers independently selected the trials and assessed methodological quality using the Jadad 5-point scale. Disagreements were resolved by consensus. Data was processed using Cochrane Review Manager 5 software. Mean difference (MD) and 95% confidence intervals (CI) were calculated. MAIN RESULTS: four studies (1535 participants) met the inclusion criteria with a Jadad score of 5. Evaluations at 60 minutes showed that corticosteroids when compared to placebo did not significantly affect SaO2 (MD: -0.90; 95% CI: -1.84, 0.04), respiratory rate (MD: -0.24; 95% CI: -1.5, 1.03) or HR (MD: -0.15; 95% CI: -2.58, 2.28). From 3 to 6 hours results favored corticosteroids (MD:-0.47; 95% CI: -0.92, -0.01) for SaO2; but there was no benefit to HR (MD: 7.52; 95% CI: 1.52, 13.52) or respiratory rate (MD:-1.12; 95% CI: -3.07, 0.82). CONCLUSIONS: The relevant clinical benefit related to oxygen saturation should be interpreted with caution since exploratory evidence suggests that combined corticosteroids and bronchodilators may have influenced the results. Efficacy, harms and applicability of combined therapy need to be clarified further.

T-030

567 – WHAT WORKS AND WHAT DOESN'T REGARDING PSYCHOSOCIAL THERAPIES IN ALZHEIMER'S DISEASE

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Background/Objective: There are currently no treatments to reverse the course of Alzheimer's disease (AD). Therapies' goal, including drugs and psychotherapy, is to slow the course of the disease. These patients have a wide range of cognitive dysfunction, behavioral and mood changes. Therefore, in addition to general psychiatric treatment, psychosocial interventions may be suitable for some patients. According to the American Psychiatric Association these psychotherapies can be divided into four groups: emotion-oriented, cognitive-oriented, behavior-oriented, and stimulation-oriented approaches. The objective of this study was to carry out a systematic review about the effectiveness of psychosocial interventions for AD treatment. Methods: Papers were retrieved from several bibliographic databases (last publication date: 2009) with established criteria of selection, data extraction and methodological quality assessment. Data were synthesized in evidence tables and classified according to its evidence level. Findings: There is a remarkable heterogeneity between studies and most of them have methodological limitations. Several trials concerning emotion-oriented therapies showed positive effects on reducing aggressive behavior. On the other hand, there is scientific evidence that cognitive-oriented approaches such as reality orientation therapies have beneficial effects at cognitive and behavior level. Other interventions in this group, like skills training, while not effective at general cognitive level, showed a tendency to improve outcomes regarding daily life activities. Meanwhile, behavior-oriented approaches seem to be effective in the treatment of depression associated with dementia. Finally, stimulation-oriented interventions are heterogeneous and often administered in combination with other therapies; among them, it is worth mentioning music therapy, which although some methodological flaws in trials, it seems could be beneficial for some AD patients. Conclusion: Since AD is a prevalent disease and these psychotherapies are usually administered, even though better methodological quality trials are needed, this systematic review allows to build a best evidence clinical decision algorithm according to AD patient characteristics.

T-031

822 – THE DEVELOPMENT PROCESS OF A CPG ABOUT 'MANAGEMENT OF TYPE 1 DIABETES MELLITUS': WHAT HAVE WE LEARNED?

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Background: We have developed a CPG (Clinical Practice Guideline) on "Management of type 1 diabetes mellitus in children and adults" that consisted of 71 clinical questions. Objectives: To optimize CPG methodology seeking for the highest degree of rigor and efficiency. To analyze the whole developing CPG process through a SWOT matrix. Methods: A joint effort has been performed between 9 clinicians, 6 patients and 2 methodological advisors for elaborating clinical recommendations. We have adapted the NICE CPG "Management of type 1 diabetes", 2004 updating some questions, and drawing "de novo" another of them. Face to face meetings and technological resources were used for communication within the GEG in each phase of the CPG. We analyzed the whole guideline developing process through a SWOT matrix - Strength, Weaknesses, Opportunities and Threats. Results: Strengths: - Best available evidence has contributed to the development of most of the recommendations (A and B recommendations level). - Guideline Development Group was composed of a multi –tasking team trained in gudelines elaborating process and systematic reviews. - Patients have been involved in the whole process. Opportunities: - Different strategies of communication were used for the development of this CPG in a strategic moment when government is boosting the research with chronic patients. - We used technological resources as web page and discussion web forum for having feedback and consensus in the decision-making of each recommendation so we recommend for futures guidelines. Weaknesses - Clinicians did not review the evidence so some aspects of the CPG had to been reanalyzed by the reviewers. - Some recommendations needed of the whole group discussion about the evidence, and many of them were graded as "Good Clinical Practice". Threats of our guideline - We have used plenty of time to answer so many questions, so we recommend dealing with shorter CPGs.

T- 032

318 – IMMUNOCYT/UCYT+™ FOR THE FOLLOW UP OF BLADDER CANCER: USING HTA FOR DECISION MAKING

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BACKGROUND Clinical benefits of biomarkers in follow-up of bladder cancer remain a controversial issue. The use of ImmunoCyt/uCyt+™ was reviewed in our hospital due to the weakness of evidence and the resources lacking to perform the test. OBJECTIVE To evaluate the effectiveness of ImmunoCyt/uCyt+™ in follow up of bladder cancer patients compared with the current recommended practice (urine cytology with cystoscopy). METHODS Systematic reviews were retrieved in Pubmed, and the Cochrane Library. Grey literature was searched. Article selection, quality assessment, data extraction, and synthesis were performed by one reviewer. Appraisal was carried out by two reviewers. Synthesis of evidence and organisational impacts were shared with an expert group (pathologist, urologist, medical laboratory technician). RESULTS One systematic review, seven guidelines and two expert panel consensus were retrieved. The aggregated results regarding sensitivity and specificity of ImmunoCyt/uCyt+™ in bladder cancer detection were respectively 84 % and 75 % (n=8 RCTs) compared to 44 and 96 % (n=36 RCTs) for cytology. According to international medical expert panel consensus, urinary biomarkers are not recommended for use in clinical practice for the follow-up after bladder cancer. In our hospital, no difference was found concerning the time for preparation and interpretation of both specimens (ImmunoCyt/uCyt+™ and cytology). However, weighted average cost per unit is 4.4 times higher for ImmunoCyt/uCyt+™. Rarity of expertise among cytologists and pathologists to perform the ImmunoCyt/uCyt+™ test was seen as critical to maintain in good standing an internal quality control. Furthermore, difficulties were also met by the pathology service to implement an external quality assessment program. CONCLUSION The contribution of ImmunoCyt/uCyt+™ in the follow-up of bladder cancer patients is not well defined. Considering scientific evidence and organisational factors such as availability of experimented human resources, costs, and quality insurance problems, the decision making was to give up the use of this test.

T-033

327 – A SYSTEMATIC REVIEW OF EFFICACY AND SAFETY OF ENDOSCOPIC VERSUS TRADITIONAL OPEN VEIN HARVEST TECHNIQUE FOR CORONARY ARTERY BYPASS GRAFT SURGERY

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Coronary artery bypass grafting is one of the most commonly performed heart surgery and the use of veins, specially the saphenous vein, is still widespread. Postoperatively there may be wound infections, bruising, pain, edema or necrosis requiring debridement in the legs that increase length of hospitalization, require antibiotics and dressings, increasing patient discomfort and hospital costs. As withdrawal of the venous graft is a very important part of the surgery, new techniques have been proposed to try to facilitate the removal of the graft and reduce its complications. The primary objective of this study was to evaluate the efficacy and safety of endoscopic versus traditional open vein harvest technique for coronary artery bypass graft surgery. We performed a systematic review in Medline, The Cochrane Library and Lilacs. The search strategy was: Patients undergoing endoscopic harvesting for coronary artery bypass grafting versus open harvesting; Outcome: infection of the saphenous vein, length of hospitalization, need for further intervention and death. After the search we analyzed one meta-analysis. Results for surgical wound infection, hematoma, and postoperative pain were favorable to the use of endoscopic harvesting and there was no significant difference in hospital length of stay. However the endoscopic harvesting was associated with greater failure of venous patency (46.7% vs. 38.0%, P<0.001) and at three years endoscopic vein harvesting had a higher rate of death, myocardial infarction or revascularization (20.2% vs. 17.4%; adjusted hazard ratio, 1.22; 95% confidence interval [CI] 1.01 to 1.47; P = 0.04). The meta-analysis showed that long-term venous patency was better in open harvesting than in endoscopic harvesting with an odds ratio of 1.26 (95% CI 1.07 to 1.49; p = 0.0039). Despite the short-term outcomes such as surgical infection and pain were better in the endoscopic harvesting, the long-term outcomes were more frequently in this new technique.

T-034

311 – HEALTH TECHNOLOGY ASSESSMENT FOR RARE DISORDERS: A MARKOV MODEL FOR FABRY DISEASE (FD), WITH ENZYME REPLACEMENT THERAPY (ERT)

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Background: Fabry disease (FD) is a lysosomal disease, caused by deficiency of the enzyme alfaGAL-A. Its incidence is estimated as 1:40.000-100.000 of male newborns. Deficiency of this enzyme leads to accumulation of GB3 in cells. Renal failure is the leading cause of morbidity and mortality in this population. Patients with advanced renal disease have dialysis or transplantation as options. There are two licensed recombinant enzymes for enzyme replacement therapy (ERT) for FD: agalsidase alfa and agalsidase beta. Their costs are about $170,000/patient/year. Aim: Evaluate the development of renal disease in FD, in those using or not ERT. Methods: A Markov model to estimate the likelihood of renal disease progression in male patients treated and not treated with ERT was built. Results: The probability of the patients who had only proteinuria to progress to more severe stages of renal dysfunction (in 3y) in those treated with ERT was 24% compared with to a probability of 32% in those who did not use ERT. There was a reduction in the likelihood of disease progression of approximately 25% in this subgroup of patients. The probability of those who had only proteinuria remaining stable in 3y was 56% in those treated with ERT versus 48% in those not treated. For those patients that had already established chronic renal dysfunction, but were not in dialysis and who received ERT, the likelihood of progression to dialysis at 3y was 2.9% compared to a probability of progression to dialysis of 4 % in those not receiving ERT. Conclusion: This model was capable of finding a subgroup of patients that could have clinical benefits from the ERT. A relevant aspect is that our model was built with clinical outcomes. The value and limitations of using 'classical modeling' in rare diseases are still under discussion. (Support CNPq/MS-SCTIE-DECITnº 33/3007 and 37/2008).

T-035

332 – INTERVENTIONS AIMING THE REDUCING OF OBESITY AND LIFESTYLE CHANGES IN SCHOOL CHILDREN: A SYSTEMATIC REVIEW OF LATIN AMERICAN AND IBERIAN STUDIES

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The objective of this research was to conduct a systematic review of the literature on intervention studies in school's environment in order to reduce obesity and lifestyle changes in children and adolescents up to 19 years old. The research was made in the electronic database SciELO (Scientific Electronic Library Online) from the Latin American and Iberian countries and the selected articles were those published up to November 2010 from the collections of Argentina, Brazil, Chile, Colombia, Cuba, Spain, Mexico, Portugal and Venezuela. Portuguese and Spanish descriptors were used according to the language of the surveyed country. At the end, 395 articles written in Portuguese, Spanish and English without restriction at the year of publication were found. Based on the reading of the title, the abstract and when necessary, the methodology of the articles, a single reviewer, taking into account the inclusion and exclusion criteria, selected 13 articles. From the analyzed studies, the intervention based on nutritional education was conducted in 13 of them, from those 10 had intervention associated with physical activity. The outcome was mainly assessed by anthropometric measurements, and/or changes in eating behavior (92.3% of studies). From these, 3 evaluated both outcomes, 5 made use of anthropometry and 4 analyzed changes in feeding behavior. Food intake was evaluated in 2 studies by weighing the food and food records and 2 others conducted tests on the schoolchildren knowledge. Positive results after interventions were found in 12 studies and 1 did not evaluate. Decreasing of body weight was found in 5 studies and other 7 showed improvement in the quality and quantity of food intake. We conclude that the school environment can be an exceptional place for the development of interventions that include nutritional education strategies in order to achieve better health conditions and nutritional status in children and adolescents.

T-036

397 – A STRUCTURED PROGRAM OF PHARMACEUTICAL CARE (PC) BENEFITS OUTPATIENTS WITH INFLAMMATORY BOWEL DISEASES (IBD) ASSESSMENT

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Background - PC is a soft technology that is an outpatient care modality aiming at providing responsible drug therapy, which has not been extensively evaluated in patients with IBD. Aims - This study aimed at evaluating the contribution of a structured PC program to the clinical treatment of outpatients with IBD assisted at a reference hospital. Methods - After giving written informed consent, 35 outpatients undergoing continuous drug therapy were randomly assigned to either a PC program (N=18) or a control group (N=17). Patients in both groups were evaluated at entrance and after a one-year follow up period. Patient knowledge on drugs used (KDU) and compliance to drug treatment (CDT). Disease clinical activity was assessed by specific indexes (DCAI) and quality of life (QOL). Results - In the PC group, there was a significant increase in patient's KDU (median; range: 80%; 40–100 vs. 100%; 100–100; $p<0.0001$), which was not found in the control group (80%; 0–100 vs. 80%; 60–100%). Also, there was a significant increase in the percentage of patients who were more CDT in the PC group (27.8 % vs. 72.2 %; $p<0.05$), but not in the control group (41.2% vs. 41.2%). There was a significant decrease in the values of DCAI in the PC group (logarithmic values: 2.20; 0.99–3.77 vs. 1.90; 0.99–3.77; $p<0.05$), but not in the control group (1.69; 0.99–3.77 vs. 1.69; 0.99–3.48; $p>0.20$). Regarding QOL, there was a statistically significant increase ($p<0.05$) only in the scores for the mental health domain, which occurred in both, PC group (57.5 vs. 65.3) and control group (56.9 vs. 67.0). Conclusions - The implementation of a structured pharmaceutical care program to outpatients with IBD gave a positive contribution to patient treatment. Therefore are necessary to continue the assessment, realizing a pharmacoeconomic analysis.

T-037

917 – PSYCHOMETRIC PROPERTIES OF A NEW MEASURE OF QUALITY OF LIFE FOR PATIENTS WITH MUCOPOLYSACCHARIDOSIS (MPS) – THE BRAZILIAN MPS-QOL: PRELIMINARY RESULTS OF THE PILOT STAGE OF THE TEEN VERSION

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Background: Mucopolysaccharidoses (MPS) are very rare lysosomal diseases. There are few studies on the impact of enzyme replacement therapy on the quality of life (QOL) of MPS patients. Moreover, there are no suitable specific measures to assess the QOL of these patients. Objectives: To present the preliminary results of the pilot stage for the validation of the teen version of the Brazilian MPS-QOL. Methods: The sample was collected during a regional meeting of MPS patients. All patients completed 2 measures for QOL: the WHOQOL-BREF-ID (a general QOL measure) and the MPS-QOL teen version. The MPS-QOL teen version is composed of 49 items, which are answered on a 3-point Smiley scale. Items cover facets such as: happiness, relationship with family and health professionals, protection from relatives and health professionals, autonomy, stigmatization, hope, death, social security, and human rights. For patients having important cognitive impairment, the tools were either applied by proxy. Psychometric properties were analyzed by the following: percentage of missing value, frequency analysis, inter-item correlation, and the exploratory factor analysis (EFA). Results: The sample was composed of 11 teenagers aged 13-17 years (MPS I=1; MPS II=3; MPS IVA= 4; MPS VI= 3; male= 7; mean age= 14.8 yrs). The measures were applied by proxy in four patients due to significant cognitive deficits. These proxies were answered by mothers. Four patients were on enzyme replacement therapy (ERT). Although 13 items presented missing values, significant missing appeared in 2 facets such as: affective life and sexual behavior. Inter-item correlations were acceptable in most items. The EFA showed a 5-factor solution (81.8% of variance explained). Only 1 item (faith) was damaged by the “ceiling” effect. Conclusions: Our preliminary findings point to the good psychometric properties of the Brazilian MPS-QOL teen version. Support: MCT/CNPq/MS-SCTIE-DECIT 037/2008 and 067/2009. On behalf of the Brazilian MPS Quality

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T-038

926 – PSYCHOMETRIC PROPERTIES OF A NEW MEASURE OF QUALITY OF LIFE FOR PATIENTS WITH MUCOPOLYSACCHARIDOSIS (MPS) – THE BRAZILIAN MPS-QOL: PRELIMINARY RESULTS OF THE PILOT STAGE OF THE CHILD VERSION

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Background: Mucopolysaccharidoses (MPS) are very rare lysosomal diseases. There are few studies on the impact of enzyme replacement therapy on the quality of life (QOL) of MPS patients. Moreover, there are no suitable specific measures to assess the QOL of these patients. Objectives: To present the preliminary results of the pilot stage for the validation of the child version of the Brazilian MPS-QOL Methods: The sample was collected during a regional meeting of MPS patients. All patients completed 2 measures for QOL: the Child Health Questionnaire (CHQ, a general QOL measure) and the MPS-QOL child version. The MPS-QOL child version is composed of 50 items, which are answered on a 3-point Smiley scale. Items cover facets such as: happiness, relationship with family and health professionals, protection from relatives and health professionals, autonomy, stigmatization, hope, death, social security, and human rights. For patients having important cognitive impairment, the tools were applied by proxy. Psychometric properties were analyzed by the following: percentage of missing value, frequency analysis, inter-item correlation, and the exploratory factor analysis (EFA). Results: The sample was composed of 8 children aged 8-12 years (MPS

II=4; MPSIIIB=3; MPS VI= 1; male= 6; mean age= 9.5 yrs). The measures were applied by proxy in four patients due to significant cognitive deficits. Three of these proxies were answered by mothers and one was answered by grandmother. Five patients were on enzyme replacement therapy (ERT). Although 19 items presented missing values, significant missing appeared only in one facet: finances. Inter-item correlations were acceptable in most items. The EFA showed a 5-factor solution (89.8% of variance explained). Six items were damaged by the "ceiling" effect in the following facets: general QOL, family relationships, happiness and affection. Conclusions: Our preliminary findings point to the good psychometric properties of the Brazilian MPS-QOL child version. Support: MCT/CNPq/MS-SCTIE-DECIT

T-039

927 – PSYCHOMETRIC PROPERTIES OF A NEW MEASURE OF QUALITY OF LIFE FOR PATIENTS WITH MUCOPOLYSACCHARIDOSIS (MPS) – THE BRAZILIAN MPS-QOL: PRELIMINARY RESULTS OF THE PILOT STAGE OF THE ADULT VERSION

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Background: Mucopolysaccharidoses (MPS) are very rare lysosomal diseases. There are few studies on the impact of enzyme replacement therapy on the quality of life (QOL) of MPS patients. Moreover, there are no suitable specific measures to assess the QOL of these patients. Objectives: To present the preliminary results of the pilot stage for the validation of the adult version of the Brazilian MPS-QOL Methods: The sample was collected during a regional meeting of MPS patients. All patients completed 2 measures for QOL: the WHOQOL-BREF-ID (a general QOL measure) and the MPS-QOL teen version. The MPS-QOL adult version is composed of 60 items, which are answered on a 3-point Smiley scale. Items cover facets such as: happiness, relationship with family and health professionals, protection from relatives and health professionals, autonomy, stigmatization, hope, death, social security, and human rights. For patients having important cognitive impairment, the tools were applied by proxy. Psychometric properties were analyzed by the following: percentage of missing value, frequency analysis, and inter-item correlation. Results: The sample was composed of 8 adults aged 18 years or more (MPS I=3; MPS IVA= 3; MPS VI= 2; female= 6; mean age= 30.87 yrs). The measures were applied by proxy in one patient due to significant cognitive deficits. This proxy was answered by sister. Three patients were on enzyme replacement therapy (ERT). Although 12 items presented missing values, significant missing appeared in 2 facets: work capacity and acessibility. Inter-item correlations were acceptable in most items. Only 1 item (facet: work capacity) was damaged by the "floor" effect and 1 item (facet: social relationships) was damaged by the "ceiling" effect. Conclusions: Our preliminary findings point to the good psychometric properties of the Brazilian MPS-QOL adult version. Support: MCT/CNPq/MS-SCTIE-DECIT 037/2008 and 067/2009. On behalf of the Brazilian MPS Quality of Life Study Group

T-040

510 – COLONY STIMULATING FACTORS (CSF) FOR THE TREATMENT OF FEBRILE NEUTROPENIA (FN) IN CANCER PATIENTS: A SYSTEMATIC REVIEW (SR) AND META-ANALYSIS (MA)

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Introduction: FN is a common complication of anti-cancer chemotherapy (Chemo). The treatment for FN includes broad-spectrum antibiotics, and supportive care. CSF are medications that stimulates the bone marrow to produce neutrophils and are largely used in FN, although the evidence of clinical studies is controversial. Objetive: To perform a SR and MA of randomized controlled trials that compared the use of CSF plus antibiotics versus antibiotics alone for the treatment of established FN against no treatment. Methods: An exhaustive literature search was performed in major electronic databases (last query december 2010). We included randomized controlled trials that compared in adults and children. A MA of the included studies was performed. Results: More than 8,500 references were screened, and 14 studies were included. Neither overall mortality (risk rate [RR] = 0.75; 95% CI, 0.49 to 1.14; P = 0.67; I2=0%) or infection related mortality (RR = 0.6; 95% CI 0.33 to 1.1; p= 0.1; I2=0%) were influenced significantly by the use of CSF. Patients treated with CSFs had a shorter length of hospitalization (hazard ratio [HR] = 0.63; 95% CI, 0.49 to 0.82; P = .0006) and a shorter time to neutrophil recovery (HR = 0.32; 95% CI, 0.23 to 0.46; P < .00001). Conclusion: The use of the CSFs in patients with established FN caused by cancer chemotherapy reduces the amount of time spent in hospital and the neutrophil recovery period, but has no effect in mortality.

T-041

773 – NEW AGENTS (NA) FOR THE TREATMENT OF METASTATIC RENAL CELL CARCINOMA (RCC): A CRITIC SYSTEMATIC REVIEW (SR) AND META-ANALYSIS (MA)

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Background: There are many new agents available for the treatment of RCC, such as Sorafenib, Sunitinib, Bevacizumab, Temsirolimus and Everolimus, but many questions about the real efficacy of these treatments are still lingering. Our aim was to perform a SR and MA of randomized controlled trials (RCTs) that tested these NA and synthesize data for an economic analysis to be performed from the Brazilian public healthcare system perspective. Methods: We performed a wide literature search in many different databases and sources, such as EMBASE, MEDLINE, LILACS, Clinical Trials Register, among others, in order to identify RCTs that compared these NA against standard care for patients with RCC. We synthesized clinical data and performed a MA, when possible. Results: For 1st line RCC treatment, we found 6 RCTs, that tested Sunitinib, Sorafenib, Bevacizumab and Temsirolimus. The use of Sorafenib and Bevacizumabe were not associated to a significant clinical benefit in this setting. Sunitinib (for low and intermediate risk RCC) and Temsirolimus (for High risk) were linked to a significant improvement in PFS. A meta-analysis showed a marginal OS benefit favoring the use of NA in 1st line treatment (RR= 0.92; 95% CI 0.86 to 1; P=0.04). For second line treatment, Sorafenib and Everolimus were linked to an improvement in PFS, but not in OS, according to the individual studies. All studies had serious methodological flaws, such as lack of important data, conclusions not coherent with the methods and changes in the methods of analysis, while the study was in course. Conclusion: For first line treatment, Sunitinib and Temsirolimus appears to be the most effective NA. For second line, Sorafenib and Everolimus may be linked to improvement in PFS. No clear OS benefit could be identified. The methodological quality of these studies are sub-optimal and these results may be seen with caution.

T-042

400 – 'EVIDENCE-BASED KNOWLEDGE BROKERING' AS A QUICK STRATEGY TO CHECK THE VALIDITY OF SYSTEMATIC REVIEWS

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Background: Despite agreeing on the need to use computerised technology to assess new knowledge from systematic reviews (SRs), even experienced hospital professionals (EHP), anchoring to previous knowledge, find themselves forced to change their old approach to day-to-day clinical practice (cognitive dissonance CD). Methods In November 2009 two teacher-brokers (2TB), during an EBM course, guided 20 EHP in a paediatric hospital to assess a Cochrane SR of general interest with the Critical Appraisal Skill Programme (CASP) questionnaire. To find out whether a different strategy for appraising SRs would produce different results 2TB compared the CASP with a simple, newly developed tool, evidence-based knowledge brokering (EBKB) assessing only the two RCTs key papers in the forest plot. Two questionnaires were sent to 20 EHP by email at 15 days (Q15d), eliciting their feelings and at 6 months (Q6m) after the course using a previously validated survey method taken from marketing, but new to the medical field, using participants as a 'reference group', assessing their subjective expected utilities (SEUs). Results When 20 EHP (mean age 46.8 years; mean average employment 23.5 years) appraised the review with the CASP questionnaire, they considered the SRs internal validity good. When they applied the EBKB they considered the internal validity poor, discovered numerous incongruences and took less time to complete the assessment (1 h VS 2.5 hrs). 18/20 EHP completed the Q15d and reported that they felt frustrated in appraising SRs but underlined the benefits of teachers' enthusiasm. 12/20 participants completed the Q6m and reported that they acquired more useful practical knowledge from analysing and appraising RCTs than from SRs (significant difference between SEUs replies for RCTs and SRs: student T test P=0.0001). Conclusions: Our survey method, taken from marketing, provides a quick and tailored means for critically appraise SRs and helps counteract CD in busy professionals.

T-043

964 – DEVELOPMENT OF ANIMATION RESOURCE AS INFORMACIONAL SUPPORT IN URINARY INCONTINENCE

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The purpose of this study was to describe the stages of development of animation source as support informational in the treatment of urinary incontinence; culturally adapted in language terms, characteristics and needs of elderly women. A descriptive study was carried out in a service of secondary attention to the health. Sub-group was determined from March to April 2007. In the first part of the study, data on social demographic and personal antecedents related to urinary leakage were collected by a form. In the second part, the technique Free Association of Words was used in order to know the empiric vocabulary adopted by the participants for the anatomy of genital organs and pelvic floor muscles. Simultaneously, a partnership was done with the G 1000 in order to elaborate the technology of images associated to the cultural expressions. Eight women with history of urinary incontinence are distinguished, from these 4 had corresponded to the sub-group. The age varied of 63 to 78 years. A high number of gestations and vaginal childbirths were observed. The time of urinary leakage varied of 1 to 8 years. A high number of cultural expressions were gotten. The animation resource will be able to contribute as strategy of clinical approach in urinary incontinence by the health professional.

T-044

967 – DEVELOPMENT OF AN INFORMATIONAL SUPPORT APPLIED TO PATIENTS WITH CEREBRAL PALSY

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Objective: To describe the steps of developing an informational support of cerebral palsy facing families and children affected. Methods: A study based on qualitative and quantitative, descriptive, developed in a participatory manner, with survey records, the period 2009.2 to 2010.1 and interviews with family caregivers of children with cerebral palsy. Results: The study found that children in care are more than eight years of age, complaints of poor coordination and difficulty in walking. In the qualitative data were obtained the following main ideas for each question to family caregivers, will issue a number of speeches allowed to make three collectives corresponding to IC's: A) "It took me a shock when I discovered that it was a special child, but it is all I have!"; B)" Can a great job, we no longer live life to help"; C)" Means to me that she is a normal child, "to the question two - only one IC: "Assistance provided here is very good", the question three - with IC's: A) "He was with another physical therapist and was transferred here"; B) "I came here looking for the physical therapy because I was told that here at the college would accept people from the neighborhood "; question four - IC's: A)" I saw the change after the physical therapy, it just progressed, especially in motor coordination and movement; "B)" I realized that was too slow, but then I seen the evolution". Conclusion: Physical therapy has great potential as information support for caregivers of children with cerebral palsy, to help them on how to cope in different situations, showing what the best treatment.

T-045

547 – TREATING MILD PERSISTENT ASTHMATIC CHILDREN WITH INTERMITTENT USE OF BECLOMETHASONE DIPROPRIONATE TO PREVENT ASTHMA EXACERBATIONS

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Background: Asthma affects approximately 25% and 20% of the Brazilian preschool and schoolchildren espectively. The annual 200,000 hospitalizations due to the disease adds up to almost 100 million reais in costs for the public health system. National and international guidelines recommend daily use of inhaled corticosteroids (ICS) in mild persistent asthma (75% cases of the disease), however recent studies have shown that the intermittent use of these medications is just as effective as its continuous use, but with a reduction of about 80% of use. The present project is carrying out to assess this innovative therapeutic regimen in the context of a multi-institutional work proposal, which integrates health services (Belo Horizonte Municipal Health Authority) and two Brazilian universities (UFMG and PUC-RS). Objective: To verify the efficacy of the intermittent use of beclomethasone dipropionate (BDP) and salbutamol in the control and prevention of mild persistent asthma in patients assisted by the Belo Horizonte Asthma Control Program. Methods: randomized controlled trial that will initiate with a 4-week run-in period, in which patients will receive up to 250mcg of BDP-HFA, once a day. Then those fulfilling the inclusion criteria will be included in the 44-week treatment phase. A total of 300 of these children will be randomized into two treatment groups, namely: 1) continuous use and 2) intermittent use of BDP-HFA. Outcomes: frequency of exacerbations, emergency room visits and hospitalizations in both groups; quality of life assessment; impact on pulmonary function and control of the inflammatory process through assessments of fractional exhaled nitric oxide. Results: The field phase began in December 2010, due to operational issues referring to the project's integration to the Belo Horizonte municipal health network.

T-046

896 – META-ANALYSIS: EFFECT OF THE INTRODUCER TECHNIQUE COMPARED WITH THE PULL TECHNIQUE ON PERISTOMAL INFECTION RATE IN PERCUTANEOUS ENDOSCOPIC GASTROSTOMY

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Background and study aims: Percutaneous endoscopic gastrostomy (PEG) tube placement is the preferred method for long-term enteral feeding for patients who are unable to take food by mouth. Increasing numbers of patients are being referred for PEG placement, mainly due to neurological diseases or to head and neck cancer. PEG can be performed by the Pull Technique or by the Introducer Technique. There are few studies comparing these two techniques. Peristomal infection is a main complication of PEG. The Pull Technique appears to be associated with higher infection rates than the Introducer Technique, although the published results are controversial. This meta-analysis was performed to determine which technique is associated with a lower risk of infection. Methods: Published studies were identified by searching the MEDLINE, EMBASE, CENTRAL - Cochrane, and LILACS databases and reference lists of articles and proceedings of two meetings: Digestive Disease Week and United European Gastroenterology Week. Two independent investigators identified studies that evaluated peristomal infection in patients undergoing PEG. Comparative studies (randomized and nonrandomized studies) and observational studies published since 1980 were included and analyzed separately. The summary effects were estimated using the random-effects model or fixed-effect model according to whether heterogeneity existed. Publication bias was assessed by visual examination of funnel plots and the Egger regression test. Results: A total of 651 articles were reviewed. Six comparative studies and ten observational studies comprising a total of 2,336 patients met the inclusion criteria. The comparative studies were homogeneous and without publication bias. The risk of infection in this study group was significantly higher with the Pull Technique (OR = 13.0, 95% confidence interval = 4.6-36.8, $p < 0.001$). Similarly, observational studies have also reported higher infection rates with the Pull Technique. Conclusion: The Pull Technique is associated with a significantly higher risk of infection compared with the Introducer Technique.

T-047

851 – BRAZILIAN BULLETIN ON HEALTH TECHNOLOGY ASSESSMENT (BRATS): INSULIN GLARGINE AND INSULIN DETEMIR TO CONTROL TYPE 1 DIABETES MELLITUS (DM1)

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Objectives: To analyze the efficacy of insulin glargine and detemir compared to NPH for DM1, in the context of the Brazilian Public Health System (SUS). NPH insulin, available through the SUS, is currently the first choice for basal insulin replacement. Methods: To identify meta-analyses and cost-effectiveness studies a search was carried out in the following databases: ME¬DLINE (Pubmed), EMBASE, Cochrane Library and the CRD. Studies published in English, Portuguese and Spanish, until October 2010, were selected. Results: Three meta-analyses and five cost-effectiveness studies were selected. The meta-analyses reported similar results about glycemic control: insulin glargine and detemir produced significante reduction of HbA1c in comparasion with NPH, however, this reduction was small and it clinical significance is questionable. Regarding hypoglycemic episodes, there were differences in the meta-analyses: one of them showed a greater reduction of the risk of nocturnal and severe hypoglycemia with the use of detemir, the other one found a decrease in the occurrence of severe hypoglycemia, when glargine was used. One of the cost-effectiveness studies (done by CADTH) stood out among the others, and showed that both detemir and glargine promoted an increase in QALY in comparasion with NPH, but this advantage is not compensated by the high cost of these types of insulin. In Brazil, the monthly costs for treatment with each of these insulins differ significantly, reaching 377% and 530% when comparing, respectively, insulin detemir and glargine against the lowest priced NPH. Conclusion: In spite of results that demonstrated a few superiority of insulin analogs, the methodological biases observed in the clinical trials could compromise the validity of these findings. Since the costs associated to these insulins are higher, the financial resources should be directed towards structuring programs that aim to maximize the advantages of the treatment currently available through the SUS.

T-048

902 – EFFICACY, SAFETY AND TOLERABILITY OF ABATACEPT FOR TREATING RHEUMATOID ARTHRITIS

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INTRODUCTION Abatacept (ABT) is a modulator that controls the stimulation of T cells, which are responsible for releasing pro-inflammation agents and for joint destruction in rheumatoid arthritis. OBJECTIVES To provide a systematic review and meta-analyses to assess efficacy, safety and tolerability of ABT, compared to placebo. METHODOLOGY Two independent reviewers searched for RCT that compare ABT 10mg/kg versus placebo, both with concomitant DMARD and within 1 year of treatment. The databases searched were: Medline, Embase, Cochrane Library, Scielo and IPA. Language and date of publication were not exclusion criteria. Only high or moderate quality studies were included[10]. All included studies were sponsored by Bristol-Myers Squibb. Efficacy and safety were evaluated based on ACR50 and serious adverse events (SAE), serious infections, malignancies and deaths, respectively; tolerability was evaluated by the withdrawals due to: adverse events, SAE and lack of efficacy. The software ReviewManager 5.0 was used. RESULTS Results of systematic review and efficacy meta-analysis are shown on figures 1 and 2. RR values were not statistically significant for any of the safety or tolerability parameters (table 1), except for RR value of withdrawals due to lack of efficacy (RR=0.28[0.18, 0.42]). CONCLUSION ABT showed a higher efficacy compared to placebo. No significant differences between groups were noticed considering safety and tolerability, except for withdrawals due to lack of efficacy, parameter in which ABT presented favorable result. REFERENCES 1.Genovese,M.C., N Engl J Med,2005. 353(11):p.1114-23. 2.Kremer,J.M., Arthritis Rheum,2005. 52(8):p.2263-71. 3.Kremer,J.M., Ann Intern Med,2006. 144(12):p.865-76. 4.Kremer,J.M., N Engl J Med,2003. 349(20):p.1907-15. 5.Moreland,L.W., Arthritis Rheum,2002. 46(6):p.1470-9. 6.Schiff,M., Ann Rheum Dis,2008. 67(8):p.1096-103. 7.Weinblatt,M., Arthritis Rheum,2006. 54(9):p.2807-16. 8.Weinblatt,M., Ann Rheum Dis,2007. 66(2):p.228-34. 9.Westhovens,R., Ann Rheum Dis,2009. 68(12):p.1870-7. 10.Jadad,A.R., Control Clin Trials,1996. 17(1):p.1-12.

T-049

703 – HEALTH RELATED QUALITY OF LIFE (HRQOL) OF PATIENTS WITH MUCOPOLYSACCHARIDOSIS: ASSESSMENT BY GENERIC INSTRUMENTS: CHAQ - CHILD HEALTH ASSESSMENT QUESTIONNAIRE AND CHQ PF-50 - CHILD CARE HEALTH QUESTIONNAIRE

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Introduction: Mucopolysaccharidosis (MPS) are a group of inherited metabolic disorders characterized by lysosomal storage of glycosaminoglycans, secondary to deficient activity of a specific lysosomal enzyme. It is a multisystem disease, which affects directly the quality of life (QoL) of patients. QoL as described by the World Health Organization is the “perception of the individual from his position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards and concerns”. There are few studies that assess QOL in patients with MPS. Objective: To evaluate the HRQoL of patients with MPS through generic questionnaires (CHAQ and CHQ PF-50). Methodology: Cross-sectional study with application of two generic instruments in a sample of 21 patients with MPS enzyme replacement therapy (ERT) or not, between 6 and 19 years (mean 11.7, SD 4.1). Data collection was performed at three institutions in Rio de Janeiro: IPPMG (UFRJ), IFF (FIOCRUZ) and HUPE (UERJ). Results: In most cases, data were obtained from the mother (86%). Items that showed the worst results (below the average) in CHQ PF-50 were changes in health, physical functioning and general health perception. Regarding ERT, there was significant association with changes in health, physical and social functioning, general health perception, family activities and social limitations / physical. Regarding CHAQ, there was a significant difference between patients on ERT (1.67) and without ERT (2.7), (p = 0.002). Conclusions: The results showed discriminative capacity of instruments between treated and non-treated patients (ERT), but no perception of improved health with ERT. The physical aspects of QoL are more easily signed by QoL instruments, demonstrating the major impact of this domain in the life of these patients. No important differences were seen in the psychological and mental health / self-esteem. MCT/CNPq/MS-SCTIE-DECIT 037/2008

T-050

546 – USE OF ORAL FLUID: AN IDEAL TOOL FOR PREVALENCE STUDY OF HEPATITIS A VIRUS IN ISOLATED COMMUNITIES

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Population-based prevalence studies are an important tool for screening of HAV infection providing important data on the susceptible groups. However, surveillances in isolated communities become difficulty due to the access to these areas and the collection of blood samples, which is the specimen conventionally used in HAV diagnosis. This situation leads to search for alternative fluids that are non-invasive and easier to collect facilitating the implementation of epidemiological studies, such as oral fluids. This study aimed to evaluate the performance of oral fluids in prevalence studies of hepatitis A in isolated communities. Samples were collected in wetland of Mato Grosso do Sul, where none data about HAV infection are available. The study population was composed by 224 volunteers aged 3 to 86 years old. This prevalence study was performed using oral fluids that were previously standardized for anti-HAV antibodies detection (98% sensibility and specificity). Oral fluid sample was obtained using a commercial device ChemBio. The swab was rubbed along the teeth/gum line for 1 min, returning to the plastic tube containing 500µL of preservative solution. Then, oral fluid was collected by centrifugation at 1300g for 10 min and stored at 4-8ºC. Eluates were tested in modify commercial EIA (ImmunoCombII HAVAb) to detect total anti-HAV antibodies after 15 days of collection. The overall prevalence for total anti-HAV was 79%, corresponding to 177 reactive EIA tests out of 224 samples. The age stratified data showed a prevalence of 50% between 0-10 years, 84% in 11-20 years and 91,9% in subjects higher than 21 years, demonstrating a strong trend for increasing HAV infection rate according to growth. These results showed that oral fluid could replace serum in HAV epidemiological studies in isolated communities since were stable in bad conditions of collection, storage and transportation as demonstrated by efficiency in detecting anti-HAV antibodies.

T-051

606 – POSITRON EMISSION TOMOGRAPHY (PET) IN BREAST CANCER: EVIDENCE ON THE ACCURACY AND CLINICAL VALUE

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Breast cancer is the leading cause of cancer and the leading cause of cancer death in women in the Brazil. Early diagnosis and better monitoring of women with breast cancer are important for a more efficient clinical-therapeutic management, with possible impact on survival and quality of life of patients and costs of the health system. The study evaluated the available evidence on the accuracy and clinical value of the Positron Emission Tomography (PET) for the following clinical indications: (1) diagnosis of primary breast cancer; (2) axillary lymph node staging; (3) assessment of response to treatment; and (4) detection of recurrent and distant metastatic disease. It also examined its influence on the decisions of clinical and therapeutic management and impact on health outcomes. The methodology used was the Rapid Review, a short form of HTA, comprising three strategies: (1) survey of evaluations produced by HTA agencies from the INAHTA database; (2) search of clinical practice protocols relating to the use of PET, at the National Guideline Clearinghouse, National Library of Guidelines and AMB/CFM Guidelines Project; and (3) literature review for systematic reviews and meta-analysis in MEDLINE, COCHRANE, LILACS and SciELO. The body of evidence about the accuracy and usefulness of PET in breast cancer is significantly weak and inconclusive. Evidence of diagnostic performance are insufficient to indicate its use in mass screening, diagnosis of primary tumor and the differentiation between benign and malignant lesions, and axillary lymph nodes staging. Evidence results are better regarding the diagnostic performance of PET in detecting recurrence or distant metastasis, and in assessing response to treatment. There is no conclusive evidence that the use of PET impacts significantly on health outcomes or is cost-effective to justify its incorporation into the Brazilian Unified Health System, making it necessary to develop local economic evaluations to support future decisions.

T-052

820 – CLINICAL PRACTICE GUIDELINES FOR BREAST CANCER IN LATINOAMERICA

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Breast cancer is the most common cancer and leading cause of cancer deaths among women worldwide. Over the past several decades, the risk of breast cancer in developed countries has increased by one to two percent annually. While data for developing countries are limited, cancer registries suggest that age-standardized incidence rates are rising even more rapidly in developing countries. Breast cancer outcomes correlate with the degree to which 1) cancers are detected at early stages, 2) newly detected cancers can be diagnosed correctly, and 3) appropriately selected multimodality treatment can be provided properly in a timely fashion. The incidence of breast cancer in Latin American countries is lower than that in more developed countries, whereas the mortality rate is higher. Variation in care is also a factor that contributes to this results for that reason is important that countries count with evidence based clinical practice guidelines(CPG) in this topic. Although healthcare strategies may differ measurably, improvement in breast cancer outcomes can be achieved using the best standard of care that is practical in a given setting. The aim of this research was to find the existing number of CPG for breast cancer in the Latin-American region and also point out its main characteristics. Understanding the state of breast cancer control programs in developing countries can help identify areas of improvement.

T-053

223 – INTERCHANGEABILITY BETWEEN PNEUMOCOCCAL CONJUGATE VACCINES AND SCHEMES

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Background Streptococcus pneumoniae (pneumococcus) is a leading cause of serious illness among children worldwide. Pneumococcal conjugate vaccines that include 7, 9, 10, 11, 13, and 15 serotypes have been developed. Objectives Assess the comparative efficacy, cost-effectiveness, immunogenicity and safety of interchangeability among Pneumococcal Conjugate Vaccines and Schemes. Search Strategy A systematic search was conducted in December 2010 on the main literature international and regional databases, generic and academic internet search and meta-search engines, Cochrane Central Register of Controlled Trials. Databases containing regional proceedings or congresses, annals and doctoral theses were also searched. No language or temporal restriction was imposed. Selection Criteria We included all randomized controlled trials, economic evaluations, systematic reviews and meta-analysis evaluating antibody response, cost-effectiveness and clinical effectiveness of the interchangeability among Pneumococcal conjugated vaccines. Pairs of reviewers independently selected and assessed the quality of the studies and discrepancies were solved by consensus of the whole team. Results 21 out of 159 studies were included. There is currently no direct data available on the interchangeability among PCV for a primary vaccine series. Some studies demonstrated noninferiority immunogenicity between PHiD-CV and PCV7. The tolerability profile of PHiD-CV was generally similar to that of PCV7, when both vaccines were coadministered with other commonly used pediatric vaccines. Regarding cost effectiveness profiles PhiD-CV and PCV13 are always more cost effective options against PCV7 if the price remains constant between different vaccines. When PHiD-CV and PCV13 are compared against each other the results vary taking into account, price, indirect effects and indirect costs. In general PHiD-CV gains more Qalys because of the prevention of more frequent but less severe events as otitis, and PCV13 prevents less frequent events but more costly in money and effects as invasive diseases (meningitis or bacteremia). Although there is no direct evidence the two scientific recommendations retrieved advice

T-054

612 – INTRAOPERATIVE RADIOTHERAPY WITH LOW ENERGY X-RAYS

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Objective: We aimed to assess the Safety and Effectiveness such as complications, diseas-specific survival rate, disease-free survival, distant metastasis-free survival, recurrence rate, quality of life, cosmetic outcome. Methods: We performed a systematic review of the literature. We searched Ovid-MEDLINE, EMBASE and The Cochrane Library and identified 54 citations, and included 6 studies that met our eligibility criteria. In Addition, KOREAMED, KMBASE, National Assembly Library and other hand searching was conducted to April 2010. Two reviewers independently screened all references, assessing included article quality and extracted data. Results: The Safety and Efficacy analysis was conducted in comparison between IORT (intraoperative radiotherapy) alone and IORT combined with EBRT(external beam radiotherapy). Safety was evaluated by death rate and procedure-related complications from 6 studies. Concerning IORT alone, the comparative study was not identified. The complication rate of IORT was 0-8.3%. No major complications were reported. When compared with EBRT alone, the complication rate of IORT combined with EBRT group (0-15.4%) was similar to the control group (0-17.3%). Severe toxicity (grade 3-4) was not reported. Effectiveness was assessed by survival rate, quality of life, recurrence rate and cosmetic outcomes from 5 studies. There was no report on survival rate or quality of life. In one study, IORT had no recurrence and good cosmetic outcome. However, it was a small (n = 24) single-arm research with short follow-up period (median 18 months). Also, the measure for cosmetic outcome was not mentioned. IORT combined with EBRT showed no differences in cosmetic results compared with IORT alone, and recurrence was not reported in the literature. Conclusion: IORT with Low Energy X-rays, which needs no shielding facilities, is a safe and highly available technique. However, more studies are needed to clarify the effectiveness of the procedure.

T-055

635 – EFFECTIVENESS AND SAFETY OF ELECTROCHEMOTHERAPY IN TUMOUR TREATMENT: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background: Electrochemotherapy (ECT) is a new technology that combines drug chemotherapy (bleomycin or cisplatin) with the application of electrical pulses (electroporation) to increase drug uptake. Aim: To study the effectiveness and safety of ECT in tumour treatment compared with chemotherapy (CT). Methodology: Systematic review and meta-analysis. The searched databases were MEDLINE (PUBMED), EMBASE, CRD and COCHRANE CLINICAL TRIALS. All studies published in any language until June 2010 were retrieved. Selected studies included patients with metastasised and primary-site cutaneous and subcutaneous nodules receiving EQT. Primary outcome was treatment success defined as complete responses (CR): no palpable or measurable tumour detected for at least 30 days after the treatment. 2x2 contingency tables comparing EQT versus CT were generated. Pooled Risk Ratio (RR) and the 95% Confidence Interval (95%CI) were calculated using a random effects model. Heterogeneity was assessed using heterogeneity chi-squared test and the I2 index. Results: 193 potentially relevant studies, 12 case-series and 14 studies with control group, were 11.3) were selected. A total of 2581 nodules in 234 patients (mean age 56.9 treated (2310 nodules in the ECT group and 198 nodules in the CT group). The histological types of tumours were melanoma, basal cell carcinoma, adenocarcinoma and squamous cell carcinoma. CR were obtained in 1489 (57.7%) of 2581 nodules. 4 weeks after treatment, the pooled RR for CR was 5.01 95%CI (2.7-9.3) (p-value < 0.01). 38 weeks after treatment (the final evaluation), the pooled RR for CR was 8.05 95%CI (3.4-18.9) (p-value < 0.01). Not heterogeneity was found. Minor side effects were reported; the most common was muscle contractions associated with the application of electrical pulses. Conclusions: ECT seems to be a safe technology and more effective than CT for the treatment of cutaneous and subcutaneous tumour nodules.

T-056

563 – EVALUATING THE EFFECTIVENESS AND SAFETY OF CORNEAL COLLAGEN CROSS-LINKING, THROUGH A SYSTEMATIC LITERATURE REVIEW

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Objective: Our purpose is to assess the effectiveness and safety of riboflavin UVA-induced corneal collagen cross-linking(CCL) for patients with keratoconus and iatrogenic keratectasia. Methods: Searches were conducted of the following databases, Ovid-MEDLINE, EMBASE, The Cochrane Library, Koramed and KMbase. Two reviewers screened all references independently, for assessing included article's quality and extracted data. Results: Total 9 studies were included(randomized clinical trial 1, non-RCT 3, case-series 5). Adverse effects were very mild in keratoconus and were not reported in iatrogenic keratectasia. We compared indirectly CCL and intrastromal corneal ring surgery. Then, increasing of tomography results in CCL group was somewhat lower than intrastromal corneal ring surgery. However, postoperative topography analysis of CCL showed increasing or being stable comparing with no treatment group of deconditioning. Also, it has clinical usefulness as a non invasive treatment. In iatroenic keratectasia, postoperative symptom was improved, but it is difficult to generalize because of one case series study results. Conclusion: Based on current literature, there is evidence that CCL is a safe and effective treatment in stopping progress of keratoconus. Further researches are needed to validate CCL treatment in patients with iatrogenic keratectasia.

T-057

461 – CURRENT PARADIGM OF MEDICAL TECHNOLOGY FOR PROVINCIAL HOSPITALS IN MONGOLIA

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Background: In Mongolia, medical technology has been ranging depending on geographical locality, infrastructure development, human resource management and application of innovative technology at hospital setting. Moreover, medical technology is used to improving the quality of health care delivered and patient outcomes through earlier diagnosis, less invasive treatment options and reductions in hospital stays and rehabilitation times. Therefore, examining of medical technology for provincial hospitals in remote areas is a current rationale for this study. Study goal: To review medical technology applications used in isolated provincial hospitals Study results: Provincial hospitals have been delivering health care services in compliance with MNS 4621:98 Standards on common clinical and diagnostic procedures and Medical technology regulations, Clinical guidelines of commonly occurred diseases and Clinical manuals. Medical staff participated in the study responded that a number of innovative and specific medical technologies such as neonatal, nursing, organ transplantation, cardio surgery, anesthesia, hepatic viral curative, hematology, endocrinology, cancer and osteoporosis is required to be developed and complied. Likewise, interventions regarding waste management, safety box, hand washing technology for surgery, medical sterilization, medical laundry, and single use technology and disease control are essential for further restructuring. Conclusions: Medical technology applied in the provincial hospitals is required to be highly improved. For instance, development of a package of clinical interventions based on clinical science and technology innovations and exclusion of old medical interventions is needed. Legal environment to initiate medical technology law needs to be updated. However, there has been predominantly observed that an integrated policy approach including provision of basic medical equipments, application of cost effective and highly efficient medical technologies and continuous postgraduate training for medical doctors and nurses is needed which is prerequisite for medical technology development.

T-058

800 – HOME VERSUS HOSPITAL CARE IN GLUCOSE MONITORING OF GESTATIONAL DIABETES DURING THE PRENATAL

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Background: Pregnancies complicated by diabetes are associated with increased neonatal and maternal complications. For the tight control of blood glucose, pregnant women are treated with home or hospital care. Objective: To evaluate the effectiveness and safety of home versus hospital care in glucose monitoring of gestational diabetes and impaired glucose tolerance during pregnancy. Type of study: A systematic review of clinical trials. Search strategy: The following electronic databases were searched: Pubmed, CENTRAL, Embase and Lilacs. The date of the most recent search was 3 January 2011. Selection criteria: We included studies if they had a randomized design, if they included gestational diabetes women and if they evaluated home versus hospital care. Data collection and analysis: Two authors selected relevant trials, assessed methodological quality and extracted data. Main results: Two studies, involving 186 participants, were included. There were a statistically significant difference favouring home care with regards to the global effect of infant deaths (RR 0.31 [IC 95% 0.10, 0.92]; p=0.04) and to the length of women postpartum hospital stay (DMP -0.66 [IC 95% -1.17, -0.16]; p=0.01). Author´s conclusions: The evidence found in this review shows that home care seems to reduce infant mortality and the length of women postpartum hospital stay, as compared to the hospital care. However, there is insufficient evidence to determine whether home care is also more effective and safe with respect to delivery hospitalizations and in reducing the incidence of preterm infants. More randomized controlled trials are needed, with standardized outcomes, to allow the combination of results in a meta-analysis. The Diabetes Research Centre of Perinatal Hospital from Botucatu Medical School will conduct soon a randomized controlled trial in order to analyze the maternal and perinatal outcomes of diabetic pregnancies and mild hyperglycemia and, the cost-effectiveness of care provided to these women.

T-059

802 – DIABETES AND PREGNANCY: COST-BENEFIT OF HOSPITALIZATION COMPARED TO OUTPATIENT CARE

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Objective: To estimate the cost-benefit and social profitability rates of hospitalization compared to outpatient care for pregnant women with diabetes or with mild hyperglycemia. Methods: This prospective observational quantitative study included all pregnant women with diabetes or mild hyperglycemia that started prenatal care in 2007, did not develop clinical problems during gestation, and gave birth at the Botucatu Medical School Hospital of São Paulo State University (BMSH-Unesp). Thirty diet-treated pregnant women were followed as outpatients, and 20 women treated with diet + insulin were managed by short frequent hospitalizations. Hospital costs were obtained based on data extracted from the patients' charts and the Absorption Costing System of BMSH-Unesp. Thus, cost-benefit and social profitability were estimated. Results: The construction of a "decision tree" showed that the successful treatment of pregnant women with diabetes or mild hyperglycemia avoided the expenditure of US$ 1,517.97 and US$ 1,127.43 for patients treated by inpatient and outpatient care, respectively . The cost-benefit of inpatient care was US$ 143,719.16, and that of outpatient care was US$ 253,267.22, with social profitability being 1.87 and 5.35, respectively. Conclusion: Decision-tree analysis confirmed that successful treatment avoided costs in both inpatient and outpatient groups. Cost-benefit analysis showed that outpatient management was more economically advantageous than hospitalization. In both groups, social profitability was greater than 1, demonstrating that both types of care provided to diabetic pregnant women have positive benefits.

T-060

293 – QUALITY OF LIFE ASSESSMENT AFTER CARDIAC RESYNCHRONIZATION THERAPY: EXPERIENCE IN A HEALTH MAINTENANCE ORGANIZATION – UNIMED BH, BRAZIL

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Background Randomized controlled trials have shown that patients with heart failure (HF) undergoing cardiac resynchronization therapy (CRT) presented improvement of functional class, physical capacity and quality of life. In Brazil, few studies have assessed patient's quality of life after CRT. Objectives To assess quality of life in patients with HF submitted to CRT. Methods Patients submitted to CRT between January 2005 and June 2008 were identified in the database of Unimed-BH. Quality of life was assessed by means of the."Minnesota Living With Heart Failure Questionnaire" (MLHFQ) after informed consent. The respondents were asked to rate the severity of their problems before and after CRT. The t test for paired samples was used to compare mean scores of MLHFQ before and after RCT. Results: Twenty-two patients submitted to CRT answered the Minnesota quality of life questionnaire. Mean age was 70.4 years and 68% were female. The average time interval between the implantation of the CR device and the answer to the questionnaire was 32 months. The Minnesota overall mean scores, before and after RCT were 47 and 28, respectively ($p = 0.002$). For patients over 70 years old, the difference between scores, before and after RCT, were 7.7 ($p=0.294$) and for the ≤70 years group this difference was 36 ($p<0.001$). Conclusion Patients with HF perceived a significant improvement of quality of life after RCT. However, this improvement was not significant among patients over 70 years. Additional studies are required to assess if the quality of life for these patients has a lower increase or if the questionnaire used to measure it needs adjustments to figure out what the elderly population perceives as quality life. This Project was founded by CNPq, EDITAL MCT- CNPQ/ANS – No 25/2007 The authors thank CNPq, MCT, ANS and Unimed-BH

T-061

390 – OBTURATOR PROSTHESES FOR MAXILLECTOMY PATIENTS: CURRENT STATUS OF THE TECHNOLOGY AND NECESSITIES FOR IMPROVEMENT

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Bearers of oral-nasal continuity due to removal, loss, or absence of the maxilla need to employ an obturator prosthesis to restore function, aesthetics and quality of life. This area of knowledge has been subjected to considerable improvement during the last decade through the acquisition of new techniques and materials that made possible the manufacture of more efficient and better customized devices. This individualized technology requires extensive laboratorial skills and craftsmanship. The lack of qualified professionals constitutes the main constraint to a wider and more universal accessibility to this technology. This study evaluates the current status of the different mold and manufacturing techniques of obturator prostheses used in the rehabilitation of maxillectomy patients. This theoretical-exploratory study used two complementary search modalities. The first was an extensive review of the national and international peer-reviewed scientific literature, as well as the academic literature in the form of master's and doctoral dissertations and articles, using the MEDLINE, LILACS, and CAPES (Brazilian Ministry of Education) databases. The second modality was a mapping of training centers and human resources for manufacturing prosthesis that are available in Brazil based on information acquired from the registry kept by the Brazilian Ministry of Education and by different related professional associations. The results offer an historical evolution of the technological development in this area and also discuss types of obturators, techniques and materials, benefits, drawbacks, and their impact on the quality of life of those treated. An appraisal of the technical limitations to be surpassed in order to achieve a better rehabilitative technology. The data expose the difficulties related to the restricted access to treatment due to the lack and maldistribution of proficient bucomaxillofacial prosthesis makers in the Brazilian national territory, the very few training centers, and the very low stimulation of specific training and research programs in the area.

T-062

410 – DISEASE SEVERITY EVALUATION AMONG DERMATOLOGICAL OUT-PATIENTS: A COMPARISON BETWEEN THE ASSESSMENTS OF PATIENTS AND PHYSICIANS

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BACKGROUND. The assessment of a patient's disease severity is an essential component in the formulation of treatment strategies. OBJECTIVE. To compare disease severity assessment by patients and by physicians, and to describe the possible discrepancies between them. METHODS. For each patient, we obtained the Physician Global Assessment (PhGA) and the Patient Global Assessment (PtGA). Data were completed for 2.578 patients. Sixty-one physicians participated in the study. We calculated the agreement between PtGA and PhGA scores using the weighted kappa statistics; a multinomial logistic regression was performed to assess the risk of disagreement considering both patient and physician variables. FINDINGS. Differences in the percentages of severity level, identified by patients and by physicians, were always statistically significant ($p<0.05$). Overall, the weighted Cohen's kappa was in the range of 0.09 - 0.34, depending on the diseases. Gender differences between patients and physicians did not influence the agreement. In the multinomial model female patients (OR=1.38; 95%CI, 1.07-1.77), patients with higher educational levels (OR=2.71; 95%CI, 2.12-3.46), and patients with impaired quality of life (OR=1.56; 95%CI 1.23-1.97) had a higher risk to be underestimated for their disease severity by physicians, independently by physician gender and experience. CONCLUSIONS. Combining the subjective report with the objective severity assessment of the lesions, dermatologists may reach a better determination of how severity of disease is perceived by their patients and how they feel about the effectiveness of treatment. PtGA and PhGA might be considered in routine clinical assessments and not only for research activities.

T-063

258 – DIAGNOSTIC PERFORMANCE OF ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES IN CROHN'S DISEASE

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Objective: Differential diagnosis of Crohn's disease (CD) and ulcerative colitis (UC) is important in disease management. However, roughly 10% of patients will be misclassified and additional 10% classified as indeterminate colitis using current diagnostic criteria. Serological markers for CD and UC are expected to increase diagnostic precision. Anti-Saccharomyces cerevisiae antibodies (ASCA) and perinuclear anti-neutrophil cytoplasmic antibodies (pANCA) seem to be useful markers for CD and UC, respectively. The aim of this study was to assess the diagnostic performance of ASCA in CD. Methods: A systematic review was conducted to identify relevant articles published in 2005-2009. MEDLINE, EMBASE and The Cochrane Library were searched for human studies. In addition, domestic databases such as KoreaMed and KMbase were searched for the literatures written in Korean. The studies on diagnostic accuracy of ASCA (IgA and/or IgG) by enzyme-linked immunosorbent assay (ELISA) technique were included. The SIGN (Scottish Intercollegiate Guidelines Network) methodology checklists were used for critical appraisal. After data exaction, descriptive analysis was carried out. Each review process was independently carried out by two evaluators. Results: The search yielded 733 studies, 11 articles (1 meta-analysis and 10 diagnostic studies) of which met our inclusion criteria. In differential diagnosis between CD and UC, ASCA+ offered sensitivity and specificity of 0.27-0.81 and 0.73-0.95, respectively. Combining ASCA+ with pANCA-, sensitivity and specificity improved to 0.24-0.89 and 0.91-1.00, respectively. In diagnosis of CD, ASCA+ provided sensitivity and specificity of 0.37-0.82 and 0.67-0.99, respectively. Combining ASCA+ with pANCA-, sensitivity and specificity enhanced to 0.35-0.86 ad 0.86-0.98, respectively. Conclusions: ASCA ELISA was specific but not sensitive for CD. When combined with pANCA testing, specificity further increased. Considering no diagnostic standard exits for CD, ASCA ELISA is an effective adjuvant method to assist diagnosing CD (particularly for differentiating between CD and UC).

T-064

231 – CONTINUOUS FEMORAL NERVE BLOCK: A SYSTEMATIC REVIEW

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Purpose: The purpose of this study was to evaluate the strength of evidence that continuous femoral nerve block is an effective treatment of postoperative pain after total knee arthroplasty(TKA). Methods: A systematic literature review was used to evaluate the safety and effectiveness of continuous femoral nerve block(CFNB). The literature review spanned from March 14, 2009 to April 30, 2009, and eight domestic databases including KoreaMed, foreign databases including Ovid-Medline, Embase and Cochrane Library were used. Key words, such as 'total knee replacement' and 'femoral nerve block,' were used to search a total of 183 documents, but only a total of 8 studies regarding evaluation of diagnostics were included in the final evaluation. The SIGN (Scottish Intercollegiate Guidelines Network) tool was used by two evaluators to independently evaluate their quality. Results: A total of 8 studies (5 randomized clinical trials, 1 non- randomized clinical trials, 1 observational study, and 1 case series) were identified for the evaluation of CFNB. A total of 3 studies mentioned the complication such as nausea, vomiting, hypotension, urine retention etc. However, the complication rate was similar or lower than other pain management procedures after TKA. All of the articles reported positive outcomes including improved pain relief, reduced frequency, intensity, and duration of post-operative pain with reduced medication consumption, improved rehabilitation, length of hospitalization, patient satisfaction etc. Reduction of pain in after TKA is better than intravenous patient controlled analgesia(IV PCA) and single femoral nerve block. The body of evidence as a whole is a level of strength of Grade B. Conclusion: The continuous femoral nerve block is a safe and useful procedure in the pain management after TKA with at least grade B evidence based on existent positive studies. Key words: continuous femoral nerve block, knee arthroplasty, postoperative analgesia, systematic review

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T-065

200 – ZAZEN FAR INFRARED RAY (FIR) THERMAL SYSTEM

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Objective: To assess the safety, effectiveness/efficacy and cost-effectiveness of Zazen FIR Thermal System for treatment of patient with cardiovascular disease. Methods: A comprehensive search strategy including electronic databases such as PubMed, Medline, OVID EBM Reviews, Horizon scanning databases, USFDA website, and from non scientific database - Google search engine was performed. Relevant articles were critically appraised and evidence graded using US/Canadian Preventive Services Task Force. Findings: There was limited and poor level of evidence to show that FIR Thermal System technology is safe for treatment of patient with cardiovascular disease. Besides, there is no information on USFDA approval or CE mark was obtained for this technology. There was also limited and fair level of evidence on the effectiveness and no retrievable evidence on the cost-effectiveness of this device. Conclusions: Based on the review, Zazen FIR Thermal System for treatment of patient with cardiovascular disease is not recommended to be used in Ministry of Health clinics and hospitals in Malaysia until there is sufficient high quality scientific evidence to demonstrate its safety, effectiveness and cost-effectiveness when applied in clinical setting. Keywords: Zazen sauna, Zazen Far Infrared Ray (FIR) Thermal System, far infrared sauna, sauna treatment, safety, adverse events, effectiveness, cost-effectiveness.

T-066

340 – ZINC SUPPLEMENTATION FOR TREATING DIARRHEA IN CHILDREN: A SYSTEMATIC REVIEW

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Objective: To update a systematic review on the effectiveness of oral zinc supplementation, alone or in addition to oral rehydration solution (ORS), for treating childhood diarrhea. Methods: This study included randomized controlled clinical trials from the Medline, LILACS, CENTRAL and EMBASE databases that evaluated children up to the age of five years old with acute or persistent diarrhea who received zinc sulfate or gluconate alone or in addition to ORS. The quality of the studies was assessed using the Cochrane Handbook. The outcomes were analyzed in terms of relative risk (RR) and mean difference (MD), along with the 95% confidence interval (95% CI). Results: Four studies out of the 248 that were identified were included to update an existing systematic review. No new studies evaluating the use of zinc in children under the age of six months were found. In comparison with placebo, zinc therapy was capable of decreasing the duration of diarrhea by -15.32 hours (95% CI: -25.85 to -4.80), and by -19.32 hours (-34.21 to -4.06) when ORS was added. The prevalence of diarrhea up to the seventh day of treatment was lower in the group that received zinc, both with and without the addition of ORS (RR = 0.54; 0.32 to 0.92; and RR = 0.64; 0.47 to 0.87, respectively). The incidence of vomiting was significantly greater in the group that received zinc compared with placebo. Conclusion: Oral zinc supplementation, alone or in addition to ORS, resulted in decreased duration of diarrhea episodes in children. Zinc administration combined with the use of ORS seems to be an appropriate public health strategy, particularly in geographic areas where children suffer from zinc deficiencies. Financial support: MCT/CT-Saúde and MS/SCTIE/DECIT, via CNPq (Edital 67/2009).

T-067

344 – EFFECTIVENESS AND SAFETY OF VACCINES AGAINST SEASONAL INFLUENZA IN PREGNANT WOMEN: A SYSTEMATIC REVIEW

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Objective: To evaluate the effectiveness and safety of inactivated influenza virus vaccine in pregnant women through a systematic review. Method: MEDLINE, Embase, Scopus, CRD, CENTRAL, mRCT, LILACS and SciELO databases were searched. The search focused on Studies for which the control group used a non-influenza vaccine or no vaccine at all. Two independent reviewers selected the studies based on the titles and abstracts. The references for these articles were further examined to identify other eligible studies. The primary outcome was the incidence of respiratory disease accompanied by fever. Baseline characteristics, methods and results were extracted into a specific form by the reviewers. Results: 785 articles were identified and seven were included in the review, two of which were randomized clinical trials RCT and five were cohort studies. The timing of vaccine administration varied between studies, occurring as follows:: at any time during the pregnancy in two studies; in the last two trimesters in two studies; in the last trimester in two studies; and at unspecified times in one study. Statistically effectiveness of the vaccine was only shown in one RCT, which was performed using high-quality methodology. No significant adverse effects were identified in the influenza vaccine group in any of the studies. Conclusion: Studies that evaluate the effectiveness and safety of the influenza vaccine in pregnant women are scarce. Since only one study showed that the vaccine is effective, it is difficult to make any generalization. Additional studies of higher methodologic quality, especially RCT, may lead to more useful conclusions. Application of the vaccine during pregnancy seems to be safe, but lack of conclusive results suggests that further investigation of its use during the first trimester is warranted. Financial support: MCT/CT-Saúde and MS/SCTIE/DECIT, via CNPq (Edital 67/2009)

T-068

345 – SUBLINGUAL MISOPROSTOL FOR PREVENTING POSTPARTUM HEMORRHAGE: SYSTEMATIC REVIEW

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Objective: To assess the efficacy and safety of sublingual misoprostol for preventing postpartum hemorrhage. Method: MEDLINE, Embase, CRD, CENTRAL, mRCT, LILACS, SciELO, ProQuest and ISI Web of Knowledge databases were searched. There were no language, accessibility, or publication date restrictions. Randomized clinical trials of sublingual misoprostol for the prevention of postpartum hemorrhage, in comparison with placebo or other uterotonics, were eligible. The primary outcome was postpartum hemorrhage (blood loss ≥ 500 mL). Other outcomes related to efficacy and safety were also considered (see below). Information on baseline characteristics, methods, and results were extracted into an online spreadsheet. The relative risk, mean difference, and 95% confidence intervals were calculated. The heterogeneity was evaluated and, when possible, the data grouped into a meta-analysis using a random-effects model. Results: Of 720 references identified, only 16 were included in the analysis (N = 5,652 patients). Most of the studies were considered of low methodologic quality. Sublingual misoprostol, at any dose, was not more effective for reducing postpartum hemorrhage in comparison with standard treatment. Sublingual misoprostol, however, is effective for reducing hemorrhage greater than 1000 mL [600 mcg vs. placebo; RR = 0.66 (CI 95% 0.45-0.98)], the use of additional uterotonics [600 mcg vs. methylergometrine; RR = 0.04 (CI 95% 0.00-0.72)], and the duration of the third stage of delivery [50 mcg vs. methylergometrine; MD = 4.16 min (CI 95% 2.20-6.12) or 600 mcg vs. methylergometrine; RR = 0.04 (CI 95%0.00-0.72)]. The drug presented a worse safety profile, causing tremors and fever, especially at higher doses. Conclusion: These findings suggest that the use of sublingual misoprostol aimed at preventing postpartum hemorrhage presents no benefits compared with the standard uterotonics. Its use should be restricted to clinics with adequate medical support, as a complement to other uterotonics. Financial support: MCT/CT-Saúde and MS/SCTIE/DECIT, via CNPq (Edital 67/2009)

T-069

891 – EFFECTIVENESS OF DIALYZERS REUSE IN END STAGE RENAL DISEASE: A SYSTEMATIC REVIEW

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Objective: To assess the effectiveness of dialyzers reuse in end stage renal disease treatment. Method: MEDLINE, Embase, CINAHL, CENTRAL, LILACS and SciELO databases were searched, besides congresses annals and theses databases. There were no language, accessibility, or publication date restrictions. Clinical studies (observational or clinical trials) of dialyzers reuse in end stage renal disease compared to single use of dialyzers were considered eligible. Mortality was the primary outcome. Independent reviewers selected studies and extracted the relevant data. A reviewer assessed risk of bias using defined criteria based on Cochrane handbook and GRADE tools, and another reviewer checked it. Meta-analysis was not performed. Results: Of 818 references identified, only 11 were included in the review (N = 705,192 patients). Studies used cohort design mainly based on patient database registry of freestanding and hospital dialysis units. All but one study occurred outside USA and only three in the 2000's (all others from the 1980's and 1990's). Disinfectants used in reprocessing dialyzers were hypochlorite, formaldehyde, glutaraldehyde and peracectic acid. Studies were rated as very low quality. Statistical significant differences in mortality were observed in few studies, either favoring single use or reuse. Due to methodological limitations this result could not be considered valid. Conclusion: These findings suggest that the use of reprocessed dialyzers in end stage renal disease has no evidence to increase or decrease mortality risk. Studies with higher methodological quality, especially randomized clinical trials, may lead to more useful conclusions. Financial support: MCT/CT-Saúde and MS/SCTIE/DECIT, via CNPq (Edital 67/2009)

T-070

182 – PEDIATRIC REQUIREMENTS: ARE THERE DIFFERENCES BETWEEN THE PRIVATE AND PUBLIC SECTOR?

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Paediatric prescription must be very precise, taking into consideration specific aspects of this population, and supporting evidence of its safety and efficiency. Frequently paediatric prescription is based on the simple modification of adult dosage and formulations, usually completely ignoring the differences between children and adults. We estimate that 30% of paediatric prescriptions belong to the group of analgesics, antipyretics (AA) and/or non-steroid anti-inflammatory drugs (AINE). The majority of the AINE drugs have their prescription restricted for children. There is a lack of Brazilian published research that can compare and evaluate the use of such medicine in patients treated by the public sector (SUS) and the private sector (N-SUS). This research and essay proposes to evaluate the indication and utilization of the AA and AINE in children, analyzing the prescriptions and information given by carers. Samples were taken from 150 prescriptions (101-SUS and 49 - NSUS) followed by interviews at nine pharmacies and eight public places. We observed the prevalence of dipyrone (61.8%) by SUS and ibuprofen (33%) at the N-SUS, $p \leq 0.05$. All the usage considered inappropriately prescribed came from prescriptions given by the N-SUS (10. 2%). Around 70% of the prescriptions were not based on scientific evidence. In 60.0% of prescriptions from the SUS and in 76.0% of the N-SUS the drug was appropriate (to the characteristics of patients, the disease and which presented no risk of serious interaction or contraindication). However, among those drugs, if the dosage, frequency and duration are appropriate, note that only 3% are prescriptions of the SUS and none of the N-SUS. The paediatric prescription in both sectors is inappropriate. The treatments are based mainly on off label usage and incomplete prescriptions in relation to the indication, frequency, dosage and duration of the treatment, and they have no clearly written instructions

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T-071

407 – THE USE OF ULTRAFILTRATION (AQUADEX FLEXFLOW) FOR VOLUME OVERLOAD IN ACUTELY DECOMPENSATED HEART FAILURE PATIENTS – A SYSTEMATIC REVIEW

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Objective Heart failure is a very common disease with high mortality and morbidity if treatment is delayed. We aim to evaluate the evidence of clinical and cost effectiveness of ultrafiltration technique in the management of volume overload in acutely decompensated heart failure patients. Methods Systematic review of literature was conducted using Pubmed (MEDLINE), NHS Centre for Reviews and Dissemination Database, Cochrane, National Guideline Clearinghouse, EMBASE, NICE databases and references of selected articles. The search terms used were ultrafiltration (MeSH), Heart failure (MeSH),(MeSH), Kidney disease (MeSH), Diuretics (MeSH), Peripheral venous catheterization (MeSH), Peripheral Intravenous Catheters, Patient readmission (MeSH), Rehospitalization, Length of Stay (MeSH). Findings Four randomized controlled trials (RCT), 1 observational study, 3 case series, 1 cost evaluation study were included and reviewed. Even though primary outcomes (such as 48-hr weight loss and fluid removal) varied across the studies, secondary outcomes such as readmission at 30 and 90 days, unscheduled visits to emergency departments and hospital length of stay were significantly better as compared to standard usual care. This technique seemed not economically attractive from a societal perspective. However, one cost-effectiveness study highlighted that ultrafiltration was cost saving in 99% of simulation scenarios using a decision model analysis from the perspective of the Medicare payer in United States. Meta-analysis was not conducted due to the heterogeneity of outcomes measures and study designs. Conclusions Despite the lack of systematic reviews and health technology assessment reports on ultrafiltration technique in the treatment the patients, a number of RCTs showed that the ultrafiltration has significant potential as a treatment option for removal of excess fluid in heart failure patients. Ultrafiltration technique still needs to be evaluated with prospective randomized control trials and cost-effectiveness studies.

T-072

359 – THE EFFECTIVENESS OF EXERCISE REFERRAL SCHEMES IN PRIMARY CARE: A SYSTEMATIC REVIEW OF CONTROLLED TRIALS

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Objectives: Assess the effectiveness of exercise referral schemes (ERS) for sedentary people with and without a diagnosed medical condition known to benefit from physical activity. Methods: MEDLINE; EMBASE; PsycINFO; Cochrane Library, ISI WOS; SPORTDiscus were searched (to October 2009) and included study references were checked. Outcomes sought were physical activity, physical fitness, health outcomes, health-related quality of life, and adverse events. Findings: Seven randomised controlled trials met the inclusion criteria, five comparing ERS to usual care, two to an alternative physical activity intervention and one to an ERS plus a self determination theory intervention. In intention-to-treat analysis, compared to usual care, there was a statistically non-significant increase in the number of ERS participants who achieved 90-150 minutes of at least moderate intensity physical activity per week at 6-12 months follow-up (pooled relative risk: 1.11, 95% CI: 0.99 to 1.25). There was no consistent evidence to support a difference between ERS and usual care in the duration of moderate/vigorous intensity and total physical activity, physical fitness, blood pressure, serum lipids, obesity indices (body weight, body mass index & percent fat), respiratory function, psychological wellbeing (perception of self-worth, symptoms of depression or anxiety) or health-related quality of life. There was no between group difference in outcomes between ERS and alternative physical activity interventions or ERS plus a self determination theory intervention. None of the included trials separately reported outcomes in individuals with medical diagnoses. Conclusions: There is considerable uncertainty as to the effectiveness of ERS for increasing activity, fitness or health indicators in sedentary people without a medical diagnosis. We failed to identify any trial-based evidence of the effectiveness of ERS in those with a medical diagnosis.

T-073

362 – PREDICTORS OF UPTAKE AND ADHERENCE TO EXERCISE REFERRAL SCHEMES IN PRIMARY CARE: A SYSTEMATIC REVIEW

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Objectives: Assess the predictors of uptake and adherence to exercise referral schemes (ERS) in primary care, in sedentary individuals with or without a medical diagnosis. Methods: MEDLINE; EMBASE; PsycINFO; Cochrane Library, ISI WOS; SPORTDiscus were searched (to October 2009) and included study references were checked. Outcomes sought were quantitative reports of uptake and adherence levels; statistical measures of the association/relationships between participant and programme factors versus uptake or adherence. Findings: Fourteen observational studies (UK, n =12) and five RCT's (UK, n = 4) provided numerical assessments of ERS uptake and adherence. There was considerable evidence of variation in levels of both ERS uptake (35 to 100% of people attending the first ERS induction visit) and adherence to ERS (12 to 82% of people taking up ERS completing the programme). ERS uptake levels were generally higher in RCTs (79%) than observational studies (62%), with no clear difference in adherence between study designs (37% vs. 48%). Women and older people appeared more likely to take up ERS. Furthermore, while older people were also more likely to adhere, women were less likely to adhere than men. There was little evidence to judge the influence of participant psychosocial or programme level factors on ERS uptake or adherence. Conclusions: A wide range of uptake and adherence levels was evident; those less interested in the ERS programme simply did not attend initially or choose to continue through to completion. It may also reflect a less than optimal referral processes (e.g. the general practitioner did not explain fully what to expect at the gym), a lack of individual tailoring of exercise, and inappropriate referrals (i.e. some patients were not ready to begin an exercise programme). Apart from participant's age and gender, we found no other evidence for other predictors of ERS uptake or adherence.

T-074

61 – LYMPHOCYTE LEVELS IMPAIRMENT IN ELDERLY MEN FROM SÃO PAULO CITY

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Changes in the immune system during aging lead to decreased protection after vaccination and increase the rates of infections and tumor development. Our aim was to compare the immune system cell percentages according with gender and age to establish the possible differences of lymphocytes subtypes among elderly population of São Paulo city. We obtained 3 mL of blood from individuals (total=235, men and women) with ages ranging from 60 to 101 years old and in agreement with the study. In summary, 100µl of blood was lysed with Tris phosphate buffer, stained during 30 minutes with monoclonal antibodies (CD3PerCP, CD4FITC, CD8Pe – tritest, CD19Pe; BD Biosciences, San Jose, California) and T and B lymphocytes percentages were determined by flow cytometry in FACSCalibur (BD Biosciences). The statistical analysis was performed by ANOVA. The comparison of men and women showed that TCD4+ (p=0.005) and CD4/CD8 ratio (p=0.010) were lower in men, whereas TCD8+ was higher (p=0.002) in this gender and B cells (CD19+) was similar among groups. When men and women were grouped by age whose range maximum was five years we observed decreasing of TCD4+ in the group of men from 75 to 79 years old (female: 46.1±8.1, male: 38.8±10.5; p=0.023). On the other hand, men from 80 to 84 years old group increased TCD8+ (female: 20.8±8.2, male: 27.2±8.2; p=0.032). Diminished B cells were detected only in the men group on the ranges from 75-79 (p=0.003), 85-89 (p=0.020) and 90-+ (p=0.002). In summary our study showed that elderly men are more susceptible to impairment on the immune response than women since the lower TCD4+ provides less help to B cells (also lower in men) for antibody production. In addition, the augmentation of the TCD8+ in this group could represent, as it is already well known, a chronic inflammation observed in aging.

T-075

868 – PREVALENCE OF TRANSMITTED DRUG-RESISTANT VIRUS (DRV) IN A PROSPECTIVE COHORT OF NAÏVE HIV-INFECTED WOMEN IN SOUTHEAST BRAZIL

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BACKGROUND: The advent of combined antiretroviral therapy (cART) has reduced the HIV mother-to-child transmission but the impact of drug-resistant virus (DRV) among those pregnant women is unknown. OBJECTIVES: To analyze the frequency of primary mutation associated with HIV-1 drug resistance and the prevalence of genetic HIV subtypes in a population of HIV-infected pregnant women. METHODS: HIV infected pregnant women antiretroviral-näive were enrolled and prospectively followed at three major referral treatment center in Southeast Brazil (Belo Horizonte, Ribeirão Preto and Rio de Janeiro). Standard questionnaire was used to collect demographic and clinical data. Samples to assay HIV viral load, CD4 lymphocyte counts and hematology profile were collected before antiretroviral initiation and at 28 weeks postpartum. The primary outcome of interest was prevalence of DRV. For genotypic analysis ViroSeqTM HIV-1 v2.0 (Celera Diagnostic, USA) was used. Mutation lists from FASTA files generated were evaluated in the website http://surveillance.stanford.edu/cpr/servlet/CPR, which exclude common polymorphisms. For subtype assignment, we submitted the data to the Stanford HIVDR website (http://stanford.edu). MAIN RESULTS: We recruited 37 pregnant women from August 2009 to August 2010. Stable union was reported by 64.8%(24/37) and mean years of school was 8.7. Licit and illicit drugs use was reported by 16.2% and 13.5% respectively. Most(67.6%) women acquired HIV through sexual exposure. The most common ARV regimen administered was zidovudine/lamivudine plus lopinavir/ritonavir(67.6%). Twenty four samples were analyzed and all samples showed high polymorphism level but there were no transmitted drug resistance mutation. Subtype B was found in 79% of samples, followed by subtypes F(13%) and C(8%). CONCLUSIONS: These preliminary results did not show any primary drug resistance among HIV-infected pregnant women naïve to antiretroviral. However, the continued monitoring of the primary resistance rates, as well as the distribution of subtypes, is important for the surveillance of viral variants transmission among the general population.

T-076

670 – TYPE 1 DIABETES CLINICAL PRACTICE GUIDELINE BASED ON BEST EVIDENCE AVAILABLE

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Background: We have developed a CPG (Clinical Practice Guideline) on Management of type 1 diabetes mellitus in children and adults that consisted of 71 clinical questions. Objectives: To optimize CPG methodology seeking for the highest degree of rigor and efficiency we analyzed the whole developing CPG process through a SWOT matrix. Methods: A joint effort has been performed between 9 clinicians, 6 patients and 2 methodological advisors for elaborating clinical recommendations. We adapted the NICE CPG "Management of type 1 diabetes"2004 updating some questions, and drawing "de novo" another of them. Face to face meetings and technological resources were used for communication within the GEG in each phase of the CPG. We analyzed the whole process of our guideline through a SWOT matrix - Strength, Weaknesses, Opportunities, and Threats. Results: Strengths: Best available evidence has contributed to the development of high strength recommendations (A and B) . Other recommendations for contextual situation were graded as GCP (Good Clinical Practice). Guideline Development Group was composed of a multi–tasking team formed in methodology and technological assessment. The economic reward has been motivating for the patients. Opportunities: The GPC has been developed in a strategic moment when government is boosting the research with chronic patients. We used technological resources as web page and discussion web forum for having feedback and consensus in the decision-making of each recommendation. Weaknesses: Nevertheless appraisal recommendations needed of the whole group discussion about the evidence, and some of them of high evidence were finally graded of consensus level. Clinicians did not review the evidence so when recommendations did not fit with the clinical objectives systematic reviews had to been redone. Threats of our guideline: We used plenty of time to answer so much questions, so we recommend shorten CPG.

T-077

656 – EVALUATION OF SECONDARY PREVENTION IN PATIENTS AFTER ACUTE MYOCARDIAL INFARCTION WITH ST ELEVATION UNDERGOING CORONARY ANGIOPLASTY

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Introduction: After an acute myocardial infarction, approximately 8% of survivors die during the first year of follow-up. Proper implementation of secondary prevention has been responsible for about 50% reduction in mortality. However, few patients are offered the most effective secondary prevention lifestyle advice, cardiac rehabilitation and use of effective drugs. Objective: Assess the prevalence of non-drug therapy and drug therapy in patients undergoing primary coronary angioplasty. Method: Cross-sectional Study. The sample included 94 patients from the medical cooperative Unimed-Rj diagnosed with acute myocardial infarction with persistent ST-segment elevation (STEMI) underwent percutaneous coronary intervention (ICP) from September 2006 to October 2010. Information lifestyle, medical care, cardiac rehabilitation and medications were provided by patients through telephone contacts between the periods from 30 days to 24 months after ICP. Results: Nearly 71% of the sample patients were men (n = 67 men and n = 27 women), with a mean (standard deviation [SD]) age of 62.0 (SD 13.3) years. During 12 months of follow-up, 21% of patients without any clinical assessment after ICP, 87% of patients did not undergo heart tests, 32% of patients reporting no physical activity after ICP, 67% body mass index ≥ 25kg/m² and 94% of patients smoking cessation. During 12 months of follow-up, 90% of patients had at least 1 pharmacy claim for aspirin, 86% clopidogrel, 83% for a statin, 71% for a beta-blocker, 38% for an ACE inhibitor or ARB. Only 23% of the patients had at least 1 pharmacy claim in all 4 key drug classes. Conclusion: In an analysis of real-world use of secondary prevention therapies in the 12 months following a hospitalization for STEMI, we found exposure rates very low: lifestyle changes, medical care, and physical activity and pharmacy claim in all 4 key drug classes. These rates are lower than those reported in some studies and guidelines.

T-078

840 – CAN INTRA-OPERATIVE RADIOTHERAPY USING INTRABEAM BE USED IN THE MANAGEMENT OF EARLY STAGE BREAST CANCER? A RAPID HTA

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Introduction: Breast cancer is the leading cause of cancer death among Singaporean women. With the national breast cancer screening program, more patients are diagnosed in an early stage and suitable for accelerated partial breast irradiation (APBI). The current practice requires 6 weeks of post-operative daily treatment using 3D conformal radiotherapy (3DCRT). Another APBI technique Intra-operative radiotherapy using Intrabeam is gaining attention by saving the treatment burden to a single-fraction intra-operative radiotherapy. We evaluate the evidence for using Intrabeam to replace conventional 3DCRT. Methods: Population: Low-risk patients with early-stage breast cancer undergoing breast conservation therapy Intervention: Intrabeam Comparison: 3DCRT Outcome: local recurrence, complication, cost-effectiveness Literature search was conducted using PubMed, NHS Centre for Reviews and Dissemination Database, and National Guidelines Clearinghouse databases. Search terms: [breast cancer] AND ([intra-operative radiotherapy] OR [APBI] OR Intrabeam). Full-text articles published in English from 1995 to 2010 were included. Findings: Six articles were considered relevant from 55 articles retrieved: 2 systematic reviews and 4 prospective single-arm studies. No RCT, guidelines, HTA or economic evaluation were found. Both reviews highlighted insufficient clinical data to determine the optimal technique for APBI delivery. One review reported 3DCRT had better coverage of target and dose homogeneity, and was suitable for tumors of various sizes, shapes or cavity locations; Intrabeam had the best sparing of normal tissue but was unsuitable for tumors of large/ irregular cavities or tumors at the breast periphery. One primary study with 854 patients reported a low local recurrence rate of 1.20% (95% CI 0.53–2.71) at 4 years and a low frequency of major toxicity at 3.3%. The other 3 studies with 24–80 patients found no or a lower rate of local recurrences (0.75%) and no complications within 12–38 months. Conclusion: Limited evidence supports a better efficacy of Intrabeam as compared with 3DCRT.

T-079

737 – PAPILLARY THYROID CARCINOMA IN AN UNIVERSITY HOSPITAL OF RIO DE JANEIRO, BRAZIL: IN THE WAY TO MOLECULAR DIAGNOSIS

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Background: Thyroid carcinomas account for approximately 90% of all malignancies of the endocrine system and 1% of all human malignancies. The papillary thyroid carcinoma generally has excellent prognosis, but there are cases of poor prognosis with distant metastases, often fatal. Prognostic and predictive factors as biomarkers of papillary carcinoma have been intensively investigated, but there is still insufficient knowledge about their carcinogenesis. The BRAF V600E mutation has been observed in 18-87% of thyroid cancers. Objective: To measure and describe the sample of patients diagnosed with papillary thyroid carcinoma (PTC) in University Hospital Gaffrée e Guinle as the initial step for subsequent molecular description of BRAF gene, as it may be an important predictive and prognostic biomarker for papillary thyroid tumor. Methods:We collected information on the variables: age, gender and histological types of papillary thyroid cancer of all records in the database. After microscopic examination by two experienced pathologists, samples considered of inadequate quality and quantity as those with histological diagnosis of non-thyroid tumor were excluded. The data was then grouped into tables containing, in addition to these variables the presence or absence of metastasis. Findings: Almost 90% of the sample were women, a percentage even higher than the ones related in late scientific studies. The mean age of these women was of 44.7 years old. There was no significant difference (p=0.845) between the mean ages of men and women, what indicates that even though the disease preferably affects women, the age range is similar for both genders. Conclusions: Middle aged women are an epidemiological risk group for the development of PTC. Since molecular description of BRAF gene might be a useful tool for early diagnosis of this cancer and prevention of associated morbidity, assessing the incidence of possible mutations in specific populations may reinforce its use as a biomarker.

T-080

243 – DESCEMET-STRIPPING AUTOMATED ENDOTHELIAL KERATOPLASTY: A SYSTEMATIC REVIEW

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Objectives: To assess the effectiveness and safety of Descemet-Stripping Automated Endothelial Keratoplasty (DSAEK). Methods: We searched MEDLINE, EMBASE, the Cochrane Library and Eight domestic databases including KoreaMed up to 30 June 2009. We included randomised and Non-randomised trial that compared with Penetrating Keratoplasty (PK) and case studies. Two reviewers independently extracted data and assessed trial quality. Quality evaluation was performed by SIGN method. Results: 3 non-randomised comparative studies and 6 case series and 2 case reports were included in the review. The safety of DSAEK was evaluated through 11 studies in terms of operating related complications. The most common complications included graft dislocations, endothelial graft rejection, primary graft failure, endothelial cell loss. The complication rates were reported graft dislocations (mean 15.6%), endothelial graft rejection (mean 2.2%), primary graft failure (mean 3.9%, range 0%–10%), average endothelial cell loss of 36.4% at 12 months in DSAEK. Graft dislocations were resolved by additional surgical procedures (rebubble procedures) in 83%. PK's complication rates were reported endothelial graft rejection (mean 3.8%, range 0-5%), primary graft failure (mean 2.2%), average endothelial cell loss of 39.6% at 12 months. The effectiveness of DSAEK was evaluated on the basis of 10 studies in terms of visual acuity and refractive results. DSAEK enabled rapid and better Uncorrected visual acuity (UCVA) and Best corrected visual acuity (BSCVA) when compared with PK. Postoperative UCVA was significantly improved 0.2~0.21logMAR when compared with PK. BSCVA was significantly improved 0.1logMAR. Postoperative refractive results found minimal induced astigmatism ranging from -1.29 to1.43D when compared with PK (-4.64~4.69D). Conclusions: The evidence reviewed is supportive of DSAEK being a safe and effective treatment for endothelial diseases of the cornea. In terms of complication rates, DSAEK appears similar to PK. It seems to be superior to PK in terms of earlier visual recovery, minimal induced astigmatism.

T-081

271 – DIAPS 79 STUDY: TREATMENT PATTERNS AND ACHIEVEMENT OF THERAPEUTIC GOALS IN A COHORT OF TYPE 2 DIABETES MELLITUS PATIENTS TREATED IN THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM

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Introduction: Analysis of a real-world population provides an understanding of not only actual practice, but also the impact of treatment on patient outcomes. The objective of this study is to document current patterns of type 2 diabetes mellitus (T2DM) treatment in a cohort of T2DM patients treated in the Brazilian private health care system. Methods: This is a cross-sectional analysis of 383 T2DM outpatients treated in 5 Brazilian cities. Data was collected by interviewing patients using a validated questionnaire complemented by medical chart review. Therapeutic goals suggested by the Brazilian Diabetes Society were used as standard treatment. Results: Mean age was 60.5 ± 9.6 years with a mean duration of diabetes of 12.2 ± 8.75 years. The frequency of associated arterial hypertension was 66.8% (n=256); obesity 39% (n= 144); and dyslipidemia 69.6% (n= 267). Microvascular complications were present in 32.4% (n=124); 8.1% (n=31) had macrovascular complications and 41.5% (n=159) had no complications. Current treatment practice was: 3.6% (n= 14) diet only; 30% (n=115) monotherapy with oral anti-diabetic (OAD); 37.8% (n=145) combined therapy with more than one OAD agents; 23.2% (n=89) combined therapy with insulin and 5.2% (n=20) just insulin. The most prescribed drug was metformin (41.4%), followed by insulin (19.1%), sulphonylureas (18.6%), DPP4 inhibitors (8.7%), TZDs (5.5%), and others (6.7%). Treatment targets were achieved in: 76.8% for systolic and diastolic blood pressure (< 130 x 85 mmHg), 19.5% for BMI < 25kg/m2, 28% for HDL cholesterol > 55 women, 37.3% for HDL cholesterol > 45 men and 28.2% reached the goal for HbA1c (within method normal range). Only 6.8% of the group (n=26) reached all the treatment targets. Conclusion: The national goals for glycemic control, blood pressure and lipid levels are often not achieved in real-world clinical practice, even with the high use of medications.

T-082

294 – IMPACT OF NON-ADHERENCE TO IMATINIB ON PROGRESSION-FREE SURVIVAL AS 1ST TREATMENT FOR CHRONIC MYELOID LEUKEMIA IN BRAZIL: TWO YEARS FOLLOW UP

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Objective: Imatinib is considered standard of care for 1st line treatment of chronic myeloid leukemia (CML) in Brazil. However, long-term treatment effectiveness is jeopardized by questionable adherence among patients receiving imatinib. The goal of this study is to document the adherence of CML patients to imatinib and the impact of these adherence levels on long-term prognosis. Methods: A longitudinal cohort analysis was performed using SIA/DATASUS data from Jan 2008 through Jun 2010. Inclusion criteria included patients ≥18 years old; diagnosed with CML (ICD10 92.1) in Chronic Phase; beginning 1st line treatment with imatinib from Jan 1, 2008 to Dec 31, 2008; and a minimum follow-up period of 6 months. Adherence of all patients that met inclusion criteria was calculated based on medication possession ratio (MPR) over a 15-month period. Patients were categorized as adherent (MPR ≥ 0.9) or non-adherent (MPR < 0.9). Using uni and multivariate logistic regression we analyzed the following covariates: adherence, age, gender, region of country and other comorbidities for their influence on progression rates. Results: In total, 386 patients, 56% males and mean (SD) age 48 (15) years, were included in the study. There were 210 (54%) patients calculated as being adherent (MPR ≥ 0.9). At the end of the 24-months of follow-up, 20% patients from the non-adherent group had progressed, versus 10% in the adherent group (log-rank p=0,02). Patients from North, South and Southeast regions of Brazil had significantly higher adherence as compared with those from Northeast or Centerwest. According to the multivariate logistic regression, lower adherence is significantly associated with higher progression rates. Conclusions: Adherence to imatinib is associated with a better progression-free survival profile, with statistical significance being observed after a 24-months period. Non-adherence was observed in 46% of the population studied.

T-083

357 – KIT73 STUDY: RELATIONSHIP BETWEEN COSTS OF CARE AND 12-MONTH GLOMERULAR FILTRATION RATES IN POST-KIDNEY TRANSPLANT PATIENTS IN THE BRAZILIAN PUBLIC HEALTH CARE SYSTEM (SUS)

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Objetictives: The objective of this study is to analyze the relationship between 12-month renal function and costs in post-kidney transplant patients from the Brazilian Public Health System (SUS) perspective. METHODS: Non-interventional, multicenter, retrospective medical chart review of patients that underwent kidney transplantation. Three years follow-up data on resource use and associated costs from adults (age≥18 years-old at time of transplantation), single kidney only transplants from Jan/2004 to Jan/2005 were collected from 7 transplant centers in Brazilian hospitals. Data were censored on graft loss. Estimated glomerular filtration rates (eGFR) at 12-month post-transplantation were calculated using the abbreviated Modification of Diet in Renal Disease equation and stratified according to the National Kidney Foundation K/Kidney Disease Outcomes Quality Initiative renal function categories. Costs were adjusted to year 2004 at an annual discount rate of 5% and converted to 2010 USD. Case mix group costing approach was used to determine average cost per day of hospitalization, stratified by cause (surgical or clinical complication) and type (general ward, ICU). RESULTS: 498 subjects were eligible for the analysis. Outpatient

care resource use and associated costs (excluding costs with immunosuppressive therapy) did not significantly vary among patients in different eGFR categories, with average annual costs ranging from 664 and 921USD in the first year, 194 and 245USD in the second and 129 and 165USD in the third year post-transplantation. However, a trend towards of increasing inpatient costs ($p<0.001$) and incidence of hospitalization per year with declining of renal function was observed. After 3 years post-transplant, 41% of stage 1 Chronic Kidney Disease (CKD) and 91% of stage 4 patients were re-admited to the hospital at least once incurring an estimated average cost of 1,239 and 3,654USD, respectively. CONCLUSION: Renal function, measured by 12-month post-transplant eGFR, is an important determinant of costs of hospitalization in kidney graft recipients.

T-084

422 – DIAPS79: COST-UTILITY ANALYSIS OF SAXAGLIPTIN VERSUS SULFONYLUREA AS AN ADD-ON THERAPY TO METFORMIN IN TYPE 2 DIABETES PATIENTS FROM THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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Objectives: This is a cost-utility analysis of saxagliptin (treatment group) vs. sulfonylureas (SU -control group) as add-on therapy in type 2 diabetic (T2DM) patients not achieving appropriate glycaemic control with metformin alone, from the Brazilian private healthcare system (PHS) perspective. Methods: A discrete event simulation model based on UKPDS68 study was developed in order to simulate 40 years for a cohort of 1,000 patients. Safety and efficacy data were based on a head-to-head clinical trial. Epidemiological and costing data were obtained from DIAPS79, an outcomes research study of the treatment patterns and costs of T2DM patients in the Brazilian PHS. Utility values were based on UKPDS62 data and other published literature. Pharmaceutical costs were based on Brazilian official ex-factory price. Insulin NPH plus metformin was defined as rescue therapy. An annual discount rate of 5% was applied to both costs and benefits. Deterministic and probabilistic sensitivity analyses were conducted to assess the robustness of the results. Results: According to the model, patients starting saxagliptin as add-on therapy to metformin remain more time within target levels of HbA1c compared to SU (6 years vs. 4 years), postponing the start of rescue therapy with insulin. Saxagliptin is associated with fewer hypoglycemia events; 7,200 vs. 14,256 events in the control group. At 10 years, a 4.4% reduction in the risk of microvascular and macrovascular events was observed for the saxagliptin population. Compared to SU, saxagliptin is associated with incremental cost of USD4,352 per patient and incremental 0.19 QALY per patient, with an ICER of USD2,347/QALY. In the probabilistic sensitivity analysis, saxagliptin had a 64% probability of being cost-effective for a willingness-to-pay of USD30,000. Conclusion: Saxagliptin can be considered cost-effective as compared to SU as add-on therapy in T2DM patients failing to achieve adequate glycaemic control on metformin monotherapy.

T-085

274 – DIAPS 79 STUDY: BUDGET IMPACT ANALYSIS OF SAXAGLIPTIN IN THE TREATMENT OF DIABETES MELLITUS TYPE 2 (T2DM) UNDER THE PERSPECTIVE OF THE BRAZILIAN PRIVATE HEALTHCARE SYSTEM

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Objectives: This study aims to model the financial impact of introducing saxagliptin as a T2DM treatment option in the Brazilian Private Healthcare System (PHS). Methods: A budget impact model was developed to estimate the annual cost of T2DM treatment per patient. The analysis estimates the economic impact to the system of all oral anti-diabetic drugs (OADs) for 3 consecutive years. Target population (T2DM patients on OADs and HbA1c uncontrolled) and patient distribution across therapeutic options are based on DIAPS79 study, a local observational study. Pharmaceutical direct costs are based on factory price (FP) and Defined Daily Dose (DDD). Univariate deterministic sensitivity analysis is conducted to analyze the impact of parameters on the results. Results: The growth in population and prevalence resulted in an increase in the target population throughout the analysis. The prevalence estimate in year 1 was 331.072 and increased to 351.908 in year 3. The growth also impacted total costs in the scenario without saxagliptin, which increased by USD1.965.024 during this period, reaching USD91.307.766 in year 3. Total costs in the scenario with saxagliptin, however, remained stable around USD88,700,000/year. Introduction of saxagliptin is expected to be economical to the PHS, with savings of USD3.445.218 in year 3. Annual savings per patient potentially impacted by the introduction of saxagliptin correspond to 8.6% of pharmaceutical costs at year 3. Sensitivity analysis demonstrated that saxagliptin price is the most impactful parameter in the model, and a 25% increase over its price would still generate savings around USD2,200,000 to the PHS. Conclusion: Introduction of saxagliptin as a therapeutic option to patients with T2DM in the PHS would save around USD5,500,000 in the next three years.

T-086

296 – CARDIOMETABOLIC DISEASE RISK AMONG SCHIZOPHRENIA PATIENTS TREATED WITH ARIPIPRAZOLE VERSUS OLANZAPINE IN BRAZIL: A COST-CONSEQUENCE ANALYSIS

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Objectives: Atypical antipsychotic medications have shown to increase diabetes and CHD risk in patients due to metabolic syndrome. To estimate the impact of the risks on treatment for schizophrenia, we performed a cost-consequence analysis associated with the use of olanzapine versus aripiprazole. Methods: A total of 173 overweight patients (body mass index ≥ 27 kglm2) with schizophrenia or schizoaffective disorder (previously treated with olanzapina) were randomized to treatment with aripiprazole or continued olanzapine monotherapy for 16-weeks following a 2-week, open-label, observation period during which subjects continued to receive olanzapine. The rate of ATP-I II metabolic syndrome, and the long term risk for diabetes and CHD was estimated and compared between arms. Brazilian costs and health resource estimates were applied to each event. Established risk functions were used to estimate diabetes and CHD risk. Results: Among all patients, the baseline rate of metabolic syndrome was 89%. At 16 weeks, 80.3% of olanzapine versus 60% of aripiprazole patients exhibited metabolic syndrome (RR:0.75; 95%Cl:0.61-0.92,p=.006). Diabetes risk increased by 1.3% in the aripiprazole group and 6.4% in the olanzapine group, risk difference = 5.1 %. CHD risk decreased by 0.6% and increased by 0.3%, in the aripiprazole and olanzapine groups respectively, a risk difference = 0.9%. Among 1000 patients, treatment with aripiprazole versus olanzapine would avert 203 metabolic syndrome events, 51 diabetes events, and 9 CHD events at a cost of USD910, USD1,111 and USD2,468, per event avoided respectively. The total cost difference was USD263,737. Risk differences were driven primarily by significant weight and lipid changes between agents, favoring aripiprazole. Conclusions: Antipsychotic-related metabolic adverse events and the consequent risk of diabetes and CHD can add substantially to health care costs among patients with schizophrenia in Brazil. Health care providers should consider these risks in their selection of appropriate antipsychotic agents.

T-087

297 – KIT73 STUDY: POST-RENAL TRANSPLANT RE-HOSPITALIZATIONS IN THE BRAZILIAN PUBLIC HEALTH SYSTEM: CAUSES, RESOURCES USE AND COSTS BASED ON DATASUS DATA

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Objectives: Post-renal transplant patients have a high risk of re-hospitalization, incurring in costs. The aim of this study is to analyze causes, resource use of re-hospitalizations in renal transplanted patients in Brazil. Methods: A longitudinal analysis of a government administrative database (Inpatient Information System - SIH/DATASUS) was performed from January 2004 to July 2009. The cohort was patients who had undergone a kidney transplant at 7 of the main transplant hospitals in Brazil, in 2004. Patient data was collected through July 2009. Demographic data (sex, age, type of donor), cause and length of re-hospitalization, resource use and associated costs (in 2004 USD) were collected. Results: 1,030 patients were eligible for the analysis. Mean age at transplant was 38.7±14.5 years, 57.6% were male recipients and 49.6% of transplant procedures were from living donors. During the study period 2,168 hospitalizations occurred in 643 patients (62%), with a total cost of USD1,568,956. Most frequent causes of re-hospitalization were post-transplant surgical and clinical complications (40.1%) and graft rejection episodes (32.4%), accounting together for 76.9% (USD1,207,406) of total expenses. Hospital services (ICU/Ward days, operation room, equipments, etc) represent the most significant part of re-hospitalization costs (40.9%), followed by diagnostic/laboratory exams (24.2%), medicines (13.6%) and health professional fees (11.0%). Re-hospitalizations were concentrated in the first (39.6%) and second (24.0%) years following transplant, stabilizing in the fourth and fifth years around 9% (200 hospitalizations/year). Patients receiving grafts from deceased donors accounted for 68.4% of total costs, and average costs per re-hospitalization were statistically different between patients receiving grafts from deceased (USD778±1,181) relative to living donors (USD632±973). Conclusion: The majority of patients who underwent kidney transplant in 2004 were re-hospitalized at least once through July 2009. Costs associated with these re-hospitalizations were concentrated in the first year post-transplant and in cadaveric renal transplant recipients.

T-088

299 – KIT73 STUDY: IMMUNOSUPPRESSANT THERAPY PATTERNS AND ITS COSTS IN THE NATIONAL RENAL TRANSPLANT PROGRAM IN BRAZIL

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Objectives: The aim of this study is to determine immunosuppressant treatment patterns and associated costs in kidney transplant patients from the Brazilian National Transplant Program. Methods: A review of the entire government administrative claim database (Outpatient Information System - SIA/DATASUS) was conducted from 2005 to 2008, to determine yearly expenses (in 2008 USD) with each IS combination. In order to assess the dynamics of the combinations used, a subset of this

population, all patients from 7 hospitals who underwent kidney transplantation in 2004, was followed from January 2005 to December 2007 to estimate calcineurin inhibitors (CNI) switching rate and treatment adherence in terms of 24-month medication possession ratio (MPR). Results: Analysis of the entire database reveals that overall IS expenses in kidney transplant patients more than doubled, from USD62,429,359 in 2005 to USD126,874,381 in 2008. This increase was primarily a results of a rise in both treatment volume and costs from 2006 to 2007. From 2005 to 2007, monthly treatment volume increased 14.7% for cyclosporine and 62.9% for tacrolimus, whereas costs increased 3.2% for cyclosporine and 93.1% for tacrolimus. The highest financially impacting combination per CNI were tacrolimus plus mycophenolate sodium (USD37,329,606 in 2008), and cyclosporine plus mycophenolate sodium (USD10,163,990 in 2008). A total of 540 patients were eligible for the subpopulation analysis. CNI therapy switch rate, from tacrolimus to cyclosporine or vice-versa was 4.3% (n=185). MPR for CNIs was 73.7% (n=224; SD=21.7%). Conclusion: From 2005 to 2008, there was a substantial increase in the expenses associated with IS drugs in post kidney transplant patients in Brazil. The study also determined that in this population there was a low switching rate of CNI and evidence of poor drug adherence. Concern is warranted and further analysis should be undertaken, regarding the poor drug adherence.

T-089

302 – MELODY BRASIL: TREATMENT PATTERNS AND ASSOCIATED COSTS OF METASTATIC MELANOMA PATIENTS IN THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM (SUS)

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Objectives: The aim of this study is to document treatment patterns of care and associated costs of metastatic melanoma in Brazil from the Public Health System (SUS) Perspective. Methods: A review of a government administrative claims database (Outpatient Information System - SIA/DATASUS) was conducted from Jan 2008 to June 2010. Patients receiving radiotherapy and/or systemic therapy for diagnosed melanoma (International Code of Disease (ICD-10) C43) stage IV were included in the analysis. Information on type of treatment (chemotherapy, radiotherapy), chemotherapy scheme, length of treatment and associated costs (in 2010 USD) were collected. Results: 2,488 patients met the inclusion criteria, 54.3% male with an average age (SD) of 56.3 (15.0) years. 42.2% lived in the Southeast region and 38.5% in the South. Less than 40% of the cases had the primary cancer site reported. Dacarbazine was the most widely used agent (administered to 1,700 patients), followed by interferon (1,059 patients) and cisplatin (435 patients). Dacarbazine monotherapy was the most commonly administered chemotherapy regimen (37.9% of the patients; average length of treatment of 3.1 months), followed by interferon monotherapy (30.1% of the patients; average length of treatment of 4.6 months) and paclitaxel monotherapy (3.5% of the patients; average length of treatment of 2.8 months). Overall cost of care expenses were USD16,238,160, 99% of the cost was attributable to chemotherapy (USD16,024,555). Total expenses in 2009 (USD6,667,687) increased 12% compared to 2008; interferon monotherapy accounted for 38.5% (USD6,245,742) of expenses, and dacarbazine monotherapy accounted for 32.2% (USD5,230,315). Conclusion: Patients with advanced melanoma, in the Brazilian Public Healthcare System (SUS), nearly all receive systemic therapy. Dacarbazine as single agent is the most common regimen, followed by interferon with a significant financial impact to the Public Healthcare System, totalizing USD16,238,160 in the last two and a half years.

T-090

353 – MELODY BRAZIL: CHEMOTHERAPY CHOICES FOR PATIENTS WITH METASTATIC MELANOMA IN THE PUBLIC HEALTH CARE SYSTEM (SUS)

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Objectives: The aim of this study was to assess treatment choices for patients diagnosed with metastatic melanoma in SUS settings Methods: The patient flow pathway was determined by patients receiving systemic therapy for diagnosed melanoma stage IV (ICD-C43) from a government administrative database (SIA/DATASUS). Patients ineligible for upfront therapy could not be captured. Systemic therapy at each line treatment and time to progression data from Jan/2008 to Jun/2010 was collected. Patients were classified as active (analyzed during all period), lost during follow-up (unknown reason) and dead. Results: Data from 1,049 patients was analyzed, 48.1% lost follow up and 8.3% had documented death. By the end of the study, 43.6% were still active. The average follow-up time was 8.6 months. All patients received at least one line of systemic therapy. First line therapy (FLT), 49.7% received dacarbazine and 29.1% interferon. By Jun/2010, 175 (16.7%) patients received second line therapy (SLT), 42.5% lost follow-up, 6.6% died and 34.2% remained in FLT. The most common SLT regimens were dacarbazine (28.0%), interferon (17.7%) and paclitaxel (14.9%) and the average time to switch from FLT to SLT was 5.5 months. During SLT, 28.0% lost follow-up, 7.4% died and 47.4% of patient remained active till Jun/2010. Thirty patients (2.9%) received a third line therapy (TLT), with an average time from the beginning of SLT to TLT of 5.2 months. Paclitaxel (23.3%) and interferon (20.0%) were the most commonly used regimens. Conclusion: For metastatic melanoma patients in the SUS, the main chemotherapy regimens in FLT and SLT were dacarbazine and interferon. Paclitaxel was the commonest TLT agent along with interferon.

T-091

358 – KIT73 STUDY: DOES TYPE OF DONOR INFLUENCE LONG-TERM COSTS OF CARE? RESULTS FROM POST-KIDNEY TRANSPLANT PATIENTS IN THE BRAZILIAN PUBLIC HEALTH CARE SYSTEM (SUS)

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Objectives: The objective of this study was to estimate resource use and associated costs of care among recipients of kidney transplant according to donor type, from the perspective of the Brazilian Public Health System (SUS). METHODS: The KIT73 study was a retrospective observational study conducted at 7 transplant centers, including 498 adult single kidney only transplant recipients from Jan/2004 to Jan/2005. Recipients were identified by donor type (living (LD) or deceased (DD)). The DD group was further stratified by standard criteria donors (SCD) or expanded criteria donors (ECD). Five-year costs were adjusted to 2004 at an annual discount rate of 5% and converted to 2010 USD. A case mix group costing approach was used to determine average costs per day of hospitalization, stratified by cause (surgical or clinical complication) and type (general ward, Intensive Care Unit (ICU). RESULTS: All 498 recipients were included in the analyses. For both groups (LD or DD), total inpatient costs of care

were higher than total outpatient costs (excluding medications) at 1 and 5 years. LD recipients incurred significantly lower costs than DD recipients: mean (SD) costs per patient were USD1,460 (USD1,813) (LD) v0.s USD2,785 (USD 3,615) (DD) (p=0.0001) in the first year; USD288 (USD599) (LD) vs. USD568 (USD1,540) (DD) (p=0.01) in the fifth year. Comparison between SCD and ECD groups, however, showed that the mean (SD) costs per patient were USD2,692 (USD3,616) (SCD) vs. USD3,767 (USD5,481) (ECD) (p=0.377); USD545 (USD1,540) (SCD) vs. USD810 (USD1,117) (ECD) (p=0.146) in the fifth year. CONCLUSION: Recipients of kidney transplants from living donors had lower costs over five years as compared to recipients of transplants from deceased donors. Among recipients from deceased donors, no statistical difference was observed in the comparison between ECD and SCD recipients.

T-092

99 – ACTIVITIES AND ORGANIZATIONAL ANALYSIS OF CENTERS WITH ORAL ANTICOAGULANT THERAPY (OAT)

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Background Atrial fibrillation (AF) is a disease at increased risk of systemic thromboembolism, stroke is the most frequent and dramatic embolic event related to the AF. Treatment with oral anticoagulants (OAT) vitamin K antagonists is now the treatment of choice for the prevention of stroke in patients with FA. Will shortly be available on the market new oral anticoagulants (dabigatran etexilate, Rivaroxaban etc..), which does not require adjustment for INR monitoring, and revolutionize the management of patients with AF and stroke risk. Aim The aim of the study is to assess the current organizational structure and measure the resources used for the monitoring of mapping centres analysis of the demand INR in patients in OAT in terms of: implementation of case studies on the in the country and regional levels; resources used by the centres and by the patient in the management of OAT. Methodology The demand analysis was performed on estimates of prevalence and incidence of atrial fibrillation in the literature or available from regional and national epidemiological centres. The search of centres was conducted on the web, supplemented by surveys and telephone interviews. Results Overall, are active in Italy about 359 centres. The centres were created according to difficulty in maintaining the anticoagulant effect in the therapeutic range (INR between 2-3). Basically you can find in the system \\\”Italy\\\” two types of centres: second level, first level. The annual organizational cost data, for patients in anticoagulant treatment in some centres analyzed express a high variability (from € 234 to € 500). Conclusion The most significant result that emerges from the analysis is that the application of the principle of \\\”vertical equity\\\”, as well as equity of access to the NHS, were strongly differentiated in the national territory.

T-093

596 – LAPAROSCOPY VERSUS OPEN ROUX-EN-Y GASTRIC BYPASS FOR MORBID OBESITY: COST-UTILITY ANALYSIS

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Objective: To estimate the incremental cost-utility ratio (ICUR) of laparoscopy versus open Roux-en-Y gastric bypass for morbid obesity in the Brazilian Public Health System (SUS) perspective. Methods: We performed a cost-utility model using a decision tree for the SUS perspective as the payer of the health services, with a one-year follow-up. The cost and complication rates information were obtained from a retrospective cohort (n> 1000) at a Brazilian center that is renowned for bariatric surgery, and from the SUS database. More specifically, we used an adjustment factor to convert the average value charged in private health plans due to the absence of actual costs for laparoscopic surgery in the SUS (unlisted). The mortality data, conversion probability (for video to open) and years with quality-adjusted life year (QALY) were from literature. A tornado diagram was created, which encouraged univariate and bivariate analyses to explore sensitivity. Result: The ICUR was R$ 84.678/QALY. The QALY and the costs of laparoscopic or open surgery were the variables most sensitive to the model. Conclusion: Compared with open surgery, the laparoscopic approach does not appear cost-effective within the SUS perspective, assuming the cost-utility threshold recommended by WHO (R$ 49,242.90). From the bivariate sensitivity analysis related to quality of life, the laparoscopic approach becomes cost-effective if there is a favorable difference in quality of life of at least 20%, keeping the other variables constant. Moreover, in the bivariate sensitivity analysis related to costs, laparoscopy would be cost-effective if its cost to the SUS were reduced by R$ 8,100.00, keeping other variables constant.

T-094

766 – MICAFUNGIN: PHARMACOECONOMIC REVIEW AND QUALITATIVE APPRAISAL OF ITS USE IN THE TREATMENT AND PROPHYLAXIS OF CANDIDA INFECTIONS

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Objective: Candida infections represent the fourth leading cause of nosocomial bloodstream infections in the world. Micafungin (MICA), a new echinocandin, is indicated for the treatment and prophylaxis of these infections. A systematic literature review was conducted, within a HTA report, in order to investigate the cost-effectiveness of MICA compared with different therapeutic alternatives in the treatment and prophylaxis of Candida infections. Methods: The literature search, which covered studies published up to December 2009, was conducted by consulting MEDLINE. Search terms used were as follows: “Micafungin”, “Cost-effectiveness”, “Cost-Utility” and “Economic Impact”. Full economic evaluations which considered subjects affected by candidemia and/or patient undergoing haematopoietic stem cell transplantation were included. BMJ referees’ checklist, proposed by Drummond et al. and weighted by La Torre et al., was used to appraise the quality of the economic evaluations included. Studies achieving a score above 90 were considered of high quality. Findings After careful evaluations of the abstracts, 5 studies were finally included in the review. Three were related to the treatment of Candida infections and 2 dealt with the prophylaxis. Two out of 5 studies were performed in Europe, two in the US and 1 in Korea. All economic analyses showed that MICA, compared with different alternatives, is cost-effective in the treatment and prophylaxis of Candida infections. According to Drummond’s checklist, 40% were high quality studies and 60% were medium quality, mainly because methods for deriving the model assumptions were not described. Conclusions Micafungin is a cost-effective antifungal strategy by providing lower medical costs and longer life expectancy than comparators, representing an important tool and a good choice for decision-makers. Nevertheless, our review highlighted that some aspects might be further developed. In particular we suggest conducting economic evaluations in the Italian context in order to provide specific data for the Italian healthcare system.

T-**095**

794 – BUDGET IMPACT ASSESSMENT FOR THE ACCESS TO THE OUTPATIENT MEDICAL THERAPY IN ASTHMA BY THE SISTEMA ÚNICO DE SAÚDE (SUS) IN BRAZIL IN COMPARISON OF THE ACCESS BY THE PATIENT IN MARKET PHARMACIES

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Objective: To compare the budget impact of access of outpatient to medical asthma therapy by the Sistema Único de Saúde (SUS) and the access by the patient in market pharmacies. Methods: A descriptive, retrospective study of demand and budget with clinical therapy to asthma in the period January 1, through december 31, 2009, in a general hospital, with specialties, tertiary, public and urban in São Paulo, Brazil. Were examined the receipts of 1,734 patients and patient characterization was done by the hospital database to obtain the list of medicines dispensed to them and its correspondent annual expenditure. It was assessed the clinical guideline receipt, the month need and the price bought by the hospital was compared with the market price obtained by the Pharmaceutical Market Brazilian Association Magazine (ABC FARMA). Findings: The study populations average age was 47.7 +/- 15.4, the median age 48.0; 25.8 % (n=448) male; 74.2 % (n=1,286) female; monthly average income R$ 1,200.00. The hospital expenditure with asthma medication in 2009 was R$ 851,559.92, the clinical guideline receipt was: salbutamol 100 mcg/doses, omeprazole 20 mg, budesonide and formoterol (400 mcg+12 mcg), fluticasone 50 mg, montelucaste 10 mg. The receipt expenditure by the hospital was R$ 118.38 and the market price to same receipt was R$ 425.95, what means to 35.5 % of the patient monthly average income. Conclusions: It was verified the need of the access to the medical asthma therapy accordingly the guidelines of the Sistema Único de Saúde of Brazil in which the pharmaceutical care must guarantee the offer free medicines to patient who cannot obtain the treatment by his own income.

T-096

536 – DISTRIBUTION OF ATYPICAL ANTIPSYCHOTICS FOR REFRACTORY SCHIZOPHRENIA TREATMENT IN CEARÁ STATE DURING 2002 – 2010

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Introduction: Promotion of technologies' rational use and awareness about the balance between user's benefits and costs are the main objectives of health technology assessment programs, HTA. Chronic psychiatric conditions require continuous drug dispensation. HTA methods provide relevant analytic tools SESA-CE is adopting, especially in the surveillance of chronic diseases and its drug treatments. Objective: To describe the consumption levels and related expenditures associated with the atypical antipsychotics used for the treatment of refractory schizophrenia in the period 2002 to 2010. Methods: Data were collected from the Pharmaceutical Assistance Coordination inventory and distribution management system. Expenses are evaluated measuring the quantities of drugs distributed, based on Defined Daily Dose (DDD) per 100,000 inhabitants, as well as the amount spent per treated patient. Expenses are presented in US dollars at a rate US$ 1= R$ 1, Brazilian Real. Results: In 2002, local Pharmaceutical Care provided drug treatment for 544 schizophrenic patients amounting to $ 1,342,824.94 expended. The highest consumed drugs in 2002 were: risperidone (average 26.89 DDD/100.000 inhabitants / day) and olanzapine (1.35 DDD/100.000 inhabitants / day). In 2010 the cohort of patients has increased to 5,975 patients, where these two drugs remained as the most frequently distributed. However, there was a considerable increase in the DDD per patient, as follows: risperidone (262.64 DDD/100.000 inhabitants / day), olanzapine (82.40 DDD/100.000 inhabitants / day). In 2010, there were registered expenses of $ 16,665,755.02. The treatment cost per patient per day has, thus, presented a 13% increase, amounting to $ 2,789.24. Conclusions: This study suggests the local increase in consumption of risperidone and olanzapine. The Brazilian Health Ministry's Clinical Protocol and Therapeutic Guidelines proposed the clozapine as second choice therapy, locally, we observed the use of olanzapine being the second most frequently chosen drug therapy in contrast with the guidelines.

T- 097

539 – TRIPLE LOW IMMUNOSUPPRESSION GROUP FOR HEART TRANSPLANTATION: OUTCOMES ASSESSMENT AND FINANCIAL IMPACT IN THE CEARÁ STATE

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Introduction: Heart transplantation is the unique possibility to improve the quality of life of patients who have refractory heart disease. Individual patient's clinical conditions adapted immunosuppressants modulation of doses. Objective: To evaluate the impact on patient outcomes and the direct costs of the immunosuppression for heart transplant patients in the Ceará State Health Department (SESA-CE). Methods: Retrospective review of Hospital do Coração Carlos Alberto Studart (HCCAS) heart transplants' medical charts and the SESA-CE Pharmaceuticals Management System (PMS), in 2010. Kaplan-Meyer actuarial event free survival and mortality were estimated according to transplantation year and age strata. Doses prescribed were correlated with reported use registered at charts and listed distributed doses. Costs are presented in US dollars at a rate US$ 1= R$ 1.00, Brazilian Real. Excel and SPSS 10.0 were used for the statistical analysis. Results: The Low Immunosuppression Group for Heart Transplantation (LIGHT) Scheme consisting of corticosteroids, mycophenolate mofetil and cyclosporine in moderate to low doses. Acute cellular rejection episodes were the most frequent complication observed. Amid the 210 survivors, transplanted from 1998 to 2010, 84% were alive in the 1st year, observed survival rates at the 3rd year was 73%, 65% were alive and well at both follow-up periods: the 5th and 10th years. In 2010, the total direct cost of immunosuppressant treatment of HCCAS's LIGHT Scheme was $ 210,996.50; an average of $ 13,187.28 per year per patient. This represented a 25% economy when compared to the program in remainder SESA-CE centers for other organ transplantations. Conclusions: HCCAS's LIGHT immunosuppressive scheme has lower financial impact than the remainder SESA-CE centers for other organ transplantation program and has promoted results similar to the best national and international rates of survival, according to the Brazilian Registry of Transplant (RBT) and the International Society for Heart and Lung Transplantation (ISHLT).

T-098

643 – OUTCOMES AND ECONOMIC CHARGES / DIRECT FINANCIAL IMPACT OF IMMUNOSUPPRESSIVE DRUGS USE FOR ORGAN TRANSPLANTATION IN CEARÁ STATE: 2006-2009

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Introduction: Immunosuppressive drugs are technological breakthroughs that allowed further development of organ transplantations. During these past 20 years, expensive specific inhibitors have emerged providing increased efficacy and reduced toxicity. Acquisition of immunosuppressive drugs for the transplantations' program is centralized in the Ceará State Health Department (SESA). A delicate balance between preserving life-saved, protecting these high technology investments and maintaining continued drug provision represents a significant financial challenge. Objective: To evaluate the outcomes and the financial charges immunosuppressive drugs use generated in the state of Ceará, during four years. Methods: Retrospective cohort study using documentary analysis of administrative public healthcare claims in the Ceará State, from year 2006 to 2009. Results: In 2006 there were 446 organ transplantations performed, and in 2009 this number rose to 767. Average hospital mortality of 15%, 18% and less than 0.6%, respectively, for heart, liver and kidney transplantation were observed, without significant variations. A gradual evolution, however, was observed in immunosuppressive drugs spending: 60.6% increase in 2009, compared to 2006 expenses, and a real consumption increase of 44.3% in the number of units of immunosuppressive drugs used for organ transplantations program. However, there was no significant variation within the multiple treatment strategies.

i.e., in the state of Ceará organs and tissues transplantation was increasingly more frequent. While overall hospital charges have paralleled near 7% increased procedure numbers per year, the financial impact of the immunosuppressive drugs have sustained over 10% yearly increase. Conclusion: The use of new technologies in health care is necessary and unquestionable. However, resource management decisions must also consider benefits required for a larger number of patients. Detailed financial impact analysis and of the survival benefit of this technology is ongoing through long-term follow-up of these patients, preliminary results will be presented.

T- 099

735 – DIAGNOSTIC EVALUATION OF THE USE OF TECHNOLOGIES IN ONE PUBLIC HEALTHCARE UNIT OF THE CEARÁ'S STATE

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Introduction: Healthcare system management is a dynamic challenge confronted with population's changing epidemiological profiles and demands, high technological density environments and with limited financing. Objective: to assess health technologies used in a Ceará's State public healthcare unit, during 2009, aiming to improve healthcare planning. Methods: data from the Ceará's State Health Department Hospital Information System, SIH, was evaluated. Direct expenses were estimated for the three more costly technologies, and were correlated with all system variables to ascertain its major determinants and outcomes per patient. Expenses are presented in US dollars at a rate US$ 1= R$ 1, Brazilian Real. Results: In 2009, 15,193 clinical procedures were performed including various technologies, amounting to $ 26,796,259.34 expended. There were 2,322 deaths in total and the overall average of 9.25 days in hospital. Both variables, length of stay and mortality rate, were significantly correlated with expenses per patient. The treatments of chronic disease were related to the largest total expenses. However, per patient the most expensive procedures consisted of Cerebral Vascular Accident (CVA), kidney transplantations (KTx) and cerebral aneurysm embolization (CAE). Amongst 945 ischemic / hemorrhagic CVA patients there were an average of 11.54 days of stay, 33.65% deaths and $ 1728.42 direct cost of hospital admission per patient. Amid 64 KTx, there was an average 5.92 days of stay, $20,491.16 costs per patient and no deaths were reported. In 36 patients who underwent CAE, average $ 31859.97 expenditure per patient was observed related to 9.39 days of stay and a 2.78% mortality. The long-term survival study of these cohorts is ongoing. Conclusion: Technology Assessment can offer improved tools for healthcare analysis. As more situational diagnoses emerge, however, courageous political decisions are required to challenge resources' management strategies, aiming to provide access to healthcare benefits to a larger number of patients.

T-100

856 – DIAGNOSTIC EVALUATION OF THE FINANCIAL IMPACT OF THE USE OF IMAGING TESTS FOR HIGH COST IN A CLINICAL UNIT CARE OF THE STATE OF CEARÁ

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Introduction: The aggregated technologies to the accuracy of diagnostic imaging have revolutionized health care practices. However, the most accurate in that area are expensive and almost always bring harm to management systems. In the public health service in Brazil this loss can be explained by errors in the completion of necessary documentation for reimbursement. Objective: To evaluate the outcomes and the financial charges computed tomography (CT) and magnetic resonance imaging (MRI) use generated in the state of Ceará, during two years. METHODS: Retrospective cohort study using documentary analysis of administrative public healthcare claims in the Ceará State, from year 2009 to 2010. RESULTS: In 2009 TC 6987 were held in different parts of the body with reimbursement by the Unified Health System (SUS) of only 3867. The damage to the hospital was approximately 44.65% of total spending. In the same period were 165 magnetic resonance angiography (U.S. $ 44,343.75) with compensation of only 36 (R $ 9,675.00). Regarding MRI, there were 5519 with compensation of 3052, ie 55.3% of the total paid in the year. In 2010 the behavior was similar with some worsening. For the TC loss was 51, 1%. For MRI was 52.3% and for MRI was 26.2%. Conclusion: The rational use of modern technologies in health runs through the rational use of available financial resources. Thus, these data indicate that the use of the tools proposed by the Brazilian Ministry of Health for treatment in health care can be extremely useful to the Secretariat of Health of Ceará for the search of the causes of financial loss in the institution studied. In order to continue benefiting the largest possible number of patients with these technologies and enable the acquisition of more modern technologies in this sector.

T-101

205 – ANALYSIS OF RELATIONSHIP BETWEEN TIME AND VALUES OF EQUIPMENTS PURCHASES IN A PUBLIC HOSPITAL

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Purchasing processes in health public institutions need improvements in speed and values, given the imbalance between investment needs and available resources. At HCFMRP-USP, requests for medical equipments are reviewed by the Committee for Evaluation of Materials, which prioritizes according to funds available and institutional planning. Purchases follow the Procurement Law and the steps in this process are long, impacting the time to incorporate new technologies. Objective The aim of this study was to analyze time intervals of purchases of medical equipments and their relations with the financial figures. Methods This research conducted descriptive statistics on four years of equipment purchases (2005-2008). From the Materials Management System were obtained time counters on the steps of the buying process and equipment values. Time intervals between request and approval were obtained from printed forms. Findings In the period of 4 years, 1,522 medical equipments were purchased. Purchases by bidding exemption took average time of 68 days while those held by bidding processes took 193 days. Average waiting time for approval of equipments purchased by bidding exemption was 228 days, while for the bidding process was 316 days. The average values per item were R$ 2,635.00 and R$ 21,811.00 for purchases without and with bidding, respectively. Through ABC curve based on total purchase values, class A presented a purchase mean time of 221 days, while classes B and C had mean times of 124 and 65 days respectively, showing statistical significance among classes (analysis of variance, ANOVA). Conclusions Approval time of purchases is excessive due to insufficient resources. Values of equipments also influence length of acquisition. Results of this study can be used as indicators to control the acquisition of new technologies, improving processes.

T-102

691 – SPINAL CORD STIMULATION IN THE TREATMENT OF FAILED BACK SURGERY SYNDROME: COSTS AND BENEFITS IN THE ITALIAN CONTEXT (PRECISE STUDY)

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OBJECTIVE: Failed Back Surgery Syndrome (FBSS) patients might be treated with Spinal Cord Stimulation (SCS) when refractory to conventional medical management (CMM). PRECISE study investigates the clinical benefits and costs of SCS (plus CMM) versus CMM alone on a 2-year horizon in Italy. Here 12-months data are reported. METHODS: PRECISE study is an observational, pre-post, multi-centre study. Eighty patients were enrolled in 9 Italian Centers to be screened for SCS and, if responders, to be implanted. Clinical (NRS pain scale), quality of life (EQ-5D, SF-36 and Oswestry Disability Index) and economic (visits, use of drugs, diagnostic tests, hospitalizations, medical aids, productivity losses) data were collected through a specifically designed questionnaire. Resource consumption and costs were collected to be evaluated [EUR 2008] according to three perspectives: patient, National Healthcare System (NHS), Society. FINDINGS: Out of 72 patients implanted (mean age 58; 61% female), 62 completed the 12-months follow-up. SCS significantly reduced pain, and improved function and HR-QoL. According to pain Numerical Rating Scale, mean pain intensity decreased from 7.4±1.3 to 4.4±2.5 and maximum pain intensity from 9.1±1.1 to 6.3±2.7. Fifty-three patients (85%) experienced an improvement in function measured with Oswestry Disability Index. All SF-36 domains significantly improved. After the implantation, monthly out-of-pocket expenditure dropped from €161.45 to €86.31. Excluding screening and implantation costs (€1,218.13 per month per patient), total NHS monthly per-patient expenditure diminished from €163.77 to €100.17 (in great part due to a reduction in hospitalizations and diagnostic exams). Similarly societal monthly per-patient expenditure decreased from €460.21 to €258.64; in particular, SCS allowed a relevant reduction of caregivers' productivity losses (from €134.98 to €72.16). CONCLUSIONS: SCS appears to be more effective than CMM alone in controlling pain and improving HR-QoL in selected FBSS patients. Therefore SCS allows a pre-post reduction in patient management costs from all the perspectives analyzed.

T-103

653 – ECONOMIC EVALUTATION OF DISEASE MANAGEMENT PROGRAM FOR CARDIOVASCULAR DISEASES

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Disease management programs aimed at monitoring and educating patient with cardiovascular risk can be a possible solution to the spread of costs for hospitalizations, new technologies and drugs. To investigate about the cost -effectiveness of a disease management program aimed to prevent cardiovascular diseases a cluster randomized trial was designed and conducted from June 2008 to June 2009. 6 primary care districts belonging to Marche and Abruzzo (Italy) were selected to take part in the study and 3 were assigned to the case group where trained nurses got the role of case manager with the specific task of educating and monitoring a number of patients at risk, thus coordinating the intervention of GPs and specialists through the entire process of care. In total, 460 patients were taken in charge by disease managers and 460 were administered with the standard care as stated by the national guidelines. Data costs were collected about GP visits, diagnostic exams, drugs and hospitalizations. The salary of the disease manager was allocated to each primary care district belonging to the case group. Patient level clinical data were collected regarding blood pressure, colesterolemy, dyslipidemia and smoking abits. Moreover, the EQ-5D was administered. Results showed how patients in the case group experienced a reduction of 46% of their cardiovascular risk and an improvement in their quality of life of 6% with respect to the standard care group. Concerning the costs, a mean saving of 167 euro/patient was also observed. Results were also stratified for different age groups and results showed an ICER ranging from euro 25.000/QALY (for patients aged 75-80) to dominance (for patients aged 50-59). The study shows how a disease management intervention for the prevention of cardiovascular diseases is a good investment in health. Primary care districts should reallocate their resources to implement disease management services.

T-104

654 – GENERALIZABILITY OF ECONOMIC EVALUATIONS IN ITALY

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The growth of health care expenditure within OECD countries invites modern healthcare systems to explore several cost containment methods. As part of Health Technology Assessment (HTA), Health Economic Evaluations (HEEs) represent essential instruments to support management and policy decisions, as far as they concur to obtain results as transferable as possible and to avoid unnecessary overlapping and waste of resources. The aim of this study was to assess the methodological quality of Italian model-based HEEs and trials in terms of their transferability in other different settings. We used a check-list for assessing the generalizability of 108 economic evaluations published up to 2010. We observed an increasing clearness of methods and generalisability of results in the course of time, a larger and more representative sample in trials and a larger adoption of transition-Markov models in models HEEs. In recent studies, Cost-Effectiveness Analyses and the use of the Incremental Cost-Effectiveness Ratio (ICER) are preferred. During the whole observation period, Cost-Utility Analyses, Cost-Benefit Analyses and Cost Minimization Analyses were not frequently observed. Given this trend, generalizability of results still appears to be an unsolved question, even if some indication of slight improvement within Italian studies have been recorded.

T-105

786 – GENE EXPRESSION PROFILING FOR GUIDING ADJUVANT CHEMOTHERAPY DECISIONS IN WOMEN WITH EARLY BREAST CANCER: A COST-EFFECTIVENESS ANALYSIS OF 1000 STRATEGIES FOR THE PROVISION OF ADJUVANT! ONLINE, ONCOTYPE DX AND CHEMOTHERAPY

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OBJECTIVES: Adjuvant chemotherapy decisions for women with early-stage breast cancer are complex. Oncotype DX, a gene expression profiling test, is validated at predicting distant recurrence-free response in patients with ER+ LN- early-stage breast cancer. This enables chemotherapy to be better targeted at higher risk patients than is possible through the use of Adjuvant! Online or clinical judgement alone. However, existing cost-effectiveness analyses of Oncotype DX have numerous limitations: in particular, they consider a limited range of strategies and do not separately consider intermediate risk patients identified through either Adjuvant! Online or Oncotype DX. Our objective was to build an Ontario-based cost-effectiveness analysis which comprehensively addresses these limitations. METHODS: We built upon a Markov model developed by Tsoi and colleagues, using data from the NSABP B-14 and B-20 clinical trials. We assumed that Adjuvant! Online and Oncotype DX may be provided separately or sequentially and considered the chemotherapy decision separately for every possible risk group, resulting in 1000 unique strategies for the provision of Adjuvant! Online, Oncotype DX and chemotherapy. RESULTS: Oncotype DX appears cost-effective for all patients, regardless of a patient's initial Adjuvant! Online risk assessment. The highest ICER is in patients at low Adjuvant! Online risk ($29,000 per QALY), while Oncotype DX dominates in patients at high Adjuvant! Online risk. Chemotherapy appears cost-effective only in patients at intermediate or high Oncotype DX risk. The highest ICER is in patients at low Adjuvant! Online and intermediate Oncotype DX risk ($64,000 per QALY). Chemotherapy is dominated in patients at low Oncotype DX risk. CONCLUSIONS: Oncotype DX appears to be cost-effective for all Ontario women with ER+ LN- early-stage breast cancer, regardless of the woman's initial Adjuvant! Online risk assessment. These results have informed the Ontario Health Technology Advisory Committee's recent deliberations regarding the funding of Oncotype DX in Ontario.

T-106

696 – COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF RIVAROXABAN IN THE PREVENTION OF THROMBOEMBOLIC EVENTS IN PATIENTS PERFORMING HIP AND KNEE ARTHROPLASTY IN COMPARISON WITH DABIGATRAN UNDER THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM PERSPECTIVE

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Objectives: To develop a cost-effectiveness and a budget impact analysis of Rivaroxaban in the prevention of thromboembolic events in patients performing hip and knee arthroplasty in comparison with Dabigatran under the Brazilian private health care system perspective. METHODS: A decision tree analysis was developed for the first 90 days, considering the occurrence of Deep Venous Thrombosis, Pulmonary Embolism and thromboembolic events, followed by a Markov model, for Post Thrombotic Syndrome and Thrombotic Pulmonary Hypertension. The time horizon of the analysis was 5 year. The cycle duration was 1 year and corresponding epidemiological and efficacy data were obtained from a critical appraisal of the scientific literature. The outcomes were expressed as the incremental number of all thromboembolic events. The analysis considered only direct medical costs. Unit costs for drugs, procedures, materials and daily hospital were obtained from Kairos Magazine (Maximum price consumers 18%ICMS), Hierarchical Brazilian Classification of Medical Procedures (CBHPM 5thedition), Simpro Magazine (Maximum price consumers 18%ICMS) and UNIDAS 2008, respectively. A budget impact analysis was developed considering an increase of 10% per year in market share of Rivaroxaban. RESULTS: Total costs associated with Rivaroxaban and Dabigatran, considering the indication for knee arthroplasty, were BRL363 (US$214) and BRL371 (US$218), respectively. The number of all thromboembolic events was the same. Rivaroxaban treatment is cheaper with same efficacy. Total costs associated with Rivaroxaban and Dabigatran, considering the indication for hip arthroplasty, were BRL332 (US$195) and BRL485 (US$285), respectively. Rivaroxaban reduces the number of all thromboembolic events in 0.0140. Rivaroxaban treatment is more effective and cheaper than Dabigatran treatment (dominant). The budget impact analysis estimated an economy of BRL3,894 (US$2,291) and BRL150,642 (US$88,613) for knee and hip indication, respectively, in 5 years. CONCLUSIONS: By this pharmacoeconomic analysis, the treatment with Rivaroxaban, shown to reduce treatment costs and events compared with Dabigatran

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T-107

699 – COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF RIVAROXABAN IN THE PREVENTION OF THROMBOEMBOLIC EVENTS IN PATIENTS PERFORMING HIP AND KNEE ARTHROPLASTY IN COMPARISON WITH NO TREATMENT UNDER THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM PERSPECTIVE

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Objectives: To develop a cost-effectiveness and a budget impact analysis of Rivaroxaban in the prevention of thromboembolic events in patients performing hip and knee arthroplasty in comparison with no treatment under the Brazilian private health care system perspective. METHODS: A decision tree analysis was developed for the first 90 days, considering the occurrence of Deep Venous Thrombosis, Pulmonary Embolism and thromboembolic events, followed by a Markov model, for Post Thrombotic Syndrome and Thrombotic Pulmonary Hypertension. The time horizon of the analysis was 5 year. The cycle duration was 1 year and the corresponding epidemiological and efficacy data were obtained from a critical appraisal of the scientific literature. Unit costs for drugs, procedures, materials and daily hospital were obtained from Kairos Magazine (Maximum price consumers 18%ICMS), Hierarchical Brazilian Classification of Medical Procedures (CBHPM 5th edition), Simpro Magazine (Maximum price consumers 18% ICMS) and search UNIDAS 2008, respectively. A budget impact analysis was developed considering an increase of 10% per year in market share of Rivaroxaban. RESULTS: Total costs associated with Rivaroxaban and no treatment, considering the indication for knee arthroplasty, were BRL363 (US$214) and BRL1,040 (US$612), respectively. And considering the indication for hip arthroplasty, were BRL332 (US$195) and BRL462 (US$272), respectively. Rivaroxaban reduces the number of all thromboembolic events in 0.0793 and 0.0246, for knee and hip arthroplasty, respectively. Rivaroxaban treatment is more effective and cheaper than no treatment in both indications (dominant). The high cost associated with no treatment patient is due to the high number of events in this group. The budget impact analysis estimated an economy of BRL206,165 (US$121,274) and BRL104,351 (US$61,383) for knee and hip indication, respectively, in 5 years. CONCLUSIONS: By this pharmacoeconomic analysis, the treatment with Rivaroxaban, shown to reduce treatment costs and events compared with no treatment.

T-108

774 – COST-EFFECTIVENESS OF LAPATINIB PLUS CAPECITABINE IN THE TREATMENT OF HER2 POSITIVE METASTATIC BREAST CANCER PATIENTS PREVIOUSLY TREATED WITH TRASTUZUMAB IN BRAZIL

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Objective: To assess the cost-effectiveness of lapatinib associated with capecitabine (LAP/CAP) versus trastuzumab plus capecitabine (TRAST/CAP) and capecitabine alone (CAP) in the treatment of HER2-positive, metastatic breast cancer patients, previously treated with trastuzumab, under the Brazilian public healthcare system perspective. METHODS: No direct comparison between LAP/CAP versus TRAST/CAP is available. Two separate studies were identified, each evaluating the efficacy of the combination treatments versus capecitabine alone in the targeted population. Study design was similar, but disease severity was slightly different between trials and the dosage of capecitabine was lower in the lapatinib group. An indirect network comparison was performed to estimate the hazard ratio (HR) for progression-free survival (PFS) and overall survival (OS) between targeted therapies. A probabilistic Markov model comprising 3 health states (stable disease, disease progression, and death) was designed for the cost-effectiveness analysis. Studied time-horizon was 1 year. Only direct medical costs were considered. Drug costs were obtained from government acquisition lists (BPS) and procedure costs from a public reimbursement database (SIGTAP). Costs were presented undiscounted in 2009 Brazilian Currency (1BRZ=0.59USD). FINDINGS: The indirect comparison of LAP/CAP versus TRAST/CAP resulted in a HR for PFS of 0.832 (95%CI: 0.527-1.314); and for OS of 1.022 (95%CI: 0.567-1.842). The analysis showed 8.41 PFS-months for LAP/CAP, 7.86 for TRAST/CAP and 6.64 for CAP. Average costs were R$71,506 for LAP/CAP, R$85,353 for TRAST/CAP and R$22,445 for CAP alone. LAP/CAP was dominant (i.e., lower costs, higher benefits) over TRAST/CAP. The incremental cost-effectiveness ratio (ICER) between LAP/CAP and CAP was R$40,214/PFS-month gained. Monte Carlo analysis showed dominance of LAP/CAP over TRAST/CAP in 86% of simulations. CONCLUSION: Combined therapy LAP/CAP was found cost-effective when compared to TRAST/CAP in treating HER2-positive, metastatic breast cancer patients, previously treated with trastuzumab in Brazil. LAP/CAP can be cost-effective against CAP under a willingness-to-pay greater than R$40,000/additional PFS-month.

T-109

570 – OPPORTUNITY COST OF CANCELATION OF CONSULTATION IN A HOSPITAL LINKED TO SUS (SINGLE HEALTH SYSTEM) IN PERNAMBUCO

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Introduction: The cancelation of ambulatory consultations implies expenses for patients, relatives, health system, in addition to opportunity costs to the health service, since all the structure is prepared for visits are not concretized. Methodology: Partial economic assessment of the cost description type in a General Clinic and Specialized in Adults in a philanthropic hospital linked to SUS, located in the state of Pernambuco. The study period was carried out from January to September 2010. The number of consultations and cancelations were collected from the Directorship of Information Technology and extracted from the computerized system of the service. The opportunity costs for the hospital were calculated from the value paid by SUS on the ambulatory consultations. Results: During the study period 64,446 consultations were scheduled in different medical specialties. From these, a total of 23,896 (37.08%) consultations were not performed due to the doctors absence or the patient. The specialization on orthopedics was the most contributed to the quantitative consultations that were not carried out, being responsible for 20.35% of the total consultations canceled. Whereas the value of R$ 10.00 per consultation paid by SUS to the linked hospital, there was an opportunity cost in the value of R$ 238,960.00 during the study period. Conclusion: The search for efficiency and quality of ambulatory assistance is important for the service management by lowering cost on the procedures and the possibility of reducing the number of hospitalizations. In addition to these to generate higher direct and indirect costs will still determine intangible costs to patients and relatives. Thus, it should be conceived alternatives to decrease rates on canceled consultations since the value of the expenditure could be directed to other activities.

T-110

950 – COSTS OF TREATING PATIENTS WITH ACCIDENTAL TETANUS IN AN UNIVERSITY HOSPITAL OF PERNAMBUCO, BRAZIL

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Background: Most patients with tetanus are admitted to hospital with mild disease, but many progress to severe forms. Given this evolutionary potential, several authors recommend treating these patients in intensive care unit (ICU), preferably in referral centers, which makes the cost of treating these patients too high. However, in the literature there is no publication about full economic evaluation of treatment of patients with tetanus. Objective: To estimate the cost of treatment of tetanus patients categorized according to severity, in an ICU of a university hospital. Methods: The study was conducted in a public referral hospital for infectious diseases in Pernambuco, Brazil. We recorded the direct costs of drugs, disposable material and exams in hospitalized patients with tetanus. Patients were classified into four levels according to disease severity, grade I being the less severe and grade IV the worst. The cost information was obtained in the sector of medical bills from the hospital. Data were organized and analyzed in Excel. Results: The mean cost for treatment of accidental tetanus per patient were: grade I: R$ 1,380.84 (mean of 14.8 days of hospitalization); grade II: R$ 3,960.49 (mean of 27.5 days of hospitalization); grade III: R$ 6,243.16 (mean of 32.7 days of hospitalization); grade IV: R$ 12,126.68 (mean of 45.2 days of hospitalization). Disposables accounted for the largest share of cost (57.73%), but their importance in the total cost showed a tendency of decreasing as the severity of disease, since the drugs, which represented the second largest expense (31.09%), tended growing in importance in the overall cost as disease severity. Conclusion: The cost of treating tetanus patients in ICU specialized increases with disease severity. The relative cost of disposable supplies is greater in milder forms of tetanus, but the relative importance of drug cost increases with the severity of the disease.

T-111

161 – UTILITY ESTIMATES FOR DECISION-ANALYTIC MODELLING AFTER TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) BASED ON NYHA CLASSES AND OTHER CLINICAL INDICATORS

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Objective: Transcatheter aortic valve implantation (TAVI) has recently emerged as an alternative intervention to the surgical procedure (surgical aortic valve replacement, SAVR) to treat aortic stenosis (AS) in frail patients with a high risk of surgical mortality. In the context of AS becoming an increasingly relevant public health problem (aging population), evidence on quality of life (QoL) being scarce and cost-effectiveness not yet modelled, this study aimed at investigating whether utilities used to derive QALYs can be mapped from the NYHA class and other clinical/somatic indicators. Methods: This paper is a secondary analysis of 72 patients 3 months after TAVI. A stepwise OLS multiple linear regression analysis was employed to find the best fit, examining observed and fitted EQ5D values in terms of: correlation coefficient and the Bland-Altman plot of agreement. Mallows' Cp statistic was used as a goodness of fit test. A validation attempt was undertaken on an independent data set of 30 cases and the mean predicted utilities per NYHA class were compared to published utilities for SAVR and heart failure. Finally, the variance-covariance matrix was included for probabilistic sensitivity analysis in future cost-utility models. Findings: The results indicate that it is possible to predict the EQ5D index after TAVI from 3 months and baseline NYHA class, EQ5D at baseline, Euroscore and history of diabetes mellitus, peripheral vascular disease, AV block, other conduction abnormalities, myocardial infarction and pulmonary hypertension. The model seems to predict well for all EQ5D ranges except for very high values of the EQ5D. The R-Sq was 67.9%. Conclusion: In the absence of QoL data having been collected alongside clinical trials, utilities can by obtained indirectly through mapping models. This could complement the current gap in QoL evidence after TAVI and help professionals and policy makers shape the future use of this intervention.

T-112

860 – COST EFFECTIVENESS AND COST UTILITY OF TRASTUZUMAB IN THE ADJUVANT TREATMENT OF EARLY HER2-POSITIVE BREAST CANCER

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Objective: to evaluate the cost-effectiveness of adjuvant Trastuzumab in six Latin American (LA) countries (Argentina, Bolivia, Brazil, Chile, Peru and Uruguay) in patients with early HER2-positive breast cancer. Methods: A Markov model was designed to evaluate life years, quality adjusted life years (QALYs) and costs under a health sector perspective. A systematic search on effectiveness, local epidemiology and costs was undertaken to populate the model. Two face to face meetings of all the countries teams were held in order to agree on model structure, required parameters and a costing template to use a common methodology for identifying costs and resource use in all countries. Two main transition probability scenarios for the no Trastuzumab cohort were built and calibrated, one using trial data (TD) and the other using local/Globocan data (LD) in order to better fit local cancer prognosis. The base case scenario was with 55-year-old women, and used a 5% discount rate. Currency used was 2010 US dollars ($). Findings: Trastuzumab discounted benefits ranged from around 0.9 to 1.1 QALY in the TD scenario, and between 1.5 to 2.6 QALY in the LD scenario. Incremental discounted costs of the Trastuzumab strategy ranged from around $39,000 to $68,000 in the TD scenario, and $40,000 to $66,000 in the LD scenario. Incremental cost-effectiveness ratios ranged from around 39,000 to 60,000 $/QALY in the TD scenario, and between 21,000 and 40,000 $/QALY in the LD scenario. We used a 3GDP threshold as a decision rule (range of 3GDPs from 5,000 for Bolivia to 36,000 for Uruguay). Conclusions: Using the usually cited threshold reported by the WHO, these study initial results suggest that adjuvant trastuzumab for early breast cancer in HER-2 positive women may not be cost-effective in most situations in the participant LA countries.

T-113

436 – INCIDENCE AND PREVALENCE OF ADULT ADHD IN A LARGE MANAGED CARE ORGANIZATION IN SOUTHERN CALIFORNIA

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OBJECTIVES: Incidence and prevalence estimates for diagnosed +/- treated adult Attention Deficit Hyperactivity Disorder (ADHD) are scarce. Study objectives included 1) estimation of incidence (IR) and prevalence rates (PR) using three methods of cohort identification; and 2) longitudinal analysis of IR and PR (2006-2009). METHODS: Using Kaiser Permanente Southern California (KPSC) electronic medical records from 01/01/2006-12/31/2009, IR and PR for adult ADHD members 18-100 years of age were calculated. Three cohorts were identified: 1) ≥1 ADHD diagnosis (DX only), 2) ≥1 ADHD DX and ≥ 2 ADHD-specific prescriptions for an FDA-approved ADHD medication(RX) or 3) ≥1 ADHD DX and ≥ 1 behavioral therapy(BT) visit. Cohorts were not mutually exclusive (i.e., patients with both RX and BT were included in the DX+RX and DX+BT cohorts). For IR calculation, an ADHD diagnosis was the first on record since time of KPSC enrollment and within the study period. Rates were compared across demographics, cohort, and year. FINDINGS: In 2006, IR ranged from 0.02% to 0.07% for DX+BT and DX only cohorts, respectively. Across the four years, IR remained stable. PR in 2006 ranged from 0.15% in DX+RX to 0.31% for DX only, and increased over time to 0.24% and 0.42%, respectively, in 2009. PR decreased for the DX+BT cohort from 0.19% in 2006 to 0.09% in 2009. PR varied slightly by gender, but sharply by age as PR in the 18-19 age group was roughly nine-fold higher than rates in 60-69 age group each year. CONCLUSIONS: In this integrated care population, IR and PR of diagnosed adult ADHD were relatively low. Consistent annual IR may suggest an accumulation of patients causing increased PR over the four year period. Similarities in PR across males and females suggest possible equalization of ADHD diagnosis rates in adulthood.

T-114

165 – COSTS OF THE TUBERCULIN SKIN TEST (TST) AND QUANTIFERON GOLD-IN-TUBE (QFT-GIT) IN BRAZIL

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Background: One-third of the world's population has tuberculosis (TB) infection. Treatment of latent TB infection (LTBI) reduces in up to 90% the risk of active TB. TST for diagnosing LTBI has serious limitations, including false-positives induced by BCG vaccination. New interferon-gamma-release assays, which are not affected by BCG, have been recently developed, QFT-GIT being the less expensive and cumbersome. Costs and cost-effectiveness of these tests are not reported in high-burden, low and medium income countries. Objective: To compare the costs of both tests from the Public Health System perspective in Brazil as a tool for cost-effectiveness analysis. Methods: We conducted a micro-costing analysis considering equipments, consumables and human resources. Since the QFT-GIT is done in batches, the minimum time necessary for laboratory staff to complete testing on one batch was calculated. Laboratory supplies used for a single batch of 20 patient specimens was recorded. Staff costs for laboratory staff were calculated using staff hourly salary. Laboratory equipment costs were assigned a per-patient cost by determining the proportion of daily time used for one batch and depreciation was calculated based on equipment durability. Findings: Mean costs were US$ 6.87 per TST and US$ 45.98 per QFT-GIT. The main cost items were consumables: the kit for QFT-GIT and the tuberculin for TST. Conclusions: QFT-GIT is six times more expensive than TST per patient tested. Cost-effectiveness studies considering QFT-GIT's higher specificity are necessary in order to evaluate if the higher costs will offset unnecessary treatment of falsely diagnosed LTBI in countries with universal coverage by BCG. Fundedy by FAPERJ, CNPq and ICOHRTA

T-115

609 – COST COMPARISON OF THREE STRATEGIES FOR CONTACT SCREENING OF LATENT TUBERCULOSIS INFECTION IN BRAZIL

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AIM:The aim of this study was to compare the costs of three strategies detection of latent tuberculosis infection (LTBI) in routine clinical practice in Brazil. METHOD:A decision tree to represent different pathways for the diagnosis of LTBI under the Health System perspective was used.The model represent a direct cost-analysis.The costs of screening for LTBI, including visits to the physician, tuberculin skin test, radiological examination and preventive treatment with isoniazid were calculated.The first strategy involved the current National Tuberculosis Programme guidelines of tuberculin skin test on close contacts; the second strategy relied on the newer interferon-gamma release assays (IGRAs), the Quantiferon TB Gold In-Tube (QTF-GIT).The third strategy involved the TST followed by confirmation of positive results by QTF-GIT.Among the advantages of the newers IGRAs are its increased specificity, since it is not affected by previous BCG vaccination and nontuberculous mycobacteria.The model's parameters were based on existing literature and considered TST to have a sensitivity of 77% and a specificity of 59%.The QTF-GIT was considered to have a sensitivity of 70% and a specificity of 96%.Micro-costing analysis of TST and QTF-GIT, including costs of equipment, consumables, nursing and staff time were used. A hypothetical cohort of 1,000 contacts was used in the analysis and a 9-month isoniazid preventive treatment with a 100% adherence rate was considered. Costs are in 2010 US dollars (US$).RESULTS:The total costs for strategy relying solely on TST was US$44,880, while the strategy using only QTF-GIT was US$73,420. The strategy using TST followed by QTF-GIT cost US$ 57,000.The TST accounted for an extra 178 patients treating for LTBI, which accounted for an extra U$ 10,500.CONCLUSION: The use of QTF-GIT for diagnosis was the most expensive strategy. Cost-effectiveness analysis taking data from high-burden lowmiddle-income countries must be done to establish its value in the diagnosis of LTBI. Funded by CNPq/FAPERJ/ICOHRTA.

T-116

761 – COST-UTILITY OF DRONEDARONE COMPARED WITH ANTI-ARRHYTHMIC DRUGS AND STANDARD OF CARE IN TREATMENT OF ATRIAL FIBRILLATION IN POLAND

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Objectives: To evaluate cost-utility of dronedarone on top of standard care compared with amiodarone, propafenone, sotalol and standard of care (SOC: including beta-blockers, calcium antagonists, digoxin, ACE inhibitors, statins, vitamin K antagonists, aspirin, in placebo arm of the ATHENA trial). Methods: A cost-utility analysis was performed based on the Markov model with states that capture crucial events associated with atrial fibrillation (AF): symptomatic AF, acute coronary syndrome, stroke, congestive heart failure, death. Results were obtained by conducting microsimulations in a lifetime horizon. Cycle length is one month. The clinical data were obtained from clinical trials included in the systematic review (2010) conducted according to HTA guidelines in Poland (2009). A mixed treatment comparison was conducted for comparison of dronedarone against other drugs. Costs were calculated from perspective of public payer and patients (in case of co-payment) on the basis of Ministry of Health data, Polish registries, surveys and relevant literature. Cost per QALY gained and cost per life year gained were calculated. Discounting according to HTA guidelines was applied: 5% for costs and 3.5% for outcomes. One-way and probabilistic sensitivity analysis were performed. Results: Dronedarone yielded 7.2 QALY which was 1.9 more QALY than amiodarone and propafenone, 2.5 more than sotalol and 0.2 more than SOC in life time horizon. Dronedarone was associated with higher total costs: 4.0k EUR more than amiodarone and sotalol, 3.9k EUR more than propafenone and 3.5k EUR more than SOC. The cost-effectiveness (ICER) threshold in Poland is 25,011 EUR. Incremental cost per QALY for dronedarone was 2,154 EUR, 2,090 EUR, 1,636 EUR and 16,233 EUR with amiodarone, propafenone, sotalol and SOC, respectively. Conclusion: Dronedarone is a new option for treatment patients with non-permanent AF and is cost-effective as compared to SOC, amiodarone, propafenone and sotalol in Polish clinical settings.

T-117

715 – DIRECT MEDICAL COSTS ASSOCIATED TO BREAST RECONSTRUCTION AFTER MASTECTOMY WITH TEMPORARY VERSUS PERMANENT EXPANDERS FROM THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM PERSPECTIVE

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OBJECTIVE: To estimate patterns of treatment, resource utilizations and direct medical costs associated to breast reconstruction surgery after mastectomy in single stage with permanent expander (Becker expander) versus two stage reconstruction with a temporary expander (Silimed) followed by silicone implant (Silimed), from the Brazilian private health care system perspective. METHODS: A systematic literature review was conducted to estimate patterns of treatment for both techniques and its complications in a 12 month time horizon. An expert panel was developed to validate resource utilization according to local. Only direct medical costs were considered and unit costs were obtained from Brazilian government official lists. Sensitivity analyses were conducted to the following parameters: Becker expander price, temporary expander brand, and silicone implant brand. RESULTS: For the two stage reconstruction, costs of preoperative, first surgery, second surgery and postoperative period were respectively 412BRL, 7,316BRL, 6,304BRL and 811BRL, with a procedure total cost of 14,845BRL. For the single stage reconstruction, costs of preoperative, surgery and postoperative period were respectively 206BRL, 13,116BRL and 1,019BRL with a procedure total cost of 14,342BRL. Thus, single stage reconstruction exhibited savings of -502BRL in the base case and -2.482BRL when a 30% discount was applied to Becker expander price within one-way sensitivity analysis. When Johnson & Johnson temporary expander and silicone implant were adopted for cost estimation, single stage reconstruction reached savings of -3,472BRL without discount and -5,452BRL with 30% discount, resulting in an additional economic advantage. CONCLUSION: Breast reconstruction in single stage with permanent expander showed lower cost when compared to two stage reconstruction. One stage reconstruction also brings benefits in terms of indirect and overhead costs, not included in this analysis and psychosocial benefits to patients that undergo only one surgical procedure instead of two. Expander cost represents the major final cost driver of single stage treatment.

T-118

957 – ECONOMIC EVALUATION OF BOTULINUM TOXIN A IN NEUROGENIC URINARY INCONTINENCE FROM THE PUBLIC PAYER PERSPECTIVE IN BRAZIL

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OBJECTIVE: To assess the cost-effectiveness of botulinum toxin A (BT-A) injection compared to oral anticholinergic medications (OA) for the treatment of neurogenic detrusor overactivity (NDO) from a public payer perspective in Brazil. METHODS: The target population consists of patients with NDO secondary to multiple sclerosis or spinal cord injury. A Markov state transition model was designed to compare the costs in 2010 BRL and effectiveness in persistent urinary incontinence-free years (IFY), with a 10-year time frame using monthly cycles. Input data were obtained through systematic review of clinical and observational studies to simulate long-term evolution of NDO patients. Based on a panel of clinical experts, NDO-related medical resource utilization patterns were assessed. Unit costs were based on Brazilian official lists (SIGTAP and BPS 2008). One-way sensitivity analyses were performed. Annual discount rate of 5% was applied to costs and benefits. RESULTS: The model estimated 7.29 and 3.00 years without persistent urinary incontinence for BT-A and OA, respectively. Total discounted monthly costs were 101 BRL and 77 BRL for BT-A and OA, resulting in an incremental 10-year cumulative cost of 2,847 BRL. While the BT-A was more expensive it was also more effective (4.29 additional years) compared to the OA strategy. The calculated ICER was 663BRL per incontinence-free year, meaning that it would be necessary to invest additional 663BRL in BT-A (as compared to OA) to achieve one incremental incontinence-free year. CONCLUSION: Considering the higher proportion of patients that discontinue OA treatment due to intolerable adverse events, the lack of other therapeutic options within the Brazilian public healthcare system and the severe negative impact of NDO in patients' health status, BT-A exhibited higher projected effectiveness with an acceptable ICER.

T-119

224 – ASSESSING THE COST OF DRUGS USED IN THE TREATMENT OF PATIENTS WITH CHRONIC HEPATITIS B IN THE TERCIARY HOSPITAL

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Background: The antivirals can induce adverse events in patients, who require concomitant medications to ensure the success of therapy. It is worth noting also the presence of comorbidities, which may be associated or not the underlying disease, contributing to the increased number of prescription drugs and cost of treatment. Objectives: Cost assessment for drugs used in treatment of patients with chronic hepatitis B, in use of antivirals, attended in the Hepatology Clinic of HCFMUSP. Methods: This is a retrospective descriptive study. The population was delineated with the outpatients who were being treated in the period from June to November 2007 and were followed until May 2009. The economic evaluation was performed by analysis of cost, per patient, for drugs used during treatment, based on unit values paid by the institution, through the purchase by bidding in the form of outcry trading. Results: We analyzed the prescriptions of 108 patients, 97.22% using lamivudine in monotherapy or combination and 2.78% using interferon-alpha. The average annual expenditure per patient treated with lamivudine was

R$ 711.72 ± 1240.65 and treated with interferon-alpha was R$ 1439.49 ± 1116.58. Based in patients treated with lamivudine (n = 105), 80.95% were on monotherapy, 15.24% in combination with adefovir and 3.81% with tenofovir. The average annual expenditure per patient treated with adefovir was R$ 2768.44 ± 1801.94 and tenofovir, R$ 950.11 ± 568.47. It was estimated that the institution spends annually R$ 79,049.05 of budget available for pharmaceutical assistance. (On January 6, 2011, $ 1.00 = R$ 1.68.) Conclusions: It was demonstrated a trend of lower cost with the use of tenofovir when compared with adefovir (p = 0.08). Then, we should be concerned with the allocation of resources to aid in selecting the most cost-effective interventions.

T-120

380 – EVALUATION OF COST AND EFFECTIVENESS OF TREATMENT FOR CHRONIC HEPATITIS C

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Background: Approximately 170 million people are chronically infected with hepatitis C virus (HCV). Hepatitis C is considered the main cause of liver disease, sometimes progressing to cirrhosis and hepatocellular carcinoma. Treatment aims to halt the progression of liver disease by inhibiting viral replication. Objectives: To evaluate the effectiveness and costs in treating hepatitis C. Methods: Retrospective cohort study with 161 patients treated with interferon alpha (INF), peginterferon alpha 2a 180mcg (PEG 2a) and peginterferon alpha 2b 80 mcg (PEG 2b), followed through prescriptions from July 2005 until October 2007 in a tertiary care teaching and research institution. Treatment cost was calculated based on values from 2005 to 2010 only of the drugs. Results: The mean medium age was 53 ± 11 years, was 51.6% of patients were female, 104 (64.6%) patients with genotype 1, and 52 (32, 3%) with genotype 3. About 30 (18.6%) patients were cirrhotic. Five groups of patients were found, according to the type of interferon used for the treatment, 55 (34.2%) patients with sustained virological response (SVR), 86 (53.4%) non-responders (NR) and 20 (12.4%) patients other answers. The use of supportive therapy was higher in those treated with peginterferon alfa 24 patients (14.9%) compared with conventional interferon alpha, 3 patients (1.9%) (p < 0.0001). The cost of treatment was higher in patients treated with peginterferon alpha 2a 180mcg when compared with other alternatives found in the study. Conclusions: SVR was similar between groups, the interferon alpha showed less use of supportive therapy and the treatment cost of peginterferon alpha 2b 80 mcg was lower than the peginterferon alpha 2a 180 mcg.

T-121

378 – COMPARATIVE STUDY OF PUBLIC AND PRIVATE COST OF DRUGS USED TO TREAT PATIENTS WITH CHRONIC HEPATITIS B WITH ANTIVIRAL THERAPY USING LAMIVUDINE

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Background: The economic impact associated along with chronic hepatitis B is relevant, since decades of productive life are compromised due to development of cirrhosis and hepatocellular carcinoma. The treatment is expensive and there's a need of pharmacoeconomics evaluations to help decision on Brazilian Unified Health System (SUS) in order to taken drugs available list inclusion. Objectives: Acquisition on public and private systems comparing costs by chronic hepatitis patients using lamivudine, who has a doctor's assessment in the Hepatology Clinic of HCFMUSP. Methods: This is a retrospective descriptive study. The population was delineated with outpatients who had been treated on the period from June up to November 2007 and had been followed up to May 2009. The economic evaluation was performed through analysis cost per patient, per drugs used during treatment, based on unit values paid by the Institution, through of purchasing by bidding in the way of outcry trading, compared with private pharmaceutical market commercial value (CMED). Results: It's had been analyzed 105 prescriptions patients, 80.95% in lamivudine monotherapy, 15.24% on combination with adefovir and 3.81% with tenofovir. The annual average expenditure per patient was R$ 711.72 according to the price which the hospital bought the drugs, R$ 2,223.71 based on the maximum price which the laboratory is allowed to sell in the domestic market and R$ 3,063.21 based on the maximum price of marketing in pharmacies or drugstores. (On January 6, 2011, $ 1.00 = R$ 1.68.) Conclusions: The annual average expenditure per patient was higher in private health system than public ($p < 0.001$), which demonstrates the advantage of buying by bidding, ensuring a substantially lower price for the treatment.

T-122

968 – PEGYLATED INTERFERON FOR CHRONIC HEPATITIS B – SYSTEMATIC REVIEW

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Introduction: In the past decade several nucleos(t)ides analogues and pegylated interferon were approved for the treatment of chronic hepatitis B leading to improvement of quality of life with decreasing mortality and need of liver transplantation. Because Brazilian Health System is Universal, the government pays and regulates all the treatment costs. With new drugs and treatment strategies (use of molecular biology and combination therapy) health care spending continues to rise at a rapid rate and forcing a demand for information for a better and efficient use of health resources. Aim: Review the literature on the treatment for chronic hepatitis B with Pegylated interferon for the treatment of chronic hepatitis B. Methods: Electronic databases (Medline and Embase) for the period from 1999 to march 2009 for studies of clinical effectiveness. Randomized controlled trials (RCTs) were included that compared Pegylated interferon (PEG) with conventional interferon (IFN), entecavir, adefovir (ADF), tenofovir (TEN) or telbivudine monotherapy for adults with chronic hepatitis B mono-infection. Short-term outcomes were biochemical, histological and virological response to treatment and drug resistance. The trials were reviewed in a narrative synthesis but a meta-analysis was not undertaken owing to heterogeneity in the interventions and comparators

evaluated. Results and conclusion: A total of 2399 references were retrieved from Embase and 1612 references from Medline. After screening of inclusion and exclusion criterias, 3991 references were excluded. Therefore 20 studies published between 1999 and 2009 were analyzed according to the AgHBe status and defined outcomes. After analyzing the references there was great heterogeneity among the studies. There was only one study that compared PEG with conventional interferon. The majority of the studies evaluated the combination of PEG + oral antivirals, and did not demonstrated benefit of combination of PEG and oral antiviral therapy at this moment.

T-123

209 – ANTIMUSCARINIC DRUGS AND NEUROGENIC DETRUSOR OVERACTIVITY: A BRAZILIAN PHARMACOECONOMIC EVALUATION

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Introdution: Antimuscarinic agents are the first-line choice for the treatment of neurogenic detrusor overactivity (NDO). The currently available antimuscarinic drugs have been widely studied in patients presenting idiopathic detrusor overactivity; however, investigations evaluating the effects of these drugs on NDO are scant, mainly when is thought in cost-effectiveness analyses. Objective: A pharmacoeconomic evaluation was developed to compare the costs and the effectiveness of oxybutynin and tolterodine in two different formulations, extended (ER) and immediate-release (IR), for the treatment of NDO, based on Brazilian maximal consumer price index and from a payer´s perspective. Methods: A systematic review of literature was conducted in order to obtain significant clinical and urodynamic data (based on expert opinion), concerning the effects of these antimuscarinic agents in the neurogenic population. Furthermore, a pharmacoeconomic evaluation was performed to compare the costs of these drugs in terms of their effectiveness in improving cystometric capacity, reducing detrusor pressure and increasing the volume of urine voided/catheterization in 24 hours. For each antimuscarinic formulation, it was calculated the costs involved with each percentual of effectiveness obtained, in a time horizon of one month. Results: The most cost-effectiveness ratio (CER) observed was oxybutynin IR in pediatric ($0.46) and adult patients ($0.48) for each increased percentual in the cystometric capacity to a level more than 30% of the baseline. With regard to the reduction of detrusor pressure to a level less than 40cmH2O, oxybutynin IR had the best CER ($0.30 for each percentual reduced), data only existed for pediatric population. Finally, for each percentual increased in the voided volume/catheterization was found $1.03 for pediatric and 1.78 for adult patients, both CER referring to oxybutynin IR. Conclusion: Oxybutynin IR was the most cost-effective antimuscarinic, based on its dominance in all the three key urological parameters chosen.

T-124

604 – COST-EFFECTIVENESS IN SCREENING CERVIX CANCER BASED ON THE DEVELOPMENT OF A MARKOV MODEL FOR THE NATURAL HISTORY OF DISEASE IN BRAZIL

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In addition to the Pap smear, traditionally used for over 30 years, new technologies have joined the diagnostic resources available for the early detection of cervix cancer. The study aimed to evaluate the cost-effectiveness of three diagnostic technologies used for early detection of cervix cancer: Pap test, liquid-based cytology and hybrid capture test for HPV. It used a model that simulated the disease progression through the various stages of cancer, related in a Markov chain to simulate a cohort of 100,000 women aged 18 to 70 years, with screening starting at age 25, as recommended by the Cervix Cancer Control Program of the Brazilian Ministry of Health. The perspective of analysis used was the public health system. Cost were expressed in 2006 US dolares e clinical benefits expressed in years of life lost from cervix cancer. Costs and outcomes were discounted at 5% per year. The comparative efficiency of screening strategies was measured through the incremental relationship of cost-effectiveness. The model estimated that without screening, the cohort of 100,000 women would have at the end of the period, 6,120 years of life lost to cervix cancer. The most effective option was the HPV hybrid capture test held annually. The triennial Pap smear was the least expensive option, but had a lower effectiveness than the same test on an annual basis. The Pap smears performed annually presented the best cost-effectiveness relation (US$ 60.933,79 per year of life saved). The study found that well organized screening programs, using a long and widely known technology - the Pap test - can be cost-effective in reducing the incidence and mortality from cervix cancer. These results, however, can only be achieved if clinical, financial and organizational investments on maintaining and improving the control program of this cancer are persecuted and conducted.

T-125

985 – TRENDS IN COST-EFFECTIVENESS OF TREATMENT OF HYPERTENSION IN SOUTHERN BRAZIL

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Introduction: Hypertension control reduces the risk of cardiovascular events. However, the high cost of hypertension might impacts on adherence and control rates. Objective: To analyze the cost-effectiveness of hypertension treatment over a ten year period, under the individual perspective, among hypertensive patients of population-based samplings, in southern Brazil. Methods: Three cross-sectional studies, conducted between 1996 and 2007, enrolled men and women, aged 18 to 84 years, detecting hypertension by the average of at least two blood pressure measurements ≥140/90 mmHg or anti-hypertensive treatment. Cost-effectiveness analysis of anti-hypertensive treatment was based on market prices (Revista ABCfarma), obtained for 1996 and 2005, and the control rate (<140/90 mmHg among those under treatment). The direct costs of treatment were calculated for the lower dose of each drug, according to the V Brazilian Guideline for Hypertension. The cost of treatment in 1996 was calculated taken into account the inflation (by IPCA-IBGE indicator), using the four weeks time horizon for analysis. Results: Participants were assessed in 1996 (n=905), 1998 (n=1174), and 2007 (n=1848). The first study detected 35.5% prevalence of hypertension, 36.2% on anti-hypertensive treatment, and 29.5% with controlled hypertension. In 2007, the rates were 34.2%, 47.9%, and 49.0%, respectively. The average cost of anti-hypertensive treatment ranged from US$ 32.84 (1996) to US$ 37.84 (2005). The incremental cost-effectiveness ratio (ICER) ranged from US$ 111.32 (95%CI 85.97-149.27) to US$ 77.22 (95%CI 69.68-86.78). Since women had higher rates of control than men, the ICER was more favorable US$ 109.10 (1996) vs. US$ 71.53 (2005), and US$ 116.04 (1996) vs. US$ 94.36 (2005), respectively. Conclusions: The anti-hypertensive treatment had higher cost-effectiveness rate in 2007 than in 1998, mostly among women.

T-126

915 – A LONGITUDINAL ANALYSIS OF COSTS BEFORE AND AFTER BARIATRIC SURGERY: EXPLORING THE RELATIONSHIP BETWEEN EXPECTED WEIGHT LOSS AND COSTS, IN A PERSPECTIVE OF A THIRD PAYER

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Background: Several longitudinal studies have shown the benefits of bariatric surgery to achieve sustained loss of excess weight in morbid obesity patients and improvement of comorbidities like type 2 diabetes, sleep apnea syndrome, hyperuricemia and some types of dyslipidemia. However, obesity has assumed alarming proportions worldwide, and it is also important to question about the costs for managing these patients. Objective: to compare costs and health care utilization before and after bariatric surgery. Methods: Data from 377 obese patients covered by a Health Maintenance Organization (Unimed-BH) in Brazil were compared one year before and after bariatric surgery. Four covariance-matrix structures were tested to better fit the data: independence, autoregressive, heterogeneous autoregressive and compound symmetric. Results: The mean age of the patients was 38.0 years old (SD10.6), body mass indexes (BMI) mean 43.0 kg/m² (SD 4.7), 83% were female, 38% had arterial hypertension and 13% diabetes mellitus. There were 53 and 96 hospitalizations before and after bariatric surgery, respectively. The mean total costs (sum of hospitalizations, exams, emergency or elective consultation) before and after surgery were U$756.94 and U$896.23 respectively. The time effect on costs showed that after bariatric surgery costs decreased faster than they increase before surgery. Younger patients presented s consistently and significantly lower expenditures than older ones, with no influence of BMI status, presence of diabetes mellitus or arterial hypertension. Hospital stay had a major influence on expenditures as well as diabetes mellitus among comorbidities. Conclusion: costs after bariatric surgery were higher than before surgery, even with the expected lowering in BMI and improvement of comorbidities. However, there was a tendency of costs to decrease thereafter. Long time follow up studies are necessary to confirm this trend of cost reduction after bariatric surgery.

T-127

367 – ASSESSING CLINICAL AND ECONOMIC IMPACT OF TAVI: IS IT ACCEPTABLE FOR A REGIONAL HEALTH SYSTEM?

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Introduction: Aortic stenosis is one of the most common valvular diseases in older adults. Although traditional surgery is still the gold standard, the percutaneous heart valve replacement with TAVI (Transcatheter Aortic Valve Implant) seems to become a valid option for high risk or surgically rejected patients. Therefore within the framework of the Regional Research Plan 2008-2010, the Health Authority of Emilia Romagna Region (nearly 4.4 million residents) decides to investigate its effectiveness and economic impact. Methods: The Coverage with Evidence Development scheme (CED) is adopted. A prospective, observational, multicentric study is designed in order to assess the effectiveness of TAVI and to calculate the full cost of both the procedure and the hospitalization from the hospital perspective. Health care resource consumption per patient is measured in detail through a bottom-up approach. Results: To date only preliminary results are available. A total of 97 patients aged on average 82.66 years (SD: 5.7) are recruited. Their logistic Euroscore is on average 23.05 (SD: 12.61). A 30-day mortality rate of 6% is observed, while 1-year mortality rate amounts to 14.2%. Mean cost of patients is 35,009€ (range: 27,121€ - 69,432€). Few cases (10%) cost from 33% to nearly 100% more than the average. The majority of cost is due to hospital-stay (12%) and innovative device (63%). Conclusion: The uptake of CED, as suggested by several authors, appears a useful strategy to manage the introduction of a new procedure. Data on effectiveness confirm previous favourable findings, while the cost analysis shows a substantial burden. Due to the shortage of financial resources the affordability of TAVI requires further attention. The large variability of cost highlights the urgency to better define the characteristics of the target population who may benefit the most from the innovative procedure.

T-128

198 – HEALTH ECONOMIC EVALUATION OF COST AND CONSEQUENCES OF THE USE OF STEM CELLS IN THE TREATMENT OF PSEUDARTHROSIS

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The purpose of this study was to evaluate the costs and consequences of the use of stem cells in the treatment of pseudarthrosis. The methodology involved a partial economic assessment of the cost and consequences of this treatment. The study scenario was the Hospital Universitário Antonio Pedro and the subjects were eight patients operated between September 2008 and May 2009. The study perspective was that of the Sistema Único de Saúde, the main financial resource for medical assistance in Brazil. Statistical treatment of the data was performed using the STATISTICA 6.0 application and the Spearman nonparametric test. The results were statistically significant within an acceptable margin of error. The average treatment cost was R$ 1.247,21 and the average time for consolidation was 12.875 weeks. The Spearman nonparametric test showed that the correlation between the total cost and the time for was -0.25, a weak indication that the total cost is inversely proportional to the time for consolidation. From this study, we can conclude that the treatment costs were not prohibitive. The small size of the sample had no significant influence on the results; the age-related findings are similar to those of other studies and lead to the conclusion that population affected by pseudarthrosis is economically active. The creation of a protocol was essential for cost evaluation, providing a framework for data consolidation and yielding a more general view of the treatment. The time for consolidation was about the same as for the best results reported in the international literature and the procedure was observed to be safe and effective. We concluded that the SF36 questionnaire is an easily applied tool that can be reliably used in the post-treatment follow-up of the patients.

T-129

973 – INFORMAL GIFTS IN PUBLIC HEALTH CARE: SCARCE RESOURCES OR GOVERNANCE FAILURE? EVIDENCE FROM ALBANIA USING LIVING STANDARD MEASUREMENT SURVEY

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Informal payments to medical staff are present in the health care systems of many of ex-communist countries of Eastern European and Central Asia and can constitute a heavy burden on patient's expenditure. Such payments are widespread in Albania in both outpatient and inpatient health care sectors. The main causes of such payments are believed to be the lack of resources and poor governance in the health sector. Despite the measures taken in the last years they are still evident in both these services. This paper looks at the two main driving factors of informal gifts in health care in Albania, lack of resources and poor governance, and explores the effectiveness of various measures seeking to reduce such informal payments over the last years. The paper uses data from Albania LSMS 2002, 2005, 2008 and employs propensity score matching to investigate how individual characteristics of people paying informally have changed over years. We find mixed evidence on the lack of resources and poor governance hypothesis. Most of the evidence found suggests that even though scarcity of resources seems to influence the amounts paid informally, governance failures in health care are the main reasons driving the probability to pay. Recent reforms and measures have had questionable effects in reducing such phenomena, and the poorest people are still prone to the adverse effects of such payments.

T-130

624 – PREFERENCES OF PATIENTS, THEIR FAMILY CAREGIVERS AND VASCULAR SURGEONS IN THE CHOICE OF ABDOMINAL AORTIC ANEURYSMS TREATMENT OPTIONS: THE PREFER STUDY

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Objective: Factors influencing the choice between endovascular (EVAR) or open repair (OPEN) of abdominal aortic aneurysm (AAA) are of increasing interest. We quantified their importance among different subjects involved in the treatment. Methods: Pre- and post-operative patients (pts), their relatives and vascular surgeons completed questionnaires evaluating 6 treatment characteristics: anaesthesia (AT); recovery time to basic everyday activities (RT); risk of re-intervention at 5 years (RR); complexity of follow-up (FU); risk of major complications (RC); additional cost of intervention (AC). Through a Discrete Choice Experiment, virtual scenarios of treatment were obtained and the relative importance (RI) of each characteristic was determined through logistic regression. Results: One-hundred-sixty pts, 102 relatives and 30 surgeons from 9 centres completed the questionnaires. RC and RR were the most important characteristics (RI=56.0% and 27.2% respectively) for all the respondents categories. Patients and their relatives considered very important also a possible out-of-pocket AC. RT and AT were among the least important characteristics including hospital AC for surgeons. The different categories of respondents showed different opinions toward different treatment characteristics depending also on possible previous treatment. Conclusion: Preferences for AAA treatment characteristics differ between groups of involved subjects. Understanding individuals preferences could help in optimizing treatment benefits

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T-131

368 – THE COST-EFFECTIVENESS OF TRANSCATHETER AORTIC VALUE REPLACEMENT (TAVI) IN PATIENTS CURRENTLY INELIGIBLE FOR STANDARD AORTIC VALVE REPLACEMENT (SAVR): AN UPDATED ANALYSIS BASED ON THE RESULTS FROM A LARGE RANDOMISED CLINICAL TRIAL

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Introduction: Early stage modelling represents an important element of the reimbursement process and is often used to inform the design of any late stage clinical trial. Such models often rely on incomplete and/or poor quality data for their construction. Early models may also be used to inform reimbursement decisions by organisations such as the National Institute for Health and Clinical Excellence (NICE) in the UK. Thus, it is important to update any early stage model when new information becomes available. We used the results from a recently published landmark RCT in patients with severe Aortic Stenosis (AS) to update an existing model. The focus of the work was to explore the impact of differences in early and late stage evidence on the cost-effectiveness of TAVI, a commonly performed procedure in patients with AS. Methods: The PARTNER clinical trial randomised 358 patients to receive either TAVI or medical management (MM). 24 month data was available. The existing model had concluded that while the ICER for TAVI vs. MM (£22,220 per QALY gained) was below the upper threshold used by NICE, it was also above the lower threshold value of £20,000 per QALY gained. Hence the cost-effectiveness argument for full reimbursement was unproven. Results: Analysis of the PARTNER data showed that the original assumption of proportional hazards was untenable. In addition, the observed treatment related adverse events were fewer and procedural success was higher. The ICER generated using the revised model was £17,900 per QALY gained. At a threshold of £20,000 per QALY gained the probability that TAVI was cost-effective increased from 35% to 88% Conclusion: The use of good RCT data to parameterise an existing early stage model has resulted in a more definitive cost-effectiveness argument for TAVI. In particular, the revised data resulted in a notable reduction in decision uncertainty.

T-132

542 – A COST-UTILITY STUDY OF NPH INSULIN VERSUS INSULIN GLARGINE IN THE TREATMENT OF PATIENTS WITH TYPE 2 DIABETES MELLITUS IN BRAZILIAN PUBLIC HEALTH SYSTEM

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Objective: Diabetes is associated with complications and failure of several body parts and represents serious impacts in health budget worldwide. This study evaluated the cost-utility of NPH insulin compared to insulin glargine in the treatment of patients with Type 2 Diabetes Mellitus (DM2), from the perspective of Brazilian Public Health System, at threshold of US$ 30.000,00 per QALY. METHODS: A deterministic sensitivity analysis was made, totaling 30.000 simulations. Acceptability curves were also made to show the hypothesis that glargine would be more cost-effective when there is an increase of the threshold per QALY. The study was conducted using the following parameters: episodes of nocturnal and severe hypoglycemias, costs of these outcomes and costs of treatment with insulins. The data are derived from: Cochrane meta-analysis, CADTH meta-analysis, CADTH cost-effectiveness study (2009) and a Brazilian study about the medical attendance cost to people with DM2 (2006). RESULTS: The cost per QALY was US$ 86.400,00 for glargine. It was noticed in sensitivity analysis that, a few cases, exists the likelihood of glargine to be more effective than NPH, for the same threshold of US$ 30.000,00. CONCLUSION: It was found that sometimes the Brazilian government was judicially obligated to purchase insulin glargine. When it has occurred, the price was lower than list price, which was one of contributing factors to change cost-effectiveness ratio between the insulins, as observed in the sensitivity analysis. Therefore, it is necessary more studies to verify the possibility to include or not glargine in the Brazilian Public Health System.

T-133

338 – ECONOMIC EVALUATION OF POISON CONTROL CENTERS: A SYSTEMATIC REVIEW

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Objective: The aim of this review is to systematically summarize and assess the existing economic evaluations of poison control centers (PCCs). Methods: A literature search was performed to identify complete economic evaluations regardless of language or publication status by searching the following databases: Medline (via Pubmed), Embase, Centre for Reviews and Dissemination Databases, Cochrane Library, Cochrane Central, metaRegister of Clinical Trials, LILACS, SciELO, ProQuest, Capes (Brazilian theses register) databases and abstracts at toxicology congresses., Two reviewers assessed abstracts for inclusion and extracted the data. Two experts assessed studies' quality with a standardized tool (Drummond 2005). Results: A total of 365 non-duplicated reports were identified, but only nine met eligibility criteria. Five studies were published in the 1990s, and four were published in the following decade. PCCs were compared to a scenario in which they did not exist. Benefits were measured as potentially avoided healthcare charges. Eight studies used cost-benefit analyses, and the other one used a cost-effectiveness approach. Only two studies did not meet at least seven of 10 quality criteria. Cost-benefit ratios ranged from 0.76 to 7.67, what means that each dollar spent on poison centers saves almost US$ 8 in other medical spending. Incremental cost-effectiveness ratios were US$ -12,000 for morbidity and -56,000 for mortality. These results indicate that a significant cost savings is realized with each successful outcome achieved by a poison center: US$ 12,000 in case of morbidity and US$ 56,000 in case of mortality. Conclusions: Investment in PCCs appears to be a rational public health policy. They could improve healthcare expenditure efficiency and contribute to the sustainability of the health system. However, the number of PCCs is decreasing in many countries. Financial support: MCT/CT-Saúde and MS/SCTIE/DECIT, via CNPq (Edital 67/2009).

T-134

772 – COST-EFFECTIVENESS OF LAPATINIB COMBINED WITH HORMONE THERAPY IN PATIENTS WITH HER2+/ HORMONE RECEPTORS POSITIVE (HR+) METASTATIC BREAST CANCER (MBC) IN BRAZIL

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Objective: To evaluate the cost-effectiveness of lapatinib versus trastuzumab both combined with hormone therapies, as first-line treatments in patients with HER2+ and HR+, MBC from the perspective of the Brazilian Public Healthcare System. METHODS: A Markov model was developed to estimate the lifetime costs and consequences of lapatinib in combination with letrozole (LAP/LET) versus letrozole alone (LET) or trastuzumab plus anastrozole (TRAST/ANA). Epidemiological and efficacy data derived from a critical appraisal of the scientific literature. Indirect network analysis assessed the relative efficacy of compared treatments. The analysis assumed aromatase inhibitor class effect. Only direct medical costs were considered. Drug costs were obtained from acquisition lists (BPS), and hospitalization/procedure costs were extracted from a public reimbursement database (SIGTAP). Costs and benefits were discounted at 5% yearly and reported in 2010 Brazilian currency (1BRL=0.59USD). Outcomes were expressed as progression-free years (PFY), life years (LY), and quality-adjusted life years (QALY). Probability sensitivity analysis (PSA) was conducted to assess model robustness. FINDINGS: The analysis showed higher health benefits for LAP/LET (0.99PFY; 3.71LYG; 2.60QALY) than LET alone (0.66PFY; 2.83LYG; 1.98QALY) or TRAST/ANA (1.14PFY; 3.31LYG; 2.32QALY). Average lifetime costs were R$99,453 for LAP/LET, R$8,191 for LET alone and R$149,060 for TRAST/ANA. Incremental cost-effectiveness ratio (ICER) of LAP/LET versus LET alone was R$276,863/PFY, R$104,145/LY and R$148,778/QALY gained. LAP/LET was dominant (i.e., lower costs, higher benefits) over TRAST/ANA considering LY and QALY and produced an ICER of R$333,795/PFY gained. PSA showed 21% of iterations with ICERs below USD$50,000/QALY gained when comparing LAP/LET versus LET alone. Also, 68% of the results showed dominance of LAP/LET over TRAST/ANA. CONCLUSION: Dual targeted therapy with LAP/LET was associated with increases in LY and QALYs. The findings suggest that LAP/LET is cost-effective against TRAST/ANA in treating patients with HER2+/HR+, MBC. LAP/LET can be considered cost-effective over LET alone at a willingness-to-pay of R$150,000/QALY.

T-135

245 – ECONOMIC EVALUATION OF CERVICAL CANCER SCREENING STRATEGIES FOR MANAGING HIV-INFECTED WOMEN IN A RESOURCE-LIMITED SETTING

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HIV-infected women, especially those with pronounced immunosuppression, are at increased risk of acquiring HPV and developing invasive cervical cancer. With the widespread availability of Highly Active Antiretroviral Therapy (HAART) there has been a dramatic increase in the life expectancy of people infected with HIV. Unfortunately, the incidence of cervical cancer among HIV-infected women particularly in resource-limited settings has not decreased. In order to assess the cost-effectiveness of cervical cancer screening in this population, we developed a Markov model which simulates the natural history of the HPV infection, as well as the HIV- mediated immunosupression among women in Brazil. Our model was calibrated using data obtained from the Brazil IPEC-FIOCRUZ Women's cohort. It was used to compare the lifetime effects, costs, and cost-effectiveness of strategies combining the cervical cytology, HPV DNA test, and colposcopy at different screening intervals for different CD4 count strata. Our results suggest that considering a very cost-effective threshold given by Brazil's GDP per capita, HPV testing followed by cytology triage every year for all HIV infected women is the strategy with best cost-effectiveness profile (ICER below the threshold and highest probability of being cost-effective in the probabilistic sensitivity analysis). However, if we consider a cost-effective threshold given by three times Brazil's GDP per capita, the same strategy at a higher frequency frequency, every 6 months, has the best cost-effectiveness profile. The results were robust to changes in the input parameters as demonstrated in one-way, threshold and probabilistic sensitivity analysis. In conclusion, our results indicate that HPV testing followed by cytology triage for all HIV infected women is likely to be cost-effective in resource-limited settings like Brazil. The results reflect the synergic effect of using a highly sensitive screening test (HPV DNA test) in sequence with a highly specific test (cytology).

T-136

940 – COST-EFFECTIVENESS OF CANDESARTAN (ATACAND®) IN PATIENTS WITH HEART FAILURE IN POLAND

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Objectives: To assess the cost-effectiveness of candesartan versus valsartan and no ARB therapy in patients with heart failure (NYHA II-IV, LVEF<40%) from the public payer perspective in Poland. Methods: As there are no direct comparisons of candesartan with valsartan and no data allowing to assess their long-term impact on utility of life, a decision model was built to simulate a disease progression in a cohort of patients over a life-long time-horizon. Treatment selection (or lack thereof) was assumed to impact multiplicatively the hazard ratio of death (with baseline risk based on Polish life-tables). The probability of hospitalization due to heart failure was included. Hazard ratios were estimated using clinical trials comparing candesartan and valsartan to placebo. Utilities depended on the NYHA stage. Hospitalization was assumed to reduce the utility down to the NYHA IV level. Direct medical costs of a drug treatment and hospitalization were analyzed. Future costs and effects were discounted with 5% and 3.5% discount rates respectively. Cost data are presented in Polish zloty (1 PLN approx. 0,34 USD). Sensitivity analysis encompassed scenario analysis, differing in the persistence of hazard rates differences, and Monte Carlo probabilistic sensitivity analysis with respect to estimation error of hazard ratios and probabilities. Findings: In a short-term scenario candesartan dominated valsartan (gained 0.016 QALY and saved 42 PLN) and was cost-effective against a lack of treatment (gained 0.017 QALY for 716 PLN, ICER amounting to 42,600 PLN/QALY). In a life-long scenario candesartan was more cost-effective than valsartan (gained 0.302 QALY for 155 PLN, ICER equal to 515 PLN/QALY) and a lack of treatment (gained 0.304 QALY for 2,368 PLN, ICER equal to 7,800 PLN/QALY). Scenario and probabilistic sensitivity analysis proved the findings robust to the assumptions of the model. Conclusions: Candesartan is a cost-effective treatment in patients with heart failure in Poland.

T-137

692 – RESOURCE USE AND ASSOCIATED COSTS FOR THE TREATMENT OF HEAVY MENSTRUAL BLEEDING WITH LEVONORGESTREL RELEASING INTRAUTERINE SYSTEM (LNG-IUS) VERSUS HYSTERECTOMY: THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM (SUS) PERSPECTIVE

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Objectives: To describe the resource utilization and the costs related to heavy menstrual bleeding (HMB) control with either an LNG-IUS or hysterectomy in the Brazilian Public Health System (SUS) on patients treated at the Department of Obstetrics and Gynecology, School of Medical Sciences, University of Campinas, Brazil. Methods: we performed an observational retrospective descriptive study with costs evaluation and budgetary impact calculation from data extracted from medical files of patients diagnosed with HMB treated either with the LNG-IUS or hysterectomy. The measured outcomes were HMB control, LNG-IUS induced complications (expulsion, uterine perforation, pelvic inflammatory disease), LNG-IUS continuation rate and hospital costs after one year, as well as, the budgetary impact of the use of LNG-IUS in the treatment of HMB vs. hysterectomy. Results: Two hundred and sixty-seven medical files were initially retrieved for analysis. A total of 246 patients were included in this study, 122 received the LNG-IUS and 124 were treated with hysterectomy. The mean age was 39.7 years in the LNG-IUS group and 47.9 in the surgery group. Mean duration of HMB in the hysterectomy group was 3.2 years, twice that of the LNG-IUS group (1.5 years) (p<0.01). Of the patients treated with LNG-IUS, 88.7% maintained the device for over one year and 83.1% had success in bleeding control with this method. Fourteen patients had to have the LNG-IUS removed prior to 12 months; however, only 1.6% because of failure in bleeding control. Costs for the LNG-IUS insertion in a one-year time horizon were R$ 762.64 versus R$ 870.03 for the hysterectomy procedure. Conclusion: When applied to the eligible population in SUS the budgetary impact of the LNG-IUS adoption was an economy of almost R$ 3.6 million.

T-138

757 – RESOURCE USE PATTERN OF PATIENTS UNDERGOING LIVER TRANSPLANTATION WITH DIFFERENT DISEASE SEVERITIES IN A REFERENCE HOSPITAL IN BRAZIL

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Introduction: Brazil has a national transplantation program and 1,334 liver transplants have been performed in 2009. Since July 2006, unadjusted MELD has been used as a severity score to prioritize patients in the waiting list. The Brazilian Public Healthcare System funds the transplantation program and reimbursement for hospitals performing transplants is defined by a fixed amount, irrespective of disease severity. Objectives: To evaluate the resource use pattern of patients undergoing liver transplantation in a reference hospital in the city of São Paulo, Brazil and to stratify the analysis by MELD quartile. Methods: Patients undergoing liver transplantation in the reference hospital between August 2006 and June 2010 were included in the analysis. Resource use was evaluated in terms of length of stay in intensive care unit (ICU) or ward, blood transfusion and hemodialysis sessions during the hospital stay, and these were segmented by MELD quartile. Results: Three hundred fifty-four patients were included in the analysis. MELD quartiles ranged from 6-13, 14-22, 23-31 and 32-58, for the first, second, third and fourth quartiles, respectively. The average resource use for the total population and segmented by first, second, third and fourth quartiles were: ICU days: 5.8, 2.9, 3.2, 5.0 and 13.1 days, respectively ($p<0.05$ between quartiles 1-4, 2-4 and 3-4); Ward days: 12.9; 9.5, 10.0, 14.6 and 18.1 days, respectively ($p<0.05$ between 1-3, 1-4, 2-3 and 2-4); Dialysis sessions: 3.5, 1.1, 1.4, 4.1 and 8.3 sessions, respectively ($p<0.05$ between 1-3, 1-4, 2-3, 2-4 and 3-4); Blood transfusions: 11.0, 3.7, 8.1, 13.1 and 20.3, respectively ($p<0.05$ between all quartiles). Conclusions: A statistically significant difference was found in terms of resource use between patients with different disease severities. This might lead to a differential reimbursement for liver transplants performed in Brazil. Further studies are needed to test the generalizability of these results to other centers.

T-139

862 – NATIONAL COST SAVINGS FROM THE BRAZILIAN HIV/AIDS ANTIRETROVIRAL UNIVERSAL ACCESS PROGRAM

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Objective: In 1996, the Brazilian government implemented a universal access program for anti-retroviral drugs to improve the treatment of HIV/AIDS. This study estimates the drug costs saved in 2010 by the program's implementation. Methods: Nationwide drug distribution data and drug prices for the Brazilian government's antiretroviral access program were obtained for 2010 from the Ministry of Health data. Drug prices for each drug were converted to daily dosage costs in U.S. dollars. Comparable average wholesale U.S. drug prices (AWP) U.S. were obtained from The Red Book and converted to daily dosage costs. The Brazilian and the U.S. daily costs were multiplied by the distribution rates in Brazil to calculate and compare the cost of the Brazilian 2010 drug distribution using the Brazilian and U.S. pricing rates. Any cost savings to the Brazilian government were also calculated. The savings calculation assumes that the Brazilian government has paid for all of the drugs distributed regardless of patient utilization rates. Secondary analysis uses pricing rates from other prominent HIV/AIDS treatment programs and countries to compare the cost savings. Sensitivity analysis was conducted on the distribution rates, pricing, and utilization rates. Findings: The Brazilian government saved $1.78 billion U.S.D. in 2010 through its pricing program. The total cost of the drugs distributed was $1.94 billion with the Brazilian pricing. This compares to $3.72 billion dollars using U.S. pricing rates. Secondary analysis showed a great variation in cost savings. Sensitivity analysis found the results to be stable. Conclusions: Significant costs savings have been realized by the Brazilian government through its drug pricing program. These costs savings should be included as part of any analysis of the overall impact of the program.

T-140

230 – COSTS OF THE PHARMACEUTICAL PROGRAM TO TREAT T2DM PATIENTS FROM HIPERDIA: GOVERNMENT HEALTHCARE PROGRAM FOR DIABETES AND HYPERTENSION POPULATION UNDER THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM

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Diabetes is a chronic disease that requires continuing care to reduce the risk of long-term complications. In this sense it is important to maintain a good therapeutic arsenal providing good treatment to mantain type 2 diabetes (T2DM) and hypertension under control, preventing complications. We decided to assess the costs of the HIPERDIA program with medication provided by the government for a future cost-effectiveness research. HIPERDIA is a program for monitoring hypertensive and diabetic patients under care in the public healthcare system. Based on that database, we searched the number of patients under treatment from 2005 to 2010 and also the number of doses of the drugs (glibenclamide and metformin) available to control T2DM (Datasus/Hiperdia). Also, we looked at the Brazilian price database (Banco de Preços) the minimum and the maximum price paid by the government for those drugs to calculate their total costs in the program. From 2002 to 2010, we found a total of 1,067,754 patients using glibenclamide 5 mg and 662,519 patients under metformin 850 mg, however it was not clear the number of patients taking both. The average dailydosewas 1.79 tablet for glibenclamide and 1.74 for metformin. In the price database from the government, we found that the average price paid for glibenclamide was R$ 0.008/daily unit (ranging from R$ 0.007 to 0.04) and for metformin R$ 0.026/daily unit (ranging from R$ 0.023 to 0.098). From January 2009 to August 2010 the total cost of this program with these 2 drugs reached R$ 1,567,145 and our projections showed that, since 2002, the government spent about R$ 9 million. Generics generated a huge price pressure for those drugs in Brazil and with this scenario it seems to be difficult to predict the plans to update the drug list to provide more effective treatments for this population.

T-141

859 – COST-EFFECTIVENESS OF URINARY VS. RECOMBINANT GONADOTROPINS IN VITRO FERTILIZATION CYCLES: EVIDENCE FOR PORTUGAL

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Objectives: To carry out an economic evaluation of urinary versus recombinant gonadotropins in ovarian stimulation for in vitro fertilisation (IVF) cycles from a public third party payer perspective, the Portuguese National Health Service. Pituitary suppression was achieved according to standardized procedures using gonadotropin-releasing hormone (GnRH) agonists in three groups of patients according to age ranges (< 34, 35-39, > 40). Methods: Effectiveness data (deliveries) were collected from the combined results of two multicentric randomized controlled trials and from the Portuguese Assisted Reproductive Technologies (ART) National Registry. Medication and ART treatment costs were obtained from official sources. Cost-effectiveness ratios amongst alternatives were estimated. Results: Urinary gonadotropins were the dominant treatment strategy, with higher effectiveness and lower costs. Cost differences ranged from 95,83€ to 159,90€ in all analysed age groups. Incremental cost-effectiveness ratios were -2.886,21€ for the ≤34 patient group, -3.386,89€ for the 35-39 group and -21.575,52€ for the ≥40 group for one extra delivery. Both unidimensional and probabilistic sensitivity analysis were used, revealing the good stability of the model. Conclusions: Urinary gonadotropins were the dominant alternative for IVF treatments in Portugal. Differences between alternatives costs and effectiveness increased with female age. The cost-savings achieved using urinary gonadotropins would allow for the delivery of an additional IVF cycle for every 20,6 cycles performed.

T-142

751 – LOCATING OVERSEAS CLINICAL PRACTICE GUIDELINES TO INFORM LOCAL GUIDELINE DEVELOPMENT

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Purpose: The Ministry of Health, Singapore (MOH), develops clinical practice guidelines with the aim of improving quality of health care and to promote the practice of evidence-based medicine in Singapore. As part of the development of MOH clinical practice guidelines, a search is done to locate relevant overseas clinical practice guidelines for the reference of guideline workgroup members. These overseas guidelines help provide an overview of the scope of the topic, as well as supplement the supporting evidence for local guidelines. Methods: An online search is conducted for guidelines published in the past five years. Databases of clinical practice guidelines searched include the Guidelines International Network's International Guideline Library, the US National Guidelines Clearinghouse and the Canadian Medical Association's Infobase. Guideline agency websites (e.g. Scottish Intercollegiate Guidelines Network, National Institute for Health and Clinical Excellence) are also searched. Medical bibliographic databases (e.g. MEDLINE, EMBASE) are searched using filters and search terms for guidelines and consensus statements. Websites of professional bodies relevant to the specific clinical topic are also searched for guidelines. Retrieved citations are assessed by medical staff for appropriateness. Relevant citations are retrieved in fulltext and a compilation of the retrieved guidelines are provided on CD to workgroup members at or before their first workgroup meeting. Conclusion: This paper describes the methods by which overseas clinical practice guidelines are located to inform local guideline development. Effective management of information resources including the ability to extract potentially relevant guidelines from overall results of database searches and the efficient use of reference management tools have facilitated local clinical practice guideline development in Singapore.

T-143

148 – HOME MONITORING OF HEART FAILURE: EARLY ASSESSMENT OF A SWEDISH TELEMONITORING SYSTEM UNDER DEVELOPMENT

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At home monitoring of key parameters in heart failure can lead to reduced costs, increased patient autonomy and better symptom control and survival. A telemonitoring system is currently under development at Linköping University in cooperation with the regional healthcare provider. The goal is to quickly stabilize the patients by fine-tuning medication in response to abnormal physiological values. This study has estimated the impact of such a monitoring system on patients' health and survival. Health economic analysis has been conducted according to a proposed framework for early assessment and decision making in research and development projects. The analysis refers to a fully developed, functioning system in which blood pressure, weight, ECG, and shortness of breath / working capacity are monitored. Costs and effects were calculated for a follow-up period of one year after patients were discharged from in-hospital treatment of heart failure. Home monitoring was presumed to occur during the first six months of the follow-up period. Data on health effects was partly collected from studies of similar systems abroad. Country specific costs were derived from the billing codes applied by the healthcare provider. The results show reduced healthcare utilization and increased health related quality of life and survival for patients in home monitoring compared with ordinary care. The monitoring system incur some costs, e.g. for procurement, maintenance and data transmission, as well as physician time for distance monitoring. However, the savings on healthcare utilization and value of health benefits seems to outweigh these costs by far. Expressed as a cost-effectiveness ratio the cost of a quality-adjusted life year (QALY) was estimated to €2240. And, if the value of a QALY is set to €45 000, a cost-benefit analysis shows a likely net benefit of around €4270 per patient in home monitoring.

T-144

188 – EARLY ASSESSMENT OF HEALTH TECHNOLOGIES UNDER DEVELOPMENT: A PROPOSED FRAMEWORK FOR CASE STUDIES IN A SWEDISH CONTEXT

Kerstin Robac1k, Linköping University, Sweden; Lars Bernfort, Linköping University, Sweden; Thor-Henrik Brodtkorb, Linköping University, Sweden

Non-pharmaceutical innovations are frequently rejected by Swedish healthcare due to lack of evidence that enables decision-making. This hampers innovative forces and leads to small businesses having difficulties getting their products tested in a clinically relevant healthcare environment. The implication of this is that society is missing out on health benefits and economic growth through new products and expanding businesses. The aim of this project was to produce a framework for early assessment and economic modelling focusing on innovations under development. It should primarily be a tool for developers in their decisions during different phases of innovation development and in their contacts with funders and healthcare decision makers. International literature has been thoroughly searched and a pilot case study has been performed. Further case studies will be added to refine the framework. Early decisions according to the proposed framework will be based on estimated effectiveness and cost-effectiveness data, diffusion potential, model reliability, and profitability for business and healthcare stakeholders. Early assessments may benefit innovation in several ways. Developers can avoid that resources are wasted on unfruitful ideas and the evidence base of ideas that pass on to further development will be strengthened. Early assessment is also a means to indicate how to direct resources for clinical trials, i.e. to identify areas where more reliable data are needed. In the end this will lead to a better basis for decisions in healthcare, shorter lead times between first marketing and widespread use for innovations that correspond to real needs, and innovations that will be passed on to clinical use in a more systematic way.

T-145

573 – COMPARISON OF INTERNATIONAL HTA AGENCIES: HOW DO THEIR CHARACTERISTICS INFLUENCE HTAS OF MEDICAL DEVICES?

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Objective: The primary objective of this study was to evaluate and compare characteristics of public HTA agencies, and to investigate the type and number of HTAs performed by these agencies on medical devices. Methods: Current agency characteristics were extracted from multiple published sources. A systematic search of medical and HTA agency databases was conducted to identify published reports evaluating 14 medical device therapies within the cardiac, cardiovascular and neurological therapy areas. Search strategy (no language restrictions, publication date 2008-2010), study selection and data extraction were performed according to a predefined protocol. Results: Data on 31 public HTA agencies (16 regional [within countries], 15 national) from 12 countries (6 European plus Argentina, Australia, Canada, South Korea, Thailand, USA) were compiled and their available characteristics summarized. Per capita HTA budget was similar for regional and national agencies (mean was 0.24US$ and 0.25US$, respectively). Yet total HTA budget differences per capita across all agencies ranged from 0.01US$-1.10US$. Only 6% of regional agencies reported more than 50 permanent staff, as compared to 33% of the national agencies. Between 2008 and 2010, 42 reports were published on the selected device therapies (15 for cardiac rhythm disease management therapies, 17 for cardiovascular and 10 for neuromodulation therapy devices). Twenty-five reports were published by public agencies in the included 12 countries, 9 of which were classified as rapid reviews, 16 as full HTAs. Agencies which published more than 3 reports tended to be younger than those which only published up to 2 reports. However, agencies with higher numbers of permanent staff did not publish more HTAs on medical devices. Conclusions: The results show that there is great variation in the size, budget and age of HTA agencies globally. However, these characteristics did not appear to influence the number or type of HTAs published on medical devices.

T-146

636 – PILOT PROTOCOL PROPOSAL FOR OBSERVATION OF HEALTH TECHNOLOGIES AFTER INTRODUCTION INTO ROUTINE CLINICAL PRACTICE

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Background: in the period 2008-2009, the Galician Health Technology Assessment Agency (avalia-t), developed a methodological document to guide the observation of health technologies after their introduction into routine clinical practice. This paper aims to describe the development of a pilot study protocol for the observation of a health technology recently introduced into the regional health care basket. Methods: the observation protocol for "sacral root stimulation for the treatment of faecal incontinence" was based on the coverage decision determination that was issued by the Galician Health Service (Spain), linking reimbursement to data collection requirements. To develop the protocol two working groups were established: 1) technical group, made up of three avalia-t technical staff members; and 2) consultant group, made up of 3 specialists in General and Digestive Tract Surgery coming from the two health care centres authorised to perform the technique. The drawing-up of the protocol was based on two basic pillars: a) systematic review; and b) consensus of experts. Results: the final protocol features a series of outcome indicators judged crucial for measuring relevant results. These indicators are provided along with all the information required for their implementation, as well as a reference standard that can serve as a benchmark for identifying and evaluating outcome deviations from what is deemed appropriate and/or acceptable for the technology in question. Conclusions and recommendations: this study presents the first protocol proposal to verify the global outcomes derived from the introduction of health technologies into clinical practice. It is essential that the current protocol be refined so that it does not solely serve as an example but can be used by different centres that apply this technology in order to obtain a standardised registry with relevant results that can be assessed and compared.

T-147

832 – COMPARISON OF EVIDENCE GRADING SYSTEMS AND QUALITY ASSESSMENT TOOLS USED IN HTAS ON SELECTED MEDICAL DEVICES

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Objective: The objective of this study was to compare and contrast evidence grading systems used in international HTAs performed on selected medical device therapies, with the main purpose of understanding; (i) the impact of applying different grading systems to the assessment of the same therapy, and (ii) whether selected HTA agencies employ particular quality assessment frameworks, and the implications of this practice. Methods: A systematic search of medical and HTA agency databases was conducted to identify published reports evaluating specific medical devices in the cardiac, cardiovascular and neurological therapy areas. No time or language restrictions were used. Study selection and data extraction were performed according to a predefined protocol. Results: 124 HTAs were included for review; of which 40 were for cardiac rhythm device management (CRDM) therapies; 48 for cardiovascular devices and 36 for neuromodulation therapy devices. Closer examination of HTAs performed on implantable cardioverter defibrillators (ICDs) (11 HTAs) and cardiac resynchronisation therapy (CRT) devices (10 HTAs) found that 68% of HTAs used some form of grading system or quality assessment of the evidence. The most commonly used were general quality checklists (23%), the Jadad scale (18%) and GRADE (9%). Analysis of individual agencies such as NICE in England, found that only 20% of NICE HTAs included for review utilised the same evidence grading system. In addition, the grading systems utilised in the included NICE submissions were primarily designed for assessment of RCT evidence only. Conclusions: Grading or assessment of evidence quality and validity is an essential tool in the evaluation of health technologies. Given the increasing variety of grading systems and quality checklists available for this purpose, understanding the implications and impact of employing different systems is essential.

T-148

228 – DEVELOPING AN EVIDENCE MATRIX FOR AN INTEGRATED CARE PATHWAY FOR STROKE

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Aim: An integrated care pathway (ICP) for stroke is being developed to improve the quality of stroke care in Singapore. A review of the evidence was carried out to identify key elements of care for the pathway and the levels of evidence and effect sizes for interventions was summarised in an evidence matrix. Methodology: The scope of the review and clinically important outcomes for stroke interventions were determined with clinical and policy workgroups. Comprehensive literature search was done for effective interventions for stroke as expressed in published international clinical practice guidelines. Identified guidelines were critically appraised with the Appraisal of Guidelines Research and Evaluation (AGREE) instrument and interventions recommended were extracted (with their supporting scientific literature) and presented as an evidence table. The workgroupss then identified locally relevant interventions for the acute phase of the stroke ICP. A further search to update the evidence and a search for economic evaluation evidence was subsequently done, and the evidence was then tabulated as an evidence matrix showing level of supporting evidence and effect size against the expert-determined outcome measures. Results: An acute stroke service, early specialist assessment for TIA, and IV rt-PA administered within 4.5hrs of symptom onset were shown to be beneficial. Stroke rehabilitation is more effective than conventional treatment in an organised inpatient multidisciplinary setting and rehabilitation should be of at least 16 hours of therapy time over 6-months; early mobilisation within 48hrs after a stroke may also be a cost-saving intervention. Conclusion: Four key elements of care in the acute management of stroke were identified through the review and presented in an evidence matrix. Further clinical expert input will be needed to localise the evidence and implement the stroke ICP. The same process may be used for determining key elements of care in other phases of stroke management.

T-149

533 – FINANCING AND BIBLIOMETRIC IMPACT OF HTA IN THE BASQUE COUNTRY

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Introduction: The evaluation of the impact of scientific activity has become a necessary process to adjust the allocation of resources for research. One of the instruments to measure research in a systematic and objective way is the bibliometric analysis. Objective: To evaluate the impact on the visibility of scientific production of the publications of Osteba, Basque Office for HTA after the finance agreement of the Quality Plan of the Spanish Health System (2006). Methodology: Comparative analysis of bibliometric production and impact of published documents (reports, articles) in 2000/2005 (pre-agreement) and 2006/2010 (post-agreement): descriptive analysis of documents (references) analysis of citations received in Scopus, ISI Wok and Google Scholar. Results: We analyzed 121 papers published between 2000-2010. The publication of reports was higher than that of articles (88 vs 33). There was an increase in the production of HTA reports as a result of the Quality Plan (37 vs 51) and lower increase in articles (15 vs 18). These documents have generated a total of 1,182 citations (548 Scopus, 366 ISI Wok and 268 Google Scholar). The average annual production were 12 documents. Journal articles compiled most of the citations (1104 vs 78). HTA reports citations were only compiled in Scopus and Google Scholar. Conclusions: The bibliometric impact of non-English documents is lower, as well as the visibility of HTA reports in comparison with articles. Conventional bibliometric tools (ISI) did not seem appropriate instruments to measure the bibliometric impact of organizations that publish mainly reports that are retrieved by other tools (Google Scholar). To measure the scientific impact in the digital age we should consider a series of new indicators, such as social network analysises, data usage, web visits, links, etc.

T-150

525 – ASSESSMENT OF ASSISTIVE TECHNOLOGY FOR THE BLIND: BOARD GAME ON PSYCHOACTIVE DRUGS

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Introduction: Assistive Technologies (AT) attend to disabled people. Adapted games are considered AT and can contribute to information access, permanent education and health promotion. Aim: Assess a board game open to the blind, addressing the use of psychoaoctive drugs. Method: AT assessment study. A board game adapted for the blind was created. It contained a board with houses, information cards about drugs, chips indicating the number of houses to move on in each round, pins and game instructions. Three special education specialists assessed Version Alpha of the game and gave suggestions. After the adjustments, the specialists assessed Version Beta, until no further adjustments were necessary. Three pairs of blind people assessed this version, played the game and gave suggestions. Three other pairs of blind people assessed the new version, called Gama. To support data analysis, the assessments with the blind were filmed. Approval for this project was obtained from the Institutional Review Board and Ethical premises were respected. Results: The specialists' suggestions for Version Alpha regarded the board size, distinguishing textures of board spaces and pawns, improving the quality of Braille print diagramming and instructions. In the experts' assessment, Version Beta was considered adequate. When blind evaluators used the game, they suggested distinguishing between the textures of the spaces and using Velcro to fix the pawn during the rounds. After the adjustments, according to the last three pairs, the AT was considered adequate, stimulating the participants' curiosity and interest. Conclusion: The game was assessed positively and considered adequate for blind people, characterizing it as an AT. It also grants access to information on psychoactive drugs in a playful way. Games are relevant for the teaching-learning process and useful in these people's health promotion. KEY WORDS: Assistive Technology, Disabled Person, Illegal Drugs.

T-151

220 – HEALTH TECHNOLOGY ASSESSMENT IN IRAN

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Abstract Health sector's decision and policy maker's request for comprehensive and scientific evidence which are produced by HTA, moreover budget limitations and requirements for efficient allocation of health technologies have caused growing trend of Health Technology Assessment. This article considering the key role of HTA in prioritization and decision making and explains the position of Health Technology Assessment in our health system. Materials and methods: This case study examines process and implementation of HTA in Iran's health system. Data have analyzed based on existing documents and HTA activities in both old and new structure. Results: according to health community growing needs and authorities discretion health technology assessment was formed as a secretariat in health economic group of Health Network office in 2007. Indeed, formation of the secretariat, getting experts and researchers support, HTA project's order and finally reports reception are considered as the main parts of first stage of HTA formation. Nevertheless, since the beginning of the year (2010) aligned with Restructuring the Ministry of Health and segregating of health deputies, Office of Technology Assessment, health standards and tariffs development has begun its activities as a subset of treatment deputy. The Department of Health Technology Assessment, In addition to reviewing and completing the job description of HTA Secretariat, has established structured activities in order to produce scientific evidence and promote evidence-based policy. Conclusion: Academic centers and international organizations such as WHO and the World Bank have recommended necessity of using HTA in health systems around the world because This interdisciplinary knowledge, will facilitate Responding to infinite needs of population with limited resources. Therefore it is necessary that more and stronger actions done in this field with the support of government. Keywords: Health system, health technology assessment (HTA), Evidence Based Policy

T-152

566 – IMPROVING COMMINICATION-IMPROVING HEALTH CARE

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Introduction: Our research's aim is to clarify the reasons and situations of reported ethical shortcomings occurred among health professionals and to maintain safe environment for patients for providing quality health care. Objective: To analyze ethical shortcomings found in health care system Methods: The meta-analyses evaluate 85 ethical shortcomings found by data base which covered 35 hospitals included 91 physicians and other medical professionals. Results: Main ethical shortcomings were regarding communication between physician and patients 51.7%, communication between nurses and patients 2.3%, communication among health professionals -10.5%, alcohol abuse 3.5%, collect illegal fee from patients-3.5%, inter personal voilence-2.3%, negligence to patients regarding timely health care and treatment 9.4%, medical malpractice 4.7%, organizational failure 5.8%, neglecting the patients' privacy-2.3%, shortcoming regarding with medical records 4.7% from total 85 reported shortcomings. Shortcomings regarding to communication skill between physicians and patients has been found mostly in the clinical and aimags central hospitals. Main reason lack of interpersonal communication skill between physician and patients were depended not only personal behavior of physicians but also insufficient time for patients regarding workload. The next frequently determined ethical problems were in descending order in communication among health professionals and negligence to patients regarding timely health care and treatment. Shortcomings related communication of health professionals almost occurred in rural hospitals between physicians and health professionals. Negligence to patients regarding timely health care and treatment and medical malpractice leads to the violation of the law in some aspects. Ethical shortcomings of health professionals were not re-occurred for those who made shortcomings once. Conclusion: Ethical shortcomings among physicians have been occurred more compared with other health professionals and communication and behavioral failings are exceeding professional errors. Recommendations: To improve undergraduate and postgraduate ethical, communication and counseling training curriculum To develop patient centered communication by enhancing reputation of medical profession and position hold in public

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T-153

611 – DIAGNOSTIC ACTIONS FOR TUBERCULOSIS AT HEALTH SERVICES IN RIBEIRÃO PRETO, BRAZIL

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Aim: To analyze delivering and realization of actions for diagnostic of tuberculosis (TB) at the first health service sought by patients in Ribeirão Preto – SP. Methods: Cross-sectional study. The study sample consisted of 98 TB patients on treatment. Interviews conducted with a structured questionnaire were collected between July to November, 2009. Data analysis was made by descriptive statistics techniques. Results: Sputum smear test was requested by most Primary Health Care Units (PHU), as well as most of reference centers (RC) with tuberculosis program teams (63.6% and 68.4% respectively). The emergency services (ES) was the health facility with lower test request (35.1%). However, X-ray was mostly requested by the RC (84.2%) and ES (82.5%). For those who sought PHU as the first contact, the median time of diagnosis was higher (13 days) than those who opted for care at RC or ES (7 days). Conclusions: Although PCT shown higher availability and deliver of both principals diagnostic tests (Sputum Smear test and X-ray), ES obtained the same median time of diagnosis with only a higher provision of X-ray. Additionally, in the district which present mostly of cases at the city, ES occupies the same physical structure of the reference center for TB control, what could enhance referral of suspect individuals by ES' health professionals to TB specialized teams. Unique characteristics of health system's infrastructure, as well as supply of technological resources to offer exams, seem to assist the central management pattern of TB control, especially about diagnosis at district health units and reference centers. Therefore, organization and dynamics of local health system reflects the agility to diagnose the disease, and could help explaining factors that led patients who sought first PHU had a longer time (almost double) to obtain diagnosis than those who sought ES and RC.

T-154

365 – FONDAPARINUX VS ENOXAPARIN - A DECISION-MAKING PROCESS

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Unfractionated heparins and low molecular weight heparins shown to reduce morbidity and mortality in the treatment of acute coronary syndrome (ACS) at the expense of an increased risk of bleeding. Studies relate the risk of bleeding with undesirable outcomes such as reinfarction, stroke and death that gives way to search for safer drugs. Fondaparinux is a synthetic pentasaccharide that preferentially inhibits activated factor X. Initially used in the prophylaxis of deep venous thrombosis in orthopedic surgery patients, fondaparinux has been studied as an alternative to heparin in the treatment of ACS without ST segment (ACSWSTE). It was created a scenario to compare two drugs in order to find what would be your medicine more cost-effective considering QALY as an outcome measure in decision trees using software TreeAge 2011. We created three decision trees, one with point estimates, other bands with fixed values and a third with probability distributions. The probabilities were obtained through literature searches and SHELF. Costs were obtained through the stock prices of SUS. Results: The usefulness of Fondaparinux was 0.905 U against 0.904 U, but with a difference between the cost was R$ 132.33 versus R$ 94.78, which made the drug more Enoxaparin a cost-effective compared to Fondaparinux. The ICER of Enoxaparin was R $ 31,843.73, which makes the drug Enoxaparin a cost-effective according to the WHO threshold. Through tornado diagram, it was observed that the odds that most influence the model were the death as there is no bleeding in the use of Fondaparinux and Enoxaparin or nonfatal myocardial infarction since there is no bleeding in the use of Fondaparinux. Noting the ICE Plot in 95.80% of the simulations, the Enoxaparin was below threshold.

T-155

584 – CONCEPTION OF A MODEL USING DATA MINING FOR HEALTH TECHNOLOGY ASSESSMENT

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Introduction: The aim of Health Technology Assessment (HTA) is to evaluate and summarize information about results (safety, benefits) and costs. It includes ethical, social and organizational impacts in their incorporation and application, supporting decision making. Since a significant amount of data is produced from health companies' transactional processes, the challenge is to apply this information agilely and usefully. Consequently, it means difficulties in creating new knowledge in terms of data processing. Therefore, it is necessary to use conducive methods from Information Technology Science to be efficient such as Data Warehouse (DW), Knowledge Discovery in Data Base (KDD), Data mining and Online Analytical Processing (OLAP), automatically. "Data Warehouse" is an integrated-data collection, subject-classified, nonvolatile, temporally variable which is used to address business issues. "Data Marts" are data subsets of companies, physically gathered in distinct areas and aggregated by subject. Consequently, it is conceivable to offer personalized data support rather than DW. KDD is an unconventional process to identify valid patterns from available data, previously unknown. This process includes data mining and algorithm selection. Method: The development process was based on the unification of DW environment and KDD. To data mining task, we used an algorithm based on association rules, creating a file with health insurance transactions, chronologically arranged with a single-identification code. These association rules are aimed at identifying simultaneous and frequent subset patterns. Results: The rules found out in this process could be assessed by experts to compare health technology utilization and current guidelines. Conclusion: This method contributes to health technology appraisal, comparative or non-comparative. Also it could be helpful to follow-up health technology utilization and its consequences on health, anytime. Moreover, it allows economic evaluations based on local evidence. This dynamic tool could empower decision makers to steer health system policies to a more effective development.

T-156

642 – AN HYBRID DATA MINING METHOD: ASSOCIATION RULES AND TEMPORAL DATA MINING

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Nowadays, companies have enough technology to store and maintain a great volume of data regarding theirs operations. As a consequence, there is an increasing demand of tools capable of discovering interesting knowledge within these databases. In order to achieve that, there were developed several data mining techniques, such as the Apriori algorithm which is capable of finding Association Rules among transactional data. Even these algorithms representing an impressive evolution on how information is discovered in databases, very often they do not take into account an important dimension of transactional data, the time. On the other hand, algorithms which consider temporal aspects of data, such as GSP, neglect non-temporal attributes. To illustrate the relevance of both aspects of data, consider the following example: Many patients whose treatment included an experimental drug have symptoms of the same disease in theirs medical records. This may indicate that the drug "caused" the disease, like a counter effect. But what if 70% of the patients shown the symptoms before they took the drug? So the pattern "drug then disease" is not feasible anymore. But, what if those 30%, where the pattern holds, were all women? Once again the pattern seem interesting, but it was necessary to include both interpretations, the chronological order evaluation and the non-temporal attribute gender association with the drug and the disease. In this work, we present an hybrid data mining method which is designed to allow the evaluation of patterns in both aspects, i.e. temporal and non-temporal, simultaneously. We use the Apriori algorithm to obtain Association Rules and then execute our algorithm - Chrono Assoc - to evaluate these patterns from its chronological perspective. Chrono Assoc is based on the assertive that in a pattern all the antecedents should occur before the consequent, otherwise it is not a cause-effect association.

T-157

46 – ANALYZING THE RELATIONSHIPS BETWEEN THE PROCESS OF INCORPORATING TECHNOLOGY AND HTA: PERSPECTIVES TO THE SUSTAINABILITY OF HEALTHCARE SYSTEM

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In the last three decades, the technologization of health care production in Brazil has intensified and remains on the rise. However, a significant part of the technologies of middle and high complexities employed by the Brazilian public healthcare system (SUS) are carried out by global institutions. This feature, shared by other countries, puts health technology assessment (HTA) as central to the expansion of the healthcare and its sustainability. Authors involved in the discussion of HTA highlight the need for a profound reorganization of its practices. They advocate the break with evaluation models based solely on econometric matrix, which focuses on cost - benefit. The process of technological development should involve discussion of the impacts of socio-technical products and processes for all sectors, professionals, managers, and social groups affected by the use of technologies. Moreover, HTA studies should influence the technologies form and content. However, this does not ensure technologies more attuned to SUS principles and guidelines, and with the national health framework. HTA in countries like Brazil have to deal with the association between domestic and imported technologies, the expertise of health professionals and the diversity of institutional environments involved in the transfer process. The HTA should also characterize the sociotechnical implications involved with the proper use of technology by the health services. There are studies on the transfer process, but little systematic knowledge about the mechanisms used for the effective incorporation of technology into routine health services of high complexity. And we argue that these mechanisms, not always formalized, are central to the HTA. We consider the incorporation of technology as a complex process that must extend from the exploration to the use of technology by the health service. We propose that the HTA research encompasses on this process throughout their length and complexity.

T-158

545 – BRAZILIAN MINISTRY OF HEALTH'S SUPPORT FOR HTA STUDIES: METHODS AND RESULTS

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Objectives: To describe the activities to support and to manage HTA studies developed in Brazil in 2010 by the Ministry of Health (MoH), in partnership with the Ministry of Science and Technology (MCT) in order to strengthen the Brazilian Network for HTA (REBRATS). Methods: (1) identification: consulting society through a website, meeting with strategic areas of MoH and researchers; (2) prioritization: workshop with decision-makers and representatives from universities; (3) support: launch of a public call for proposals in partnership with the MCT; (4) monitoring: initial, intermediate and final meetings, with previously supported projects (2005-2009) aiming to bring together decision-makers and researchers, and (5) dissemination: provide data to support the REBRATS information system. Results: (1) in 2010, 157 requests were identified for HTA studies on the website and ten priority studies were chosen by policy-makers; (2) considering the budget constraints (US$ 1.2 million), eight topics were prioritized for the public call for proposals; (3) after full disclosure, 65 proposals were received and 11 supported (antiviral therapy for HIV [1], system models for primary hypertension [2], safety of monoclonal antibodies [2], therapy options for mood disorders [2], primary referrals to specialized network [2], liposomal amphotericin B for disseminated cutaneous leishmaniasis [1], cost-effectiveness of PET in oncology [1]); (4) 34 previously supported projects were monitored (hepatitis [5], record linkage database [7], dyslipidemia [1*], pulmonary arterial hypertension [1*], diabetes [1], macular degeneration [1], wounds [4], cost-effectiveness analysis [14]) and two (*) of them directly supported decision-making in the MoH. (5) 193 studies, in Portuguese, were included in the REBRATS Database. Conclusion: In 2010, in Brazil, despite limited resources, MoH strategies to support HTA studies allowed a greater involvement of decision-makers and incentive to research institutions.

T-159

576 – BRAZILIAN HEALTH TECHNOLOGY ASSESSMENT BULLETIN: EDITORIAL PROCESS, DISSEMINATION STRATEGIES, CRITICAL EVALUATION AND INITIAL IMPACT

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Objectives: This study reports on the Brazilian experience of developing a specialized bulletin on health technology assessments (HTA). Methods: The editorial process, format and dissemination strategy of the publication are presented. A critical evaluation of the editions available was made using the checklist of the International Network of Agencies for Health Technology Assessment. The initial impact was estimated based on retrospective observational measurement of the types of publications that use the bulletin as a source of information. Results: The bulletin has the aim of providing practical and easy-to-use information on health technologies, in order to promote use and decisions regarding use that are more rational, along with focusing on political and regulatory matters involved in access to such materials. So far, twelve issues of the bulletin have been produced. The bulletin has not presented any significant limitation that would compromise generalizations of its results within the Brazilian context. On the other hand, the initial impact of the bulletin has been small, which may be related to its exclusively electronic dissemination format. Conclusions: It is hoped that the bulletin will promote continuity of HTA actions among health-sector managers and professionals in Brazil.

T-160

591 – METHOD FOR PRIORITIZING ALTERATIONS REQUESTS OF BRAZILIAN ESSENTIAL MEDICINE LIST (RENAME)

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Objective: To describe a method for prioritizing alterations requests (AR) in RENAME and the implications of its use in this process, carried out by its Technical and Multidisciplinary Commission of Updating (COMARE). Method: Using the latest edition of RENAME (2010), an AR form was sent to the main representatives of the Ministry of Health, state health departments and municipal health departments, and also to the authors of the National Therapeutic Formulary 2010. The AR received were organized systematically to filter out irrelevant comments and possible duplications. COMARE defined the following prioritization criteria: epidemiological relevance; importance for public health; relevance for hospital services; sociopolitical pressure; and prior analyses. Each member attributed a weight to each criterion (1 to 3) and a score for each criterion for each AR (1 to 5). Analysis was performed in conformity with Donaldson (1992) proposal. From the AR with highest scores, a calendar of meetings was scheduled. Results: 130 AR corresponding to 19 pharmacological groups to be assessed were received. Systematization of these excluded duplications and irrelevant comments, and 111 AR remained. The criterion with the greatest weight was epidemiological relevance. The AR with greatest median values were: diuretics; antiasthmatics; medications used for treating/preventing osteoporosis; cefalosporins; medications against toxoplasmosis and adjuvants; antimalarial drugs; plasma fractions for specific purposes; analgesics and antipyretics; vitamins; antiparasitic agents and anthelminthic agents. To analyze these AR, seven meetings were scheduled. Conclusions: The method used required prior knowledge of some of the topics put forward in the AR that were received, especially sociopolitical pressure and relevance for hospital services. Reflection on the priorities led to coordinated preparation of a timetable, taking into consideration the various interfaces discussed. It was concluded that the method was effective for defining the analyses on AR and may be reproducible in similar processes.

T-161

157 – CRITICAL INCORPORATION OF HEALTH TECHNOLOGIES IN PUBLIC HOSPITALS AND HEALTH CENTERS IN THE PROVINCE OF TIERRA DEL FUEGO: BIBLIOGRAPHIC REVIEW OF INTERNATIONAL EXPERIENCES FOCUSING ON KEY PLAYERS, ENABLERS, OBSTACLES, OPPORTUNITIES, PROCESSES AND TOOLS

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The adoption of health technologies in hospitals is carried out in a complex environment under the influence of multiple factors, posing a problem for health authorities. With the aim of providing tools for the critical incorporation of health technologies in the Argentine Province of Tierra del Fuego, including process design and the creation of the necessary instruments, a non-systematic review was completed searching documents published from 2000 to 2008 on electronic databases such as MEDLINE, LILACS and Google Scholar, on websites of Health Technology Assessment Organizations, and other technical reports (health technology assessment networks and organizations, Observatories, etc), written in Spanish, English, and Portuguese. Documents relating to the incorporation of health technologies were chosen that described policies, methods, processes, proceedings, instruments, standard forms and/or the results of such incorporation in public health care providers, with some degree of health technology assessment. Such documents also analyzed the main players, their stakes, obstacles and enablers of critical health technology incorporation. Forty-nine reports were obtained from ten countries and two international organizations. It can be sustained that the formal and explicit introduction of health technology evaluation in hospitals has progressed without a uniform pattern. The need to make these processes more reasonable has drove countries to develop policies, structured procedures and tools based on the rationale behind health technology assessment. Experiences have shown that, despite the initial skepticism and medical concerns (because of information overload, administrative tasks, processes seen as a means to limit innovation, cut expenses and increase control over their professional autonomy), the implementation of such structured procedures has eased the progressive use of information in the decision-making process and, consequently, a more responsible adoption of biomedical technologies. Use of a shared language among doctors and managers and explicit transparent processes in decision making has been appreciated in the international experience.

T-162

158 – SURVEY OF COMPLEX AND HIGHLY SPECIALIZED MEDICAL EQUIPMENT IN THE PROVINCE OF NEUQUÉN (ARGENTINA): DISTRIBUTION, CONDITION, FUNCTIONALITY AND ACCESSIBILITY

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The survey was conducted for the purpose of acquiring and updating data regarding the existence, condition and distribution of complex and highly specialized medical equipment in the province, and creating a database to simplify its management pursuant to safety, effectiveness and equity criteria, and analysis of coverage, level of utilization and access, in addition to contributing elements for the innovation, maintenance and timely replacement of such equipment. The survey was based on: experiences in health technology management improvement, easy-to-use and standardized tool development initiatives, and recommendations from technical organizations. The equipment covered by the survey was included according to: staff requirements, user diversity, level of utilization, price, and number of health care processes depending on their operation. Data collection sheets and relevant guidelines were pre-tested, improved and applied in a pilot experience in public hospitals with inpatient facilities, chosen for convenience to finally adjust instruments, field work, workload, data processing using Access, and analysis with Epi-Info, to then extend the survey to the rest of the health care providers with or without inpatient facilities. Preliminary findings lead to conclude that the tool helps to identify gaps and difficulties in technology cycle management, to recognize offer-related asymmetries and inequities, and to generate monitoring and mandatory reporting indicators. The database thus created will become an integral part of the Provincial Health Information System. The ultimate goal is to promote the use and demand of information for a management focused on supervising obsolescence and investment-divestment needs as a means to ensure the maintenance and renewal of diagnostic and treatment equipment. This will guarantee timely and equitable access for patients suffering from pathologies that require such equipment at all levels of provincial health care. The work also aims at making headway in assessing the results obtained in terms of diagnostic and therapeutic effectiveness.

T-163

746 – HTA ON DENOSUMAB: METHODS AND LIMITATIONS TO ESTIMATE THE BURDEN OF DISEASE AND THE COSTS OF OSTEOPOROSIS IN ITALY

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Objective: Denosumab is a human monoclonal antibody to the receptor activator of nuclear factor-kappa B ligand (RANKL) approved by FDA and EMA for the treatment of osteoporosis, that is a major problem in post-menopausal women. As part of the Health Technology Assessment (HTA) project on this innovative drug, a study was carried out to estimate the burden of disease and the costs associated to osteoporosis in Italy. Methods: Epidemiological data were retrieved using PubMed, Cochrane and Embase and Health Search database (registry of Italian General Practitioners) in order to collect data about hip fracture in women aged 65 years or more. Cost of illness analysis was conducted from Italian Healthcare Service perspective: indirect costs were not considered. Institutional data sources and national tariffs were consulted to estimate all costs (Euros, update 2010) for diagnostics, follow-up, medication and hospitalization. The main cost driver of osteoporosis was considered to

be hospitalizations for hip fractures; women aged 65 years or over, admitted to hospital in 2005, were thus considered. Findings: About 4 million of Italian women are now affected by osteoporosis and it is estimated that in 2025 they will be 4,7 million. Every year, about 70,000 women are admitted to hospital for hip fractures. Direct costs sustained for hip fractures occurred in people aged ≥65 were estimated in 467 million in 2005. The real epidemiological and economic impact of osteoporosis is difficult to estimate: in Italy it is not currently available a codification for osteoporotic fragility fractures, so we had to make the assumptions that all fractures occurred in 65 years and over women could be attributed to osteoporosis. Conclusions: The estimates of the burden of disease and of the costs of osteoporosis in Italy suffer from an underestimation that has to be taken into account in the HTA approach.

T-164

427 – MEDICAL ETHICS AND HEALTH TECHNOLOGY ASSESSMENT IN BRAZIL

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In Brazil, the health care system is one of the gateways to the health technologic horizon. The inclusion of new technologies among the medical therapeutic or diagnostic options must attend, at least, the essential aspects of safety and efficacy. The Brazilian Federal Council of Medicine (CFM) states that doctors should have guaranteed their autonomy in choosing their actions, but taking responsibility and appropriate scientific reasoning. The direct discussion with the referring physicians and the dissemination of knowledge in health technology assessment, always based on scientific evidence, are valuable tools for the sustainability of health systems and the ethical exercise of Medicine. In this context, any application for incorporation of health technologies performed by a physician must be accompanied by disclosure of potential conflicts of interest of the requester. During the assessment, must be assured extensive discussion, including the requesting physician, particularly as it relates to the reasoning of the main requirements of safety, efficacy and advantages of the proposed technology over the existing standard. The hierarchy of scientific evidence, with their quality assessment, and the already established methods of health technology assessment should be prioritized by the medical and academic community. There is need for continuous and intensive qualification in health technology assessment, including the members of the Federal and Regional Councils of Medicine, whereas in Brazil, the diagnostic or therapeutic procedures, to be recognized as valid and usable for the national medical practice, should be submitted to approval of the Federal Medical Council, as required by CFM Resolution No. 1.609/2.000. The construction of a consistent model based on ethical and scientific evaluation of health technologies can generate a higher quality standard of care for society, with consequent reduction of the conflicts in the national health system.

T-165

290 – ANNUAL ASSESSMENT OF COSTLY HOSPITAL MEDICAL SERVICES IN AUSTRIA: HIGH-INTENSITY FOCUSSED ULTRASOUND (HIFU) FOR THE TREATMENT OF PROSTATE CANCER

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In Austria, costly hospital medical services that are reimbursed not only by the Diagnosis Related Groups (DRG)-system but receive extra tariffs are listed in the hospital benefit catalogue. Each year, hospitals are asked to submit applications to the Ministry of Health for new medical interventions to be included in this catalogue. Annually, the Ludwig Boltzmann Institute for Health Technology Assessment is commissioned by the Austrian Ministry of Health to evaluate the submitted medical interventions concerning efficacy and safety. Our assessments are based on systematic reviews for each intervention and a summary of the scientific evidence according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. In this context, we have reviewed the scientific evidence concerning High-Intensity Focussed Ultrasound (HIFU) for the treatment of prostate cancer that has been published in the last decade and have assessed the quality of evidence using the GRADE approach. Our systematic review suggests that the available evidence on efficacy and safety of HIFU in prostate cancer is of very low quality, mainly due to lack of control groups. However, most of the limitations identified for HIFU treatment also apply for conventional treatment options. The lack of high-quality evidence of HIFU provokes controversy among urologic experts not only in Austria but over the whole of Europe, which is reflected in the differing international guidelines concerning the application of HIFU. Overall, we emphasise the importance of conducting (randomised) controlled trials of good quality and sufficient size comparing HIFU with conventional treatment options, such as RP and radiotherapy, or with active surveillance. Most importantly, patient-relevant outcomes, such as overall survival, cancer-specific survival, adverse events and quality of life have to be considered to assess the true role of HIFU in prostate cancer.

T-166

717 –FROM EFFICACY TO EQUITY IN RARE DISORDERS: CLINICAL AND POLICY DECISIONMAKING ON GROWTH HORMONE FOR PATIENTS WITH PRADER-WILLI SYNDROME USING THE EVIDEM HTA WEB MODEL

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Objective: Develop a comprehensive web-based validated EVIDEM Health Technology Assessment (HTA) report structured by criteria of decision to facilitate the development of clinical practice guidelines (CPGs) and policymaking for growth hormone (GH) in patients with Prader-Willi syndrome (PWS), a rare disorder with serious long-term consequences. Methods: An extensive literature review was performed to identify and synthesize available evidence (scientific and colloquial) on GH for PWS for 19 criteria of the EVIDEM framework using a standardized methodology. The framework was adapted to include a CPGs module. Evidence tables, critical analyses of studies, and synthesis of data by criterion, were validated by a wide range of experts using an interactive web site. Results: The web site provided transparent access to synthesized evidence at three levels of detail for 13 scientific criteria of the EVIDEM MCDA model including: disease severity, size of population, therapeutic context and unmet needs, treatment outcomes (efficacy/effectiveness, safety, patient-reported outcomes), type of treatment benefit at population and individual levels, and economic impact on medical and non-medical expenditures. Sub-criteria were defined for each efficacy measure including growth, body composition, exercise tolerance, metabolic effects, bone health, cardiovascular health, psychomotor development, and behavioral outcomes. Critical analyses of studies that rated their validity and relevance were hyperlinked to synthesized evidence. Evidence for the six contextual and ethical criteria, including utility, efficiency, fairness, system capacity, stakeholder pressures, and political/historical context, was synthesized. CPGs questions were identified and structured by decision criteria (CPGs module). Conclusion: The HTA “by criteria” web model provides a pragmatic means for systematic consideration of a wide range of criteria, seamless access to information and identification of questions to guide clinical practice and evidence-based decisionmaking. Such approaches are expected to promote collaborative, user-oriented HTA and ultimately optimize resource allocation and healthcare system sustainability.

T-167

785 – COST-EFFECTIVENESS ANALYSIS AND BUDGET IMPACT ASSESSMENT: A GRAPHICAL WAY TO COMBINE THE TWO FOR THE AID OF DECISION MAKERS

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OBJECTIVES: Cost-effectiveness analysis (CEA) has traditionally been seen as a means of satisfying a specific and explicit social objective subject to a fixed budget constraint. As a result, existing CEA methods largely ignore budget impact considerations in health systems where budgets are not fixed. In particular, none of the traditional methods of presenting results (such as the cost-effectiveness plane, ICER tables and CEAC graphs) can be used to summarize the results of a CEA and budget impact assessment simultaneously. Our objective was to develop such a method in a manner which is meaningful to decision makers. METHODS: We present a novel way of combining cost-effectiveness and budget impact considerations into a single graph. To do this, we disaggregate the incremental costs of the new technology into those which fall on the health budget and displace other technologies (resulting in forgone health) and those which lead to an expansion of the health budget (resulting in a net budget impact). The incremental health benefit of the technology and any forgone health are combined to give the net health benefit of the technology, which is plotted against the net budget impact. RESULTS: Our method clearly reveals the trade-off between the cost-effectiveness and budget impact of the technology in question. This trade-off is simultaneously revealed across a range of plausible values of the cost-effectiveness threshold. CONCLUSIONS: Decision makers who are concerned with both the cost-effectiveness and budget impact of new technologies have tended to consider each of these separately, with the inherent trade-off between the two blurred in the process. Our proposed method makes this trade-off explicit and does so across a range of threshold values, enabling analysts to provide meaningful information to decision makers while respecting decision makers' authority in determining the appropriate threshold to use.

T-168

513 – HTA DEVELOPMENT: WHAT IS THE APPROPRIATE ECONOMIC ANALYSIS?

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BACKGROUND: Throughout their growth cycle, developing countries have taken different paths towards the establishment of their healthcare systems and pharmaceutical regulatory pathways. The rapid growth and necessity for improved medical care has created the common dilemma of balancing quality, access, and costs. Reference pricing, claw-backs, and restricted reimbursement lists are some of the cost-containment approaches used globally, but the goal of attaining greater efficiency has elicited the development of HTA in many markets. OBJECTIVES: To examine the utility of each type of economic analysis currently utilized by HTA bodies and discern the value provided to each market's system and the role the pharmaceutical industry can undertake to improve efficiency. METHODOLOGY: Primary and secondary research was conducted in Brazil, Germany, Korea, Mexico, Poland, and the United Kingdom. Research was aimed at understanding the level of HTA development within each market, the economic analyses most commonly used for the evaluation of pharmaceuticals, and the reasoning behind the chosen methodology. The research results were then contrasted against the type, breadth, and quality of healthcare coverage available in each market in order to ascertain any existing correlations. CONCLUSIONS: A combination of a country's level of development and the type of healthcare system in place was determined to be the main driver behind the type of economic analysis utilized by the associated HTA body. Additionally, results demonstrate that the role established for the HTA body's specific function under the regulation of pharmaceutical pricing or access overwrites the perceived validity of different types of economic analyses within the country. Finally, a noticeable role exists for the pharmaceutical industry as a key contributor to the development of emerging HTA bodies.

T-169

540 – EUROSCAN DATABASE AS A SOURCE FOR THE IDENTIFICATION OF POTENTIALLY OBSOLETE TECHNOLOGIES

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Aim: to assess the usefulness of new and emerging health technology databases to identify potentially obsolete technologies (POTs) Material and methods: EuroScan database was chosen to pilot the usefulness of new and emerging technology databases in POTs identification. The technologies classified as substitutive until May 2008 were chosen from the database. Information on the year of identification, agency, technology type, indication and current technology or technologies replaced by them were exported to SPSS. Duplicated and related technologies were identified. Clinical practice standards (Practice Guidelines) and health technology assessment reports were searched in the National Clearinghouse Guidelines (NCG) and INAHTA and CRD databases, respectively. To contextualize the technologies identified as obsolete, 201 questionnaires, where the possible obsolete technology/technologies were compared to the new one, were prepared and sent by e-mail to health professionals of different medical specialties (members of our identification network). Results: From the initial 270 selected technologies, 201 files were finally obtained (26 technologies were duplicated, 5 were too generic and 59 were related). Most guidelines did not mention the new technologies, and the identified assessment reports did not provide enough evidence on its/their efficacy/safety in comparison with what already exists. 201 questionnaires were sent to 70 experts. To obtain their response, a reminder e-mail and telephone contact were needed. Conclusion: EuroScan is not recommended as a primary source of POTs identification, but it could be used as a complementary source in a long-term and integral strategy. For that purpose, the following should be improved: the quality of the information about existing technologies to be replaced and the definition of the specific indications to do this replacement.

T-170

767 – ECONOMIC EVALUATION OF HEALTH PROGRAMS: A CONTEXT THAT CAN CAUSE INEQUITY IN ACCESS

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The efficient allocation of health care resources has been a concern for governments. The economic evaluation of health technologies provides a set of methodological tools which can be used as a means to generate the knowledge that help policy makers to allocate health resources efficiently. However, the efficient allocation of health care resources should be viewed as a competing dimension upon which decisions are made, in addition to that of equity. The aim of this work is to demonstrate that in some conditions, which combine health technologies with specific characteristics with particular methodological choices made during the economic assessment, the outcome of the HTA study may contribute to the promotion of inequity in the access. Assume a disease can be treated using Ta and Tb (both with a long-run effect), with Ta providing more QALYs than Tb, and that the adoption of Ta requires a patient with specific characteristics. Thus, only some patients can access Ta. Suppose that under current practice all patients medically suitable for Ta receive it. Assume that technology To can be used to help patients becoming eligible for Ta. A new health technology, Tn, for this same purpose is developed. The objective is to conduct an economic evaluation to compare Tn with To. We develop a simple decision analytical model to argue that when the analyst chooses the long-run as the time horizon and QALYs as measure of effectiveness to compare To with Tn, then the consequences of the decision process can be a deployment of resources that promote iniquity in access to Ta. The conclusion from this work is that under some HTA contexts if wrong methodological decisions are made then the economic evaluation as a process to help the efficient allocation of resources can contribute to the promotion of inequity of access to medical

T-171

472 – PARENT PREFERENCES OF TREATMENTS FOR ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD): RISK BENEFIT TRADE OFFS AND VARIATIONS ACROSS EUROPE

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OBJECTIVE: Pharmacological therapies are effective in treating symptoms and impairments associated with ADHD. However, the drugs can be associated with side effects such as nausea and an increased risk of misuse/abuse. Further, differences in the prevalence, treatment, and attitudes to ADHD exist between North EU (UK, Netherlands, Germany) and South EU (Italy, Spain, France). A stated preference discrete choice experiment (DCE) survey was conducted to determine the preferences of parents in European countries regarding different aspects of stimulant ADHD medication. METHODS: DCE surveys for parents of children (6-12) and adolescents (13-17) with ADHD were developed based on published literature, discussions with clinicians, and parent interviews. Survey attributes included: Degree of symptom control; Duration of symptom control; Potential for treatment abuse (only included in adolescent survey); Frequency of medication; and Risk of side effects – vomiting, appetite loss, and sleep disturbance. Parents of children (n=380) and adolescents (n=220) were recruited across the six EU countries (n=100, each) following IRB approval. FINDINGS: All DCE attributes were important (P<0.01). The best improvements in symptom control were important to parents (Child Odds Ratio=6.37; 95% CI=5.79-7.01; Adolescent OR=4.85; 95% CI=4.28-5.49). Twelve hours of symptom control compared with 4-6 hours was also valued by parents (OR=1.59; 95% CI=1.41-1.79). A 1% increase in risk of each side effect was valued similarly; OR range from 0.95-0.98 (95% CI=0.94-0.99). Risk of treatment abuse (OR=0.97; 95% CI=0.97-0.98) and need for additional daily doses were also important (OR=0.89; 95% CI=0.83-0.94). Interaction effects identified North EU parents valued symptom control and avoidance of side effects significantly more highly than South EU. CONCLUSIONS: Clinical effectiveness was the most important driver of parental preference for ADHD medication across all countries. Parents also preferred treatments with less frequent dosing, less side effects, and less risk of substance abuse. Differences emerged between North and South EU

T-172

386 – EVALUATION OF PROCESS TECHNOLOGY FOR DIAGNOSTIC MEDICAL IMAGING BREAST CANCER

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With the continued growth of expenditures on health, the changing epidemiological profile and increased mortality from breast cancer have demanded health managers to define strategic actions that ensure women access to effective and safe technologies. This context, clinical engineering has an important role to contribute in supporting the decision making of managers in health with development methods of Health Technology Assessment. This research aims to assess the technological process of diagnostic medical imaging of cancer breast health services in the Public Health in Santa Catarina State, Brazil. The technological process was evaluated based on the methodology for the Health Technology Management and the Brazilian Federal Resolution 453/98. The technological process is modeled based on three pillars: infrastructure, human resources and technology. In infrastructure, it was analyzed the risks and ergonomic environment seeking to gauge the proper accommodation of technology and quality of life in the workplace. Human resources, or health professionals involved in execution mammography examinations are assessed on the appropriate use of technology. And technology, in this case, mammography trials were conducted with development performance test protocols based national and international standards. In the search results, there has been a lack of periodic testing for quality control, lack of human resources training in the use of technology as well as other activities in order to maintain the service quality of mammography. With this methodology, are being generated tools and indicators that allow a proper assessment of technical medical equipment and mammography services contributing to the effectiveness of the technological process in health.

T-173

376 – IMPLEMENTATION OF LOCAL HTA INITIATIVES IN DEVELOPING AND EMERGING COUNTRIES: A REVIEW OF EXPERIENCES

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This abstract presents only preliminary results. The project is not yet completed. Objective: The objective of this study is to review the application of Health Technology Assessment (HTA) at the local (hospital) level in developing and emerging countries (DEC). This review will provide a starting point for identifying the conditions of HTA implementation in hospitals in DEC through the analysis of experiences conducted in these countries. Methods: A systematic review of the literature was conducted to document the experiences of DEC regarding HTA at the hospital level. A standardized search strategy was developed by an information specialist and a bibliographic search was performed in the Pubmed and Embase databases, in scientific journals specialized in HTA (the International Journal of Technology Assessment in Healthcare and Health Technology Assessment), and the websites of INAHTA and HTAi. The search led to a total of 616 references published between 1980 and 2009 that were screened by reviewing their titles and abstracts. Of these, 53 references were selected according to inclusion and exclusion criteria defined previously and a full text copy was obtained to then undergo a detailed evaluation by two reviewers. The final screening is underway. Conclusion: This systematic review will contribute to the identification of priorities in the process and methodology of implementing HTA in hospitals in DEC. It offers an assessment of interventions related to HTA at the local level as well as the barriers and facilitators. In addition, the identification of these experiences may be considered as precursor of the problems that developing countries are likely to face as they are receiving an increasing number of complex technologies.

T-174

593 – SCREENING PROGRAM EVALUATION OF UTERINE CERVICAL CANCER IN GOIAS, BIENNIUM 2006 AND 2007

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Objectives: Estimate the coverage rate, check the periodicity of its realization, calculate the prevalence of cervical cancer precursor lesions and verify the sample adequacy of the Pap smears. Methodology: Study based on data from the Uterine Cervical Cancer Information System-SISCOLO in 2006-2007 in the state of Goias. The offer was evaluated by examining the ratio of cervical screening indicator and target population, represented by the total number of cervical screening in the female population 25 to 59 years on the female population 25-59 years. Were also analyzed the variables previous cytology and cytology previous time. The quality of the method was analyzed by the variable sample adequacy. Results: The mean ratio in the State of Goiás during 2006-2007 was 0.12, and the North Central macro-region had the highest ratio (0.15) half the minimum parameter of 0.3. Regarding timing, it was noticed that in the prior age bracket of 25 to 59 years, the majority was the one year interval, followed by two years, in all macro regions. The analysis of the frequency in which women had taken the tests was limited by the high percentage of no information and do not knows. Regarding the prevalence of injuries, it was observed that in the age group of 25 to 59 years, there was a predominance of atypia of undetermined significance (ASC-US) and low-grade squamous intraepithelial lesion (LSIL) in all macro regions. The percentage of unsatisfactory samples in the state of Goias remained around 1% and in all geographical regions macro regions the main reason was due to desiccation (inappropriate fixation). Conclusions: A coverage rate below the estimated need and a shorter interval than recommended, problems in data quality, higher prevalence of LSIL and atypical cells of ASC-US. Financial Support: Edict MCT/CNPq/MS-SCTIE-

DECIT nº 37/2008.

T-175

791 – INCORPORATING RESULTS FROM A DISCRETE CHOICE EXPERIMENT INTO A DISCRETE EVENT SIMULATION MODEL: THE CASE OF MONITORING INDIVIDUALS WITH OCULAR HYPERTENSION

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For the last two decades HTA has focused on QALYs as the main health benefits valuation technique. Valuations based on QALYS are recommended by the National Institute for Health and Clinical Excellence (NICE) and the Scottish Medicines Consortium amongst other agencies. However, this measure does not reflect all important benefits. Factors beyond health related quality of life must be valued, e. g. patient experience factors are relevant, particularly in chronic conditions where medical staff-patient interaction would be prolonged. Likewise, Markov models and decision tree models are the most often chosen modeling approaches for economic evaluations but such approaches may not be ideal to address the complex decision problems faced by health care decision-makers. This has led support for more sophisticated approaches, such as discrete event simulation (DES) models, to become more widely used. In this paper we bring these two approaches together. We developed a DES model for the economic evaluation of monitoring schemes for individuals with ocular hypertension together with a Discrete Choice Experiment designed to elicit preferences for monitoring services for the detection of glaucoma for people with ocular hypertension. The DES model simulated individuals with a set of characteristics: those relevant for the intervention (e.g. intra ocular pressure) and general ones (e.g. gender and age). Willingness to pay weights were obtained for Discrete Choice Experiment attributes. However, these weights can be tailored according to individual characteristics such that a person specific measure of benefits can be obtained. This is helpful not just to better characterize uncertainty but also to explore heterogeneity between sub-groups. This allows consideration of whether a customized or a one size fit all health care strategy should be followed. Further challenges and opportunities from merging these two distinct methods will be discussed.

T-176

952 – THE GLOBAL FORMULARIZATION OF MEDICAL DEVICE TECHNOLOGIES

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Health Technology Assessments have historically been used to evaluate technology based upon available clinical evidence and have recently become a means to cut health care costs globally. This practice has gained such traction that in recent years all levels of health care have implemented some process of evaluating and “formulizing” technology. This practice has taken many forms, including national system reviews resulting in implant ratings, private insurers developing coverage policies for specific technologies, and perhaps the most pervasive and least formalized, hospital purchasing committees, which have formed to evaluate the use and price of technology. Unfortunately this trend has resulted in few best practices to date, and very little research has addressed whether such evaluations are actually able to reduce costs without sacrificing quality of patient care. Recently, Anirban and Philipson studied anti-psychotic drugs that are used to treat schizophrenia. These authors found that patients do not all react the same way to this broad class of medications. The authors demonstrated why reimbursement policies based on “one size fits all” can inadvertently reduce quality and impact patient’s health, while failing to save money. With more than 17,000 hospitals globally, it may be possible that evidence based purchasing decisions have a larger unintended consequence of limiting access to those patients that would benefit most from specific technologies. Therefore, sponsors must improve the focus of clinical evidence development, clearly identifying ideal patients and demonstrating value. Likewise, decision-makers must be willing to consider the broader question of which specific technology is best suited for which specific patients. For example national joint replacement registries are often used to judge performance and often collect demographic information on patients, surgeons and hospitals and yet this data is not used to stratify and refine the evaluation of performance. In each case, cookie cutter approaches will not suffice.

T-177

616 – FACTORS INFLUENCING DECISION-MAKING ON NEW NON-DRUG THERAPEUTIC INTERVENTION IN TERMS OF SAFETY AND EFFICACY/EFFECTIVENESS IN SOUTH KOREA

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Objective: To explore what factors have influenced decision making of new health technology assessment in terms of safety and effectiveness. Specifically, to analyze what factors supported a positive decision and what factors acted negatively. Methods: We analyzed decision makings of a new health technology assessment (nHTA) committee on 53 non-drug new health technologies in Korea from July, 2007 to Dec, 2010. The scope of committee is mainly focused on safety and efficacy/effectiveness but not cost nor cost effectiveness. Every decision makings were based on a systematic review of literature. The members of committee consisted of health care professionals, policy maker, lawyer and representatives from Non-Government Organizations. Decision makings on therapeutic interventions were included while ones on diagnostic procedures were excluded. Results: The factors found to have influence on decisions are as follows; the presence of evidence of comparable effectiveness compared to alternatives, existence of alternative interventions, consistency of results, and relevant duration of follow-up, critical organ save, quality of evidence of alternative intervention, quality of evidence of indexed technology, and amount of studies. Conclusion: This qualitative analysis of past decision makings provides us good understanding of what values decision-makers in Korean nHTA committee consider in the context of safety and effectiveness. These findings will help us to develop an appraisal guideline and to enhance more objective decision making process in Korean nHTA.

T-178

221 – EVALUATION OF PHYSICAL ACTIVITY – WHO RAN AWAY WITH THE ADVERSE EVENTS COSTS?

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Objectives: Current published estimates of the cost-effectiveness of interventions to promote physical activity, including those published by the National Institute for Health and Clinical Excellence, have excluded the cost of injury. This study seeks to estimate the costs that are incurred through injury as a result of increasing physical activity. Methods: Data were extracted from the literature, for the population of active commuters, on the risks of injury during the activity for different types of injury and the unit cost of each type of injury. A model was developed to estimate the cost of injury, to the National Health Service in England, resulting from two interventions aimed at increasing cycling and walking. In addition, the implications upon injury costs of possible government policies to increase the level of physical activity were considered. Findings: The population of active commuters yields an expected annual cost to the NHS for cycling and walking injuries of £11.7 million and £4.7 million respectively. Initial calculations provide an estimated cost per mile walked to the NHS of £0.25 (£0.16/km) and £0.8/mile cycled (£0.5/km). These findings suggest that, to be cost-effective, the cost to the NHS of each mile cycled, ceteris paribus, would need to deliver health returns that are almost three times those of walking. Conclusions: This study shows that, to date, estimates of the cost-effectiveness of interventions to increase physical activity have been optimistic. The cost of injury, for different types of physical activity should be taken into account in future health economic evaluations.

T-179

474 – HEALTH TECHNOLOGY ASSESSMENT: IS ACCESSIBLE PRIMARY CARE FOR THE POOR

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Background: The economic and social development strategy of Mongolia for 2010 has stated of introducing a new health technology focused on prevention rather treatment. The Health Sector Master Plan for 2005-2015 stresses the need to provide essential health services to the people of Mongolia, with emphasis on the elderly, adolescents, and the poor. Therefore, exploring of potential factors encountered to disadvantaged groups to seek for primary care is increasingly needed. Objective: To study underlying causes affecting accessibility of primary care for the poor is the current rationale for the survey Methods: 500 households were involved in the quantitative and 74 family doctors, nurses, social workers and heads of administrative units of the selected districts in the qualitative surveys Findings: 55.6% of the respondents expressed that they are able to obtain health care services when required, 26.6% said sometimes they are not able to obtain it and 12.6% said no. The main reasons for not being able to obtain necessary health care services are poor living condition, lack of money to get treated (20.4%), some tests and screening cannot be performed at family clinics (16.2%), poor service quality, insufficient family practitioners' knowledge and skills (8.6), family clinic is located far (5.0%). Conclusions: Majority of the respondents urge that skilled physicians and nurses, medical supplies and equipment, comfortable environment and friendly communication are very influential in family clinic health care and service. They were also pressed out ways to bring family clinic's service closer to the population by improving of quality of service at family clinics and involving of health volunteers in service provision. Issue was addressed about introduction of new health technology initiative such as mobile clinics. Mobile clinics could solve most of the accessibility problems, especially for the poor and disabled groups.

T-180

428 – MORTALITY, HEALTH CARE SERVICES UTILIZATION AND COSTS AFTER IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR THERAPY IN A HEALTH MAINTENANCE ORGANIZATION, – UNIMED BH

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Background: Sudden cardiac death is an event with 95% mortality. The implantable cardioverter defibrillator (ICD) therapy aims to prevent patients' sudden cardiac death from malignant ventricular arrhythmias. Data on health services utlilization and costs after ICD are scanty. Objective: To evaluate mortality, utilization of health services and costs of patients submitted to ICD therapy. Methods: Data on mortality, utilization of health services and direct costs were extracted from the administrative database of a health maintenance organization (HMO) Unimed-BH, one year before and after ICD implantation. Deaths registered on the HMO database were paired with the Mortality Information System of the Ministry of Health. Results: Between January 2005 and June 2008, 52 patients were included in the study. The median age was 68 years and 60% were male. Four patients (7.7%) died within one year after implantation. In the year before ICD implantation 79% patients had emergency care consultation, 50% had at least one hospitalization and 38% were admitted to an ICU. These figures were respectively 71%, 50% and 35% in the year following ICD implantations (no statistical significance). Mean costs for ICD implantation were R$71.588,60 (SD R$14.412,53). The average health care costs were R $ 10,722.87 in the year before and R$ 9,445.01 in the year after implantation (p=0.57) Conclusion: ICD implantation did not have any impact on hospitalizations, emergency care and costs. Patients with severe heart failure have an expensive profile of health care utilization, even after ICD therapy. The high costs of this technology along with the high prevalence of heart failure in the population will certainly have a huge impact on public as well as private health budget. This Project was founded by CNPq, EDITAL MCT- CNPQ/ANS – No 25/2007. The authors thank CNPq, MCT, ANS and Unimed-BH

T-181

183 – INCORPORATION OF PATIENT PREFERENCES IN A PATIENT DECISION AID OF THE CLINICAL PRACTICE GUIDELINE OF CELIAC DISEASE, IN A DEVELOPING COUNTRY

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Objective: To describe the incorporation of patients view and preferences in the development of a patient decision aid based on the Clinical Practice Guideline (CPG) of Celiac Disease, in Argentina. Methods: The development of the CPG of Celiac Disease was based in multidisciplinary team including professionals and patients. We used the Guideline Adaptation Process defined by the AGREE Collaboration and the National Ministry of Health. The recommendations were developed using SIGN's methodology. The final CPG was presented in 5 different formats: complete version, short version for doctors, short version for patients, algorithms and a patient decision aid. The patient decision aid resumed the information and recommendations about appropriate food, symptoms related to its condition, diagnostic tools and treatment of the celiac disease. After the patient decision aid was developed, a group of 10 patients received the brochure and graduated the items with a scale of 0 (no understandable language) to 10 (well understandable language). The items were 1) the definitions used, 2) the symptoms mentioned, 3) the diagnostics steps and 4) the recommendations for treatment. Results: The patients considered that the definitions (median 8; range 8-9) and the symptoms (median 8, range 8-10) were expressed in an understandable language. In relation to the diagnostic (median 5, range 5-9) and the treatment (median 5, range 5-8) they considered that the language used was not so clear. After the study, these items were redefined in a multidisciplinary group work with the patients and finally it was described in an understandable language. Conclusions: The patient preferences and view are very important tools in the development of a patient decision aid of a CPG. This evaluation by patients allowed us to reformulate the information and recommendations in a well understandable language before its dissemination to the public.

T-182

473 – ENABLING HEALTH, INDEPENDENCE AND WELLBEING FOR PATIENTS WITH BIPOLAR DISORDER THROUGH PERSONALISED AMBIENT MONITORING (PAM)

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Bipolar disorder (BD) is a chronic and recurrent mental disorder associated with two types of recurrent severe episodes (mania and depression) interspersed with periods of remission and occasional mild symptoms. Early detection of transitions between the normal, manic and depressed stages is crucial for effective treatment. BD sufferers can self-manage their condition effectively via self-awareness and long-term monitoring. To date, most self-management interventions have been manual and diary-based. Such interventions are not only time-consuming and expensive, but are also unreliable. Moreover, they are less accurate in detecting the onset of depression. Personalised Ambient Monitoring (PAM) project developed an automated unobtrusive system of sensors to support the early detection of acute bipolar episodes. The system collects a range of personal activity information from patients via a sensor network consisting of small sensors, mobile phones and computers. The data from this system are used to develop an "activity signature" for that individual in various health states. Operational Research modelling is a key aspect of the project. Simulation was used to help design the architecture of PAM, involving the minimum number of sensors of various types required to provide a robust personalised monitoring system for different patients. A unique and novel disease state transition model for bipolar disorder was developed, using data from the clinical literature. This model was then used as the basis for a Monte Carlo simulation to test a range of monitoring scenarios. The feasibility of obtaining enough information to derive such a signature from a limited set of sensors to identify the clinical states is analysed statistically. The minimum best set of sensors suitable to detect both aspects of the disorder is identified, and the performance of the PAM system for a range of personalised choices of sensors is evaluated.

T-183

590 – TRAINING IN PREVENTION OF CERVICAL CANCER TO COMMUNITY HEALTH AGENTS

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Introduction: The impact of Family Health Strategy on cervical cancer screening has not been demonstrated. To achieve this goal it is essential provide adequate training to Community Health Agents (CHA). Objective: Contribute to the training of the CHA to prevent cervical cancer. Method: Study conducted with the CHA from Goiânia-GO. The training took place in July 2009, 69 CHA participated in the training, two refused to participate in the study and one did not meet the data collection instruments. The CHA knowledge on the cervical cancer prevention before and after the training was assessed through pre-test and post-test and was compared by the McNemar test, adopting a 5% error. Results: The knowledge improvement after the training was observed regarding the finality of the cytopathology and the women readiness to take it, about the causing agent and risk factors for cervical cancer, and the results of cytopathology ($p < 0.05$). Conclusions: There was a satisfactory outcome regarding the CHA learning after the training on the cervical cancer prevention. It is important to highlight that, although several CHA reported to have been trained on the prevention of cervical cancer, many still don´t have sufficient knowledge for the correct orientation of women. This study data were presented to the Municipal Health Secretariat of Goiânia and an "Action Plan for the Prevention of Cervical Cancer" was developed. The action plan includes not only CHA training, but also training to all professionals who make up the 166 family health teams in the county. This study served as a subsidy in the identification of gaps in CHA training and qualification regarding the knowledge on cervical cancer prevention and helped to establish a plan for continued vigilance in the prevention of this disease in Goiânia-GO. Financial Support: Edict MCT/CNPq/MS-SCTIE-DECIT Nº37/2008; Edict nº6 PROEXT 2009-MEC/SESu; Edict nº2/2010 FAPEG (scholarship).

T-184

387 – CURRENT SITUATION OF EARLY DETECTION OF DISEASES IN MONGOLIA

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Background The early detection of diseases which is one of the main components of the health care technology is the actions and screening intended to diagnose diseases before its symptoms emerge and detect its adversities. In Mongolia a national program of "Healthy Mongolian" was introduced for the first time in 2008 which was aimed to early detection of some of prevailing diseases but there are very few assessments on implementation and outcome of this technology. Purpose of the survey: Analyze current situation of technology for early detection of diseases and identify further approaches. Expected outcome: The results of the survey will facilitate efficient and effective organization and rational introduction of early detection of diseases technology. Coverage of the survey: The survey involved 860 medical doctors and health sector professionals from over 60 health care establishments and 960 customers both from urban and rural areas. Findings of the survey: Though the hospitals use questionnaire, test and laboratory diagnose methods for early detection of diseases majority of the health sector professionals responded that the early detection technology barely existent in the nationwide and most of the diseases are discovered in their late stages after full symptoms are revealed or the patient comes to the hospital by himself/herself. 34.7% of the health sector employees rated the early detection capacity as good, 53.0% as satisfactory and 12.3% as poor whereas 48.4% of the customers rated it as good, 40.0% as satisfactory and 11.6% as poor. It is interesting that the health sector professionals were less satisfactory than the customers in early detection technology. Majority of the respondents from health sector concluded that there were some achievements in detecting diseases in their early stages within framework of "Healthy Mongolian" national program, however the outcome is not sufficient and basically implementation of this technology is stagnant

T-185

779 – DECISION-ANALYTIC PROSTATE CANCER SCREENING MODELS – A REVIEW OF METHODOLOGICAL MODEL CHARACTERISTICS

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BACKGROUND: Despite results from randomized trials, there is still controversy whether prostate specific antigen (PSA) screening for prostate cancer causes more benefit than harm. This question has also been investigated by various decision-analytic models. Sensitivity analyses suggest that the results of these models strongly depend on the assumed treatment and quality-of-life (QoL) effects. However, not all models have considered these aspects. OBJECTIVES: To systematically review decision-analytic PSA screening models with focus on methodological characteristics. METHODS: We performed a systematic literature search for decision analytic PSA screening models in several databases. All studies modeling the effect of screening were included. Methodological characteristics and results of the models were extracted into evidence tables and compared. RESULTS: 28 models were included. The majority were economic models (46%), followed by benefit-risk (29%), explanatory (18%) and other models (7%). Model types used were Markov models (54%), decision trees (14%) or other (25%). Screening strategies varied widely among the studies, differing in PSA cut-off, accompanying screening tests, and screening intervals. Diagnostic confirmation was typically done by biopsy (93%). Most studies did not explicitly model effectiveness of treatment. In most studies, treatment was not an issue due to a short time horizon. Eight studies (29%) explicitly modelled treatment, 2 considering only prostatectomy, and 6 prostatectomy and other therapeutic options. Prostate cancer mortality was modelled by 14 (50%) studies, all reporting a reduction due to screening. However, the 3 studies that additionally considered QoL did not show an overall beneficial effect of screening on QALYs. Overall, only 7 (25%) models considered QoL, of which only 3 (11%) had a lifelong time horizon. CONCLUSION: PSA screening models differ in important methodological aspects. Although benefit of prostate cancer screening strongly depends on treatment effectiveness and QoL effects, only 4 studies considered both of these important determinants. In particular, personalized decision

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T-188

750 – DETERMINING AN EVIDENCE MATRIX FOR A STROKE INTEGRATED CARE PATHWAY

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Aim: An integrated care pathway (ICP) for stroke is being developed to improve the quality of stroke care in Singapore. A review of the evidence was carried out to identify key elements of care for the pathway and the levels of evidence and effect sizes for interventions was summarised in an evidence matrix. Methodology: The scope of the review and clinically important outcomes for stroke interventions were determined with clinical and policy workgroups. Comprehensive literature search was done for effective interventions for stroke as expressed in published international clinical practice guidelines. Identified guidelines were critically appraised with the Appraisal of Guidelines Research and Evaluation (AGREE) instrument and interventions recommended were extracted (with their supporting scientific literature) and presented as an evidence table. The workgroupss then identified locally relevant interventions for the acute phase of the stroke ICP. A further search to update the evidence and a search for economic evaluation evidence was subsequently done, and the evidence was then tabulated as an evidence matrix showing level of supporting evidence and effect size against the expert-determined outcome measures. Results: An acute stroke service, early specialist assessment for TIA, and IV rt-PA administered within 4.5hrs of symptom onset were shown to be beneficial. Stroke rehabilitation is more effective than conventional treatment in an organised inpatient multidisciplinary setting and rehabilitation should be of at least 16 hours of therapy time over 6-months; early mobilisation within 48hrs after a stroke may also be a cost-saving intervention. Conclusion: Four key elements of care in the acute management of stroke were identified through the review and presented in an evidence matrix. Further clinical expert input will be needed to localise the evidence and implement the stroke ICP. The same process may be used for determining key elements of care in other phases of stroke management.

T-189

752 – RAPID TECHNOLOGY ASSESSMENT OF SPECIALISED GLUCOSE MANAGEMENT TEAMS FOR HOSPITALISED PATIENTS WITH DIABETES

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Aim: A rapid technology assessment of specialised glucose management teams for hospitalised patients with diabetes was conducted as part of the development of a national integrated care pathway for diabetes mellitus. Methodology: A systematic search was conducted for systematic reviews, HTA reports, clinical practice guidelines (CPGs), and primary studies on the following databases: NHS-CRD (DARE, HTA & NHS EED), the Cochrane Library, EMBASE, MEDLINE and the US National Guidelines Clearinghouse. A Google search was also conducted and relevant articles identified from reference lists of retrieved articles were also retrieved. Results: A systematic review of diabetes case management in multiple clinical settings was identified, and showed that diabetes case-management by a nurse-led team resulted in better blood glucose control (i.e. lower HbA1c) than management by a single clinician. Sub-group analyses showed that diabetes case-management was effective in academic centres but not in Veterans Affairs hospitals. Several primary studies were also reviewed. The primary study of highest methodological quality reviewed was a randomized controlled trial, which found that, on average, patients managed by a diabetes team had better glycaemic control after one month and fewer readmissions compared to patients who received standard care. Findings from case-control studies suggested that multidisciplinary hospital diabetes team management was associated with fewer delayed discharges, less inappropriate discharge planning and shorter lengths of hospital stay. The American Diabetes Association and the American Association of Clinical Endocrinologists also issued guidelines which were positive about using multidisciplinary, team-based management of hospital patients with diabetes. Conclusion: The evidence supporting the use of specialised hospital glucose management teams over standard hospital care in the management of hospitalised patients with diabetes is promising but still limited. More studies, as well as better-quality studies, are required for stronger conclusions about the effectiveness of specialised hospital glucose management teams.

T-190

144 – ELECTRONIC MEDICAL PEDIGREES CAN IDENTIFY INDIVIDUALS AND FAMILIES AT INCREASED RISK OF CANCER IN COUNTRIES WHERE ACCESS TO GENETIC TESTING IS LIMITED

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Knowledge about Hereditary Cancer Syndromes and Familial Cancer has expanded dramatically over the past decade. Advances in microarray and DNA and RNA sequencing technologies have led to the identification of mutations and polymorphisms associated with an increased risk for developing cancer. Quantitative assays measuring gene and protein expression herald an era of personalized medicine where such assays will guide treatment selection. And yet public and private health systems in middle and low resource countries have been slow to establish genetic counseling services concerned that genetic testing technology is still prohibitively expensive. Health system policymakers and managers are overlooking the value of medical pedigrees. The U.S. Surgeon General offers a free on-line medical pedigree construction tool, available in English, Spanish and Portuguese) and the Brazilian National Familial Cancer Network has developed a computerized pedigree tool. Scientifically validated algorithms that use pedigree data to estimate risk are increasingly available. Thus, even where genetic testing is not available or is prohibitively expensive, a carefully constructed medical pedigree can identify unaffected at-risk individuals. These individuals can receive enhanced cancer surveillance using conventional screening tests (e.g. mammography, colonoscopy) by initiating screening at an earlier age and narrowing screening intervals. The yield in terms of early diagnosis of cancer is likely to be higher and more cost-effective when screening is intensified in those whose risk is two to 20-fold higher than the general population. Health systems should make these tools available and encourage primary care providers, oncologists, and even the lay public to use them. Training programs for medical geneticists and genetic counselors need to be expanded so that access to genetic counseling services can be increased. Electronic medical pedigrees constitute a low cost approach to collect and store family history information and promote cancer genetics counseling in low and moderate resource countries.

T-191

627 – DEMANDS AND EXPECTATIONS FOR HTA IN GALICIA: A QUALITATIVE STUDY

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Background: It is recognised that one of the main challenges of HTA agencies is to translate scientific evidence into useful information for decision making. The aim of this study is to explore the opinion of decision-makers and clinicians in Galicia (NW Spain) regarding the utility of the different products and services developed by the Galician HTA agency, as well as elucidate whether there are especificic barriers and/or facilitators that could aid the implementation and use of HTA. Method: qualitative study based on in-depth semi-structured interviews of 20 experts intentionally selected (10 health care professionals and 10 decision makers). The interviews were tape recorded and transcribed for inductive thematic analysis. Results: the study highlights the great interest in health technology assessment activities, but the majority of informants make reference to the exclusive use of HTA at the macro level (policy making) and to its underuse in clinical practice decisions. In general terms, informants valued positively all HTA initiatives but showed certain scepticism regarding “coverage with evidence development” and “obsolete technologies”. The observation of health technologies after approval was perceived as more logic approach, even though not for all technologies. Several factors were identified as key to guarantee HTA use: greater diffusion of HTA activities and availability of results, involvement of health care professionals in the selection and prioritisation of relevant research, contextualization and adaptation of results to the local context, increase in organizational support and greater financial resources. Conclusions: in our country, the present study is the first to contrast end-user´s opinion regarding the utility of recent activities of HTA agencies (monitoring studies, identification and assessment of obsolete technologies). Even though it is acknowkedged that decison_making environments are context sensitive, we believe many of the proposals made to improve these activities could be applied by other international HTA communities.

T-192

1003 – HORIZON SCANNNING FOR THE BRAZILIAN HEALTH SYSTEM

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Given the importance of developing horizon scanning activities for health care technologies in Brazil, the present work had the objective of producing subsidies for the elaboration of guidelines to develop a horizon scanning system in Brazil. To aid that elaboration process, the case of technologies designed for the secondary prevention of osteoporotic fractures after menopause, was analyzed. Initially, a review of the concept of horizon scanning in health care and of the related international governmental experiences was carried out. The available sources and studies indicate a consensus on that: a) recommendations made by a horizon scanning system must be supported by the best available early scientific evidence of the consequences on the health of the individuals and on the health system of the adoption of new/emerging technologies; b) the horizon scanning system must act in a transparent way, making explicit the criteria and methodology it uses. The horizon scanning exercise related to the secondary prevention of osteoporotic fractures enabled the identification of a new drug, called denosumab; phase I and phase III trials of that technology have been recently published and were analyzed. Limitations faced in such exercise made it possible the identification of some specific difficulties associated to technology assessment at the beginning of the life cycle. The review of the international experiences with horizon scanning of health care technologies indicate that, for developing a horizon scanning system in Brazil, collaboration with developed countries’ units is essential, taking into account the qualified and experienced staff of such units as well as the amount of work and time involved in the analysis of each technology and the inherent urgency of such activities. Finally, key actors, specially those at central government level, must be articulated for the discussion and elaboration of the guidelines towards the creation of such system

T-193

951 – ANTIHYPERTENSIVE PRESCRIBING TRENDS AND THE UTILIZATION, COMBINATION AND POTENTIAL DRUG-DRUG INTERACTIONS RELATED TO ANGIOTENSIN-CONVERTING ENZYME INHIBITORS AND ANGIOTENSIN RECEPTOR BLOCKERS IN TAIWAN

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Objective: This study aims to evaluate the utilization trend of anti-hypertensive drugs and assess the switching and combinations of potential drug-drug interactions (DDIs) related to angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) in Taiwan. Methods: This cross-sectional study used a nationwide sampled, longitudinal dataset from National Health Insurance (NHI) claims constituting of 1,000,000 beneficiaries. Data of hypertensive adult outpatients from 2006 to 2008 were extracted to evaluate the utilization and cost of anti-hypertensive drugs. Continuous prescriptions of ACEIs and ARBs were used to follow the switching and combining between ACEIs and ARBs, and DDIs. The descriptive statistics, Wald chi-square test, Student's t-test and a simple linear regression analysis were used to assess above outcomes. Findings: Calcium channel blockers (CCBs; annual prescribing rates 29-31%) and beta-blockers (20-22%) were the most frequently prescribed anti-hypertensive drugs. Of all antihypertensive drugs, CCBs and ARBs were the most costly, and only the cost of ARBs significantly increased during study period. ARBs (13-17%) were found to be more frequently prescribed than ACEIs (9-12%). The cost and utilization of ARBs were increasing ($p<0.001$) but those for ACEIs were decreasing. The NHI's price reduction policy implemented on November 2006 and September 2007 significantly decreased cost of ACEIs (e.g. enalapril, lisionpril), but cost of ARBs still remained consistently increasing trends. Of the 141,082 patients who used ACEIs or ARBs, 3.6% had potential DDIs. Of the 79,235 patients using continuous prescriptions for ACEIs or ARBs, 17% had switched between ACEIs and ARBs, 63.9% and 55.6% ever used more than one ARBs or ACEIs, and only 4% ever combined ACEIs and ARBs. Conclusions: The utilization and prescribing patterns of ACEIs and ARBs are not justified by current clinical and cost-effectiveness evidence. To ensure quality of care, it is necessary to add clinical and prescribing indicators into reimbursement criteria.

T-194

954 – IS THE PRESCRIBING ADJUSTED BY EVIDENCE? – A CASE STUDY TO EVALUATE ANGIOTENSIN-CONVERTING ENZYME INHIBITORS AND ANGIOTENSIN RECEPTOR BLOCKERS UTILISATION AND PRESCRIBING PATTERNS FOR TREATING HYPERTENSIVE OUTPATIENTS IN SOUTHERN TAIWAN

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Objective: This case study aims to evaluate the utilization, switching and combinations of angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) in southern Taiwan. Methods: This cross-sectional study used a regional, longitudinal medical claim database constituting of the whole 3.26 million beneficiaries from the Kaoping Division of National Health Insurance in southern Taiwan. Data of hypertensive adult outpatients who have been prescribed ACEIs or ARBs from 2006 to 2008 were extracted to evaluate the utilization and cost of anti-hypertensive drugs. Continuous prescriptions of ACEIs and ARBs were used to follow the switching and combining between ACEIs and ARBs, and DDIs. The descriptive statistics, Wald chi-square test, Student's t-test and a simple linear regression analysis were used to assess above outcomes. Findings: Of all, 2,769,790 (44.5%) and 3,4450,081 (55.5%) prescriptions of ACEIs and ARBs were prescribed to 369,768 adult hypertensive outpatients. The majority of ACEIs were prescribed in physician clinics (37.0%), while ARBs were mainly prescribed in medical centres (35.5%). However, compound preparations of ACEIs and ARBs were mainly prescribed in regional hospitals. The cost and utilization of ARBs were increasing ($p<0.001$) but those for ACEIs were decreasing. Of the 339,462 patients who have

been prescribed continuous prescriptions for ACEIs or ARBs, 21.2% (n=71,988) had switched between ACEIs and ARBs; 12.8% (n=43,509) and 20.6% (n=69,719) ever used more than one ARBs or ACEIs, and only 3.5% (n=11,986) ever combined ACEIs and ARBs. Duplicating of same active components was the most common condition for combining more than one ARBs (94.2%) or ACEIs (93.4%). Conclusions: Although there was only a small proportion, the ACEIs or ARBs combinations are increasing and used the utilization and switching prescribing patterns of ACEIs and ARBs are not justified by current clinical and cost-effectiveness evidence. Further studies will explore the budget impacts of these prescribing patterns.

T-195

742 – "GRANT" ROLE OF PHARMACOEPIDEMIOLOGICAL AND PHARMACOECONOMICAL SEARCHING IN QUALITATIVE DRUG PROVISION OF POPULATION OF THE REPUBLIC OF KAZAKHSTAN

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Object: learning quality of drug provision in frame of guaranteed volume of free medical helping to patients with social-meaning diseases. Materials and methods: interviewing with questionnaire method of employees medico-prophylactic foundings, which take part in formulation of Log-book list and buying drugs at social-meaning diseases: oncopathology (including haemoblastoses), hemophilia, tuberculosis, diabetes. Results: in condition of sufficient financing take place the non rational using of health budget, and result of this is the shortage of necessary drugs. Low or not effective, out-of-date drugs, drugs which haven't conclusive base and pharmacoepidemiological, pharmacoeconomical facts are bought. At making log-book the analysis of the disease structure by each nosological form, volume of using, effectiveness and safety of drugs, and also cost of disease treatment course are not taken into account. Decision of entering preparation into log-book are not taken after estimation of total expenses, it takes by purchase cost of preparation. All this indexes are affected on quality of treatment and also on quality of patient life. Appointed problems connected with absence of specialists in clinical pharmacology and pharmacoeconomy at log-book commission of medico-prophylactic foundings. Conclusion: in the republic take part problems at drug provision of medico-prophylactic foundings, which connected with formulation of Log-book and list of drugs which should purchased.

T-196

842 – INTERNATIONAL ACCREDITATION PROGRAM: A MODEL OF SUSTAINABILITY FOR PUBLIC HEALTH SYSTEMS

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Health Public institutions have a high potential to implement improvements in their management and operations processes, training human resources, promote and incorporate the various types of available technologies, positioning itself as well, so competitive and cost-effective in its segment market. The proposal to insert them in accreditation programs focused on international standards of quality and safety, may represent a very feasible alternative to meet the urgent need to achieve results and earnings quality and visibility, but also to redirect these results and align the priorities and needs national policies for the sector. Since 2009, the Hospital Alemão Oswaldo Cruz develops a project that supports the improvement of management of four public hospitals, through initiatives worldwide recognized success to introduce and improve the quality and safety culture in these institutions, which could be the initial step to discuss and build a proposed model focuses on continuous improvement of processes of care and management at all levels. The benefits obtained can be the strategy to meet the growing demands in evaluation of services and technologies and achieving sustainability as desirable and necessary in the setting of hospitals.

T-197

877 – THE EVOLUTION OF HEALTH TECHNOLOGY ASSESSMENT IN BRAZIL: AN ECONOMIC INTERPRETATION

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Health technology assessment (HTA) in Brazil was instituted as a process (conducted by CITEC) at the federal level in 2006. This presentation reviews the structure, process, and status of HTA in Brazil through the lens of a general economic framework that characterizes the evolution of HTA in emerging markets. The underlying conceptual model focuses on two key dimensions: the level of spend (the quantity of resources available) and the degree of centralization (who makes decisions on health care funding). These two dimensions influence which health services are appraised and what is focus of the appraisal. In interpreting the evolution of HTA in Brazil, four key features are important. First, the existence of a constitutional right to healthcare creates a need to define more explicitly what is included in healthcare. Second, HTA in Brazil has been tied to the broader international HTA movement. Although there is recognition that health technology is broader than just pharmaceuticals, in practice, the focus is on pharmaceuticals. Third, the right to healthcare, enforced through the courts, creates a significant budget problem for affording high-cost, innovative, and life-saving medicines, such as orphan drugs. Fourth, CITEC's inability to process submissions expeditiously has led to a review backlog, thereby creating a barrier to the actual incorporation of the new technologies. This situation, added to the lack of transparency about the recommendations given, opens space for other noneconomic factors to play into the decisions about the incorporation of new technologies in Brazil. Also, in terms of process, clear parameters for decisions have not been made transparent. These issues are further heightened in a country with a substantial inequality of income and wealth. In Brazil, the discussion about which right—universal coverage vs. comprehensive coverage—should prevail has not been answered, since without enough funding, one or both of these will be affected.

T-198

521 – PROPOSAL OF ASSESSMENT INDICATORS FOR LASER TREATMENT FOR BENIGN PROSTATIC HYPERPLASIA

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Benign prostatic hyperplasia (BPH) is one of the leading benign tumours among males over the age of 50 years. Surgical treatment aims at improving symptoms of urinary obstruction and patients' quality of life, with transurethral resection of the prostate being the standard treatment. To reduce TURP-related complications, new alternative treatments have been developed in recent years. Notable among these are various laser techniques. Objective: To draw up a quality-indicator proposal for assessing the results of the implementation of such techniques in clinical practice. Method: Reviewers staff of the Galician Health Technology Assessment Agency examined the scientific evidence and selected the most indicative outcome variables in surgical treatment of BPH. These were then agreed with health professionals having expertise in this field and finally used to draw up the proposed quality indicators. Results: The variables for drawing up the proposed quality indicators and standards were selected on the basis of scientific evidence drawn from the systematic review, clinical practice guidelines and the consensus of expert health professionals. The quality-indicator proposal is made up of 19 indicators. This is an initial proposal, which constitutes a first step towards drawing up definitive indicators to be defined in accordance with established consensus methods. The indicators submitted amount to an initial proposal that envisages a wide range of indicators covering the whole health care process devoted to BPH pathology. Conclusions: A total of 19 quality indicators have been proposed. These must now be prioritised, agreed and validated with expert health professionals in order to establish the definitive quality indicators and standards. The number of indicators to be defined as the most relevant for assessing surgical treatment of BPH should be kept to a maximum of 15.

T-199

469 – AVAILABILITY OF EVALUATION OF TUBERCULOSIS CONTROL PROGRAM IN BRAZILIAN PRISONS

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The high incidence of tuberculosis in prisons, 25 times higher than in the general population and cure rates below 60% (MS, 2010), makes this population a priority of the National Tuberculosis Control Program (NTCP) . The purpose of this research is the assessment of TCP in prisons, considering: the description of the management model and intervention; the development of program logic model and the theoretical model of evaluation. The methodology used is that proposed by Thurston and Ramaliu (2005). The present study is limited to the first step which is called availability study (AS). This step helps to determine the focus and evaluative purposes, enabling a deeper understanding about the program and offering an appraisal of the operational process of evaluation. The AS was executed through documentary analysis, interviews, discussions with managers and technicians of the Health Coordinator of the Secretariat of Penitentiary Administration (SPA) as well as with directors of prison health units. The interviews and discussions were held in two prisons in one of the two selected states. The results of the first step (AS) were: (a) description of the program identifying the goals and objectives, (b) review of available documents, (c) modeling (program logic model) of available resources, planned activities and expected impacts; (d) obtaining a preliminary understanding of how the program operates, (e) development of a theoretical model of assessment and identification of the presumed main causal connections, (f) identification of users and other stakeholders of the evaluation, (g) reaching an agreement with the users of the evaluation regarding the assessment procedure. Conclusion: This availability study gave an important base for the agreement of the prison staff involved in the realization of formative assessment. Furthermore, the study was important in identifying the need, feasibility and rationalization of assessment resources.

T-200

447 – FAMILY HEALTH PROGRAM AND TRADITIONAL PRIMARY CARE: COMPARATIVE PERFORMANCE EVALUATION CONCERNING THE PROGRAM OF CONTROL OF HYPERTENSION AND DIABETES

Luis-Eugenio de-Souza, UFBA, Brazil; Guillermo Etkin, ISC/UFBA, Brazil; Priscila Teixeira, ISC/UFBA, Brazil

Hypertension and diabetes mellitus are serious public health problems, with high prevalence rates. If well managed, their negative consequences to life expectancy and quality can be reduced. The Unified Health System (SUS) in Brazil offers to its users a Programme for Prevention and Control of Hypertension and Diabetes (Hiperdia), developed at the primary care level. Considering that they are chronic conditions, the effectiveness of the Programmme depends on continuity of care over the years. The traditional strategy of primary care is based on the acute health conditions, which leads to intermittency of contacts between professionals and patients. However, the SUS is changing its model of primary care, with the Family Health Units (USF), which has the creation of links between users and services as one of its principles. This strategy reached 50% of population coverage throughout the country in 2009. It is expected that the effectiveness of Hiperdia is higher in the USF than in conventional units. The present study evaluated the performance of the Family Health Units and the Traditional Primary Care Units (UBT), concerning the control of hypertension and diabetes mellitus. The performance was evaluated based on attributes of supply, coverage and cost-effectiveness. We analyzed data, made available by the Ministry of Health, from 15 cities, three on each macro-region of Brazil, who have both USF and UBT with Hiperdia implemented. Preliminary analysis indicates that the supply of Hiperdia is high in all regions of the country. The population coverage lies in 30% of the target population. Most patients are women with hypertension, medium or high cardiovascular risk, under treatment with at least one medication. The effectiveness - estimated by the proportion of complications of hypertension and diabetes - and the cost are still being calculated. Complete analysis will be presented at the HTAi 2011 Conference.

T-201

858 – CHRONIC CARE MODELS EFFECTIVENESS: A LITERATURE REVIEW

Luis-Eugenio de-Souza, UFBA, Brazil; Madalena Passos, UFBA, Brazil

The Chronic Care Model (CCM) is presented as a management model of primary health care services to patients with chronic diseases. The prevalence of chronic diseases is increasing worldwide, affecting the quality of life of people and generating high costs for health systems. In Brazil, for example, a recent study shows that the frequency of previous medical diagnosis of hypertension was 24.4% of the population. The MCC appears as a technology of management of services to patients with chronic diseases, which proposes changes in the organization of the health system, aimed at producing better results. The MCC provides guidelines and indicators for assessing the quality of care, the risk of complications. It also emphasizes the person, offering individualized plans of care and promoting empowerment for the self-management of disease. Then. question that arises is: Does MCC, in fact, produce better results in terms of quality of life of patients and in terms of reducing or controlling costs? To answer this question, we carried out a synthesis of specialized literature on the effectiveness and efficiency of chronic care models, baesd on an extensive search of publications in the following databases: Cochrane, Web of Science, PubMed, Lilacs and SciELO. This work is part of a research project on \\\”Management of people with hypertension in primary care: evaluation of the model of care\\\”, funded by CNPq and the Brazilian Ministry of Health, to assess the effectiveness of the CCM in primary health care services in Brazil.

T-202

814 – INTERNATIONAL HEALTH LAW: A TOOL TO FULFILL HEALTH POLICIES IN DEVELOPING COUNTRIES

Marco Aurelio Antas Torronteguy, Fiocruz – Fundação Oswaldo Cruz, Brazil; Maria Celia Delduque Nogueira Pires de Sa, Fiocruz – Fundação Oswaldo Cruz, Brazil

Developing countries face a double challenge: first, to get access to health technologies developed abroad and, second, to obtain know-how to carry out HTA concerning properties, effects and impacts of those foreign technologies. There is a way to face it, which is the international cooperation, constructed and achieved through Law. In this context, the International Health Law could be a useful tool to establish rules not only to facing international health matters, as a pandemic disease, but also to elaborating international public policies or just minimum standards of health policies. OBJECTIVE: The main purpose of this research is to investigate at which extent International Law rules health cooperation. In particular, we seek to verify the main legal paths of this fragmented field of Law, in which there are multiple instances and transversal rules (intern and foreign law, international organizations etc.). This implies trying to verify whether is possible or not elaborate conceptually the recent field of International Health Law. METHODS: It is a social science research, also in progress, through a dialectical method of the contradictions encompassed by the theme (intentions/contradictions of international cooperation; soft/hard law; developed/developing countries; public health/market approach etc.). The documental study starts from results of a previous research concerning bilateral agreements which have been celebrated between Brazil and some African countries. Now, we are investigating other international legal acts (treaties and political declarations), as bilateral and multilateral agreements. FINDINGS: Health cooperation demands social participation and horizontal relationship. CONCLUSIONS: South-South cooperation promotes access to technologies, but must be improved (by democracy and transparency) and our hypothesis – International Health Law is a tool to develop health policies in developing countries – could be more deeply investigated. Finally, this work intends to contribute to understand that International Law and Public Health have much to contribute each other.

T-203

916 – THE ROLE OF HTA IN THE MEDICINES PRICING AND REIMBURSEMENT PROCESS IN ITALY

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HTA principles could play a relevant role for drug regulatory agencies. While the EUnetHTA Joint Action is reviewing its Core Model to adapt it to pharmaceuticals, the Italian Medicines Agency (AIFA) is going to review its HTA approach evaluating how this could be better implemented during the assessment phase of new drugs. In the pilot phase, a multidisciplinary group is active. Pharmacists, health economists, physicians, statisticians are testing and designing a new workflow for drug assessments. It aims to support the decision making process of both the Scientific Committee, responsible for marketing authorization, and Price and Reimbursement Committee, which define drug prices. Therefore, it’s necessary to provide independent and reliable scientific evidence, estimate drug relevance for Italy given current epidemiologic and population trends, define drug place in therapy, as well as estimate economical implications for the National Health System (NHS).Great attention is paid to drug innovation given the current clinical practice and comparators already present on the market. In this pilot phase, more than 10 medicines were evaluated and a Multiple Technology Appraisal (MTA) was conduced on incretins for diabetes therapy. A multidisciplinary group combining both experience with literature and health databases and competences in the pharma field permitted to have a practical experience on how HTA principles could be better translated and transferred to the Italian drug environment. Collaboration with AIFA Rapporteur, who present drug reports to Committes, must be improved. Furthermore, an optimatization of the HTA workflow is required in order to increased the number of evaluated drugs on a yearly base. Finally, a more interactive communication with Industries represent the further step to take, in order to improve the quality of information submitted by producers.

T-204

765 – HEALTH SERVICES' PERFORMANCE FOR EARLY DIAGNOSIS OF TUBERCULOSIS, SAO JOSE DO RIO PRETO, SP – BRAZIL

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Aim: To analyze performance of the first health service sought by patients for tuberculosis (TB) diagnosis in Sao Jose do Rio Preto - Brazil. Methods: A descriptive exploratory study conducted from July to November, 2009, with TB patients in treatment, using structured questionnaire based on theoretical framework of Primary Health Care (PHC) dimensions. Confidence intervals for proportions were used to analyze the indicators, and health services were classified as: PHC units, emergency services (ES) and specialized services. Results: The first health service sought by the patient at the beginning of TB symptoms was the ES (48.5%), followed by the PHC (30.3%). ES and PHC have shown, respectively, low suspicion of TB (21% and 40%) and low smear requests (29% and 43%), resulting in high request of referral for consultation with other professionals (50% and 47%). Only 35.4% of interviewed were diagnosed at the first health service sought. Hospitals (45.5%) diagnosed the majority of cases. 75% of patients had to go up to 5 times to health services, with a time spent up to 30 days until diagnosis. Patients who sought PHC units were diagnosed later (median of 60 days). Conclusion: PHC didn´t constitute the first contact care for most patients, as it is expected from recommendations of national health policy. The ES, despite being the most sought, haven't shown efficiency, and satisfactory performance for the diagnosis of TB was only found at specialized services (including hospitals). The sputum smear test, though being considered as a low-cost technology, is not prioritized to obtain the diagnosis, given the low suspicion of the disease. Effective control of TB implies in qualified human resources and supply/availability of tests for obtaining early diagnosis and early treatment, independent of which type of health care is seek first.

T-205

572 – EUPRIMECARE. PRIMARY HEALTH CARE SYSTEMS IN EUROPE: FRAMEWORK FOR CLASSIFICATION OF MODELS, AND MEASURING QUALITY AND COSTS

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Objective: EUPRIMECARE is a project funded by the 7th Framework whose objective is to analyse the costs and the quality – including access, equity and satisfaction – of different primary care (PC) models in Europe. EUPRIMECARE aims to establish a common research method to explain PC models in EU countries and propose a best practice for assessing quality and measuring the associated costs. Methods: The project has been structured in 8 work packages (WP). The WP2 is aimed towards describing PC systems in terms of five control knobs: financing, regulation, organization, paying and behaviour. A template to obtain relevant information from the seven countries participating in the consortium was developed. Information was analyzed through Principal Component Analysis (PCA) and was complemented with a descriptive review as well as with a literature search. WP3 and WP4 have the objective to develop and apply a methodology to measure costs in PC. Based on a literature search and using focus groups WP5 will propose feasible and relevant indicators to measure quality in several dimensions (appropriateness, access-equity, and satisfaction) which in WP6 will be measured through medical records review, and a population survey. Finally, WP7 will determine the existing relationship between PC models, costs and quality. Findings: Data gathered from the templates has allowed to conduct a PCA which has identified three main components which, respectively, 29%, 21% and 17% of the overall variance. A framework to classify PC models has been developed. This framework includes variables that showed statistically grouping capacity, from PCA, and were considered relevant by the investigators. Discussion: We propose a framework to identify a series of characteristics that appear to be relevant in terms of classifying PC systems. Next steps will explore the validity of those models and determine the characteristics, in terms of quality and costs, of those

T-206

874 – THE HEALTH STATUS OF THE PATIENT DIAGNOSED WITH DEPRESSION IN THE MADRID COUNTY (SPAIN)

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Objectives: Determine the comorbidities, psycho-drugs prescription and the incapacity for work of patients diagnosed with depression in the Madrid County (MC). Methodology: Restrospective observational study. Population included: All adults over 24 years old with at least one attendance to the health centre in 2006 and patients with a diagnosis of depression (International Classification of Primary Care - I). The study was conducted in six of the eleven health areas of the MC. The electronic medical records for Primary Care were used. A stratified analysis by age and sex was carried out and comorbidities, psycho-drugs and incapacity for work in the depressed patient were analyzed and compared with those of the general population using tests hypothesis. Results: Out of 1.324.679 included patients, 7,8% had been diagnosed with depression and had an average age of 54 years. The ratio men/women were 1/2 with a progressive increase of age, having women longer incapacity of work periods. The prescription of psycho-drugs was higher for women and older patients. The more prevalent comorbidities were: musculoskeletal and respiratory conditions for both sexes, with no differences to the general population. When stratifying by sex, musculoskeletal conditions were more frequent in women and respiratory conditions were for men. The overall health problems in patients diagnosed with depression did not show differences when stratified by age and sex but it was different when compared to the general population, being nearly double for these patients. Conclusions: Depression is an important health problem associated with comorbidities, affecting predominantly women, higher prescription of psycho-drugs and longer incapacity of work periods. Future studies to determine the impact of this disease in the usage of health service in Primary Care at the MC are being proposed.

T-207

549 – PUBLIC HEALTH OBSERVATORY ON THE STATE LEGISLATURE: A TECHNOLOGICAL DEVELOPMENT PROJECT CASE REPORT

Maria Celia Delduque, Luiz Carlos Amora Nogueira e Dolores Delduque Nogueira, Brazil

INTRODUCTION The Constitution has given health a fundamental right status. Health actions and services through public policies are obligations of the State. Elaboration of public policies is part of legislative and also executive jurisdiction. In Brazil, the process of federal law making is reserved only to Parliament. In order to follow law making process related to health is proposed a Public Health Observatory within Oswaldo Cruz Foundation office in Brasilia. OBJECTIVES The Observatory intends to expand the social control mechanisms on the right to health by offering a database available on the internet that shall contain information about draft bills and other legislative proposals on health issues, in the Parliament. METHODS First law proposals pending at the Senate and the House of Representatives will be collected. Later, a systematization using previously established parameters will take place. Last, all the data will be available to the public through the database. RESULTS The website will allow users to query and follow legislative proposals on public health. CONCLUSIONS For democratic participation in health, it is necessary to create means for citizens to control the law making, including budgeting, which occurs within the Legislative Branch, and, thereby, to permit interventions to the process. Besides that, the Observatory provides information about health technology including projects about medication, equipment, protocols and assistance programs among others.

T-208

550 – PUBLIC HEALTH OBSERVATORY ON THE STATE LEGISLATURE: A TECHNOLOGICAL DEVELOPMENT PROJECT CASE REPORT

Maria Celia Delduque, Fundação Oswaldo Cruz, Brazil; Giliana Betini, Ministerio da Saúde, Brazil; Luiz Carlos P. Romero, Senado Federal, Brazil; Denis Murahovschi, Senado Federal, Brazil; Martinho Silva, Fundação Oswaldo Cruz, Brazil; Jarbas Cunha, Fundação Oswaldo Cruz, Brazil

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T-209

532 – IMPLEMENTATION OF HEALTH TECHNOLOGY ASSESSMENT IN THE STATE OF CEARA

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Background: In the Ceará State, the decision-making process, including healthcare planning, was highly centralized until recent developments. For political reasons and budget pressure, the Ceará government adopted a Health Technology Assessment (HTA) initiative. Aiming to foster analytic methods and mechanisms to plan and control the state healthcare network, the Ceará government adopted a broad definition of the health technologies, including: drugs, equipments, technical procedures, organizational systems, education, information and support, healthcare programs and protocols. Objective: To describe the process of the HTA implementation for decision making in the Ceará State Department of Health, Secretaria de Saúde do Ceará (SESA-CE). Methods: Descriptive and exploratory study using a qualitative approach, through document analysis techniques. Results: The HTA policy initiative began in 2000 as proposal for the Ceará Public Unified Healthcare System, SUS-CE, where a preliminary discussion document was prepared. The reference: El Desarollo de la Evaluación de las Tecnologías em Salud en América Latina y el Caribe guided this document. Concurrently, the Health Economics Unit was created within the organizational/administrative structure of the SESA-CE. Until 2002 the HTA work was not formalized in the structure of the SESA-CE, when the SESA Directive 986/2002 established the formal HTA Working Group. In 2007, the SESA-CE has created the Center for Science, Technology and Innovation in Health (NUCIT) in its administrative structure, within the Coordination Management of work and Health Education (CGTES). Amid NUCIT's mandates, one is to foster the HTA policy, which resulted in the institutionalization of the SESA-CE Commission for Technology Assessment (CATS) in 2009 and deployment of HTA centers (NATS) in Ceará State teaching hospitals; two of them are already very active. Conclusion: Implementation of HTA methods by CATS is leading to evidence-based SUS-CE incorporation of drugs, equipments, technical procedures, organizational systems, education, information and support, healthcare programs and protocols.

T-210

534 – IMPLEMENTATION OF THE CENTERS FOR HEALTH TECHNOLOGY ASSESSMENT ON TWO TEACHING HOSPITALS OF THE STATE OF CEARA

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Introduction: Two public teaching hospitals in the Ceará State healthcare network, the first being reference in the heart transplantation domain and the second being reference for kidney, liver, pancreas and corneas transplantation, won competition and grants from the Health Ministry in order to implement Hospital Centers for Healthcare Technology Assessment (NATS). The group involved in the NATS deployments has been participating in courses, lectures and meetings of the Brazilian Network for Health Technology Assessment (REBRATS), since October 2010. Objective: To describe the process of implementation of NATS in two public hospitals. Methods: The study had a qualitative approach and descriptive exploratory method. Results: For implementation of the NATS, at each hospital, a technical group was established by their General Director. Within their organizational structure, the NATS technical group is, thus, subordinate to the Hospital General Direction. The composition of these groups required strict professional profile criteria including: being a regular institutional employee, having completed Evidence-Based Medicine training or having a postgraduate or latu sense research background in related areas and / or officially proven technical experience of at least ten years, supported by their immediate superior manager. The NATS implementation process in the Teaching Hospitals of the Secretaria de Saúde do Ceará (SESA-CE) has also set strict goals to be met, consisting of evidence-based health technologies incorporation or exclusion studies, practices and processes; to train personnel for the correct use of HTA and to undertake evidence-based production of scientific and technical knowledge documents about issues required by SESA or the Health Ministry, as well as, to review the clinical protocols about the most prevailing diseases within their catchment population. Conclusion: Both NATS technical groups and their Hospital General Direction have engaged in dissemination of health technology assessment (HTA) culture and decision-making based on scientific evidences.

T-211

286 – ADVERSE HEALTH EFFECTS OF EXPOSURE TO MICROWAVE THERAPEUTIC EQUIPMENT – CURRENT KNOWLEDGE STATE

Maria Das Graças Anguera, FMUSP/UNIOESTE, Brazil; Reinaldo José Gianini, FMUSP, Brazil

Equipments of non-ionizing radiation for therapeutic purposes are used in physiotherapy. The microwave is one of the resources available in this area, operated at a frequency of 2.45 GHz. Their physiological effects are characteristic of heat therapies by diathermy, such as analgesic, anti-inflammatory and antispasmodic. Practice with warranted occupational safety by physiotherapists is rare. It is likely that this is due to the lack of knowledge from these professionals regarding assessment and risk management of this type of therapy. Aiming to find Brazilian studies related to the therapeutic equipment of microwaves, a literature search was accomplished in the database of the PubMed and Scielo using the following key words: electromagnetic fields, electric field, radio frequency, microwaves, occupational exposure, electromagnetic field exposure, radio frequency exposure, microwaves exposure. The search was extended to the database of CAPES (theses and dissertations) for the period from 1999 to 2009. The results showed that therapeutic equipment of microwave was not the object of study in the associations between exposed microwaves operators (physiotherapists) and adverse health effects in PubMed and Scielo.. Only two studies were found in CAPES database, both Master Level's - one accomplished in 2003 and another in 2009. Based on the results of this research, the authors suggest that the Brazilian authorities related to health surveillance and education must pay attention to this area of health care, with the purpose of promoting studies for dissemination of knowledge about Microwave exposure and effects. Promoting appropriate assessment and management of the risks related to the microwaves therapies, science and technology can improve living conditions and contribute to the interest of humanity. Keywords: microwaves, physiotherapy, national studies, adverse effects, exposure.

T-212

1000 – TECHNOLOGY DIFFUSION IN PUBLIC-PRIVATE SYSTEMS: MEDICAL IMAGING IN BRAZIL

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Brazil is a country that has suffered an intense process of medical imaging diffusion as well as a sustained economic growth after 2004. Between 2005 and 2009, there was an expansion of the supply of equipments of computed tomography (TC) in 50% and of nuclear magnetic resonance (NMR) in more than 100%. They reached 15, 8 TC per million inhabitants and 6,26 of NMR per million inhabitants in 2009. However, the distribution is extremely unequal considering the region of the country and the availability to the public system. Technology incorporation and diffusion is an active process influenced by many factors related as to political decisions as market forces. Objective: To evaluate the role of economic growth and private health insurance coverage in the diffusion of TC and NMR in Brazil between 2005 and 2009. Methods: Exploratory analysis of official data – growth domestic product (GDP) per capita, TC and NMR per 1 million inhabitants and availability to public system; population with private health insurance (%) from states of Brazil. Statistics analyses were performed. Findings: There was a relation between the variables in both years and in almost all the states. The clearer relation was between TC and NMR rates and GDP per capita. The rates of equipments supply in the public system were much lower than to private sector. The relation between GDP per-capita and TC and NMR supply to public system was not so clear. Conclusions: The findings suggested that economic factors were associated with diffusion of these medical equipments, frequently joined to private health insurance coverage. In a context of economic growth and a good sort of factors inducing the enlargement of the private health plans market, there is a need of discussing the regulation of acquisition of expensive technology in order to guarantee the sustainability of the

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T-213

560 – NUSS PROCEDURE FOR PECTUS EXCAVATUM TREATMENT: MINI-HTA

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Objective: To describe a mini-Health Technology Assessment (mini-HTA) elaboration process in a university hospital on Nuss bar use for Pectus excavatum correction, in comparison to the conventional technique (Ravitch). Methods: Based on a structured question, we developed a search strategy to identify eligible articles through the Cochrane, Medline (via Pubmed), Trip, and Centre for Reviews and Dissemination databases. Studies with a high level of evidence (systematic reviews) were selected and critically evaluated by the reviewers. The results were synthesized in order to support the decision-making process in the hospital. The technical content of the mini-HTA was reviewed by a specialist in thoracic surgery at the same hospital. Results: We found 13 systematic reviews. The systematic review by Nars (2010) was selected due to its higher methodologic quality. This review included and summarized in a meta-analysis nine observational cohort studies. Effectiveness did not differ between the Nuss technique and that of the conventional Ravitch technique. The Nuss bar, however, had a higher incidence of reoperation (odds ratio [OR]: 5.68; CI95% 2.51, 12.85), pneumothorax (OR: 6.06; CI95% 1.57, 23:48), and hemothorax (OR: 5.60; CI95% 1.00, 31.33), compared with the Ravitch technique. Conclusion: Until more evidence can be obtained, the Nuss procedure will not be recommended as a treatment for Pectus excavatum in our hospital. The mini-HTA elaboration process involving impartial investigators in the hospital has led to increased patient protection in the decision-making process. The preparation of such technical reports can be adapted in other hospitals.

T-214

747 – DIAGNOSIS OF TUBERCULOSIS (TB): THE USER'S ROUTE IN THE HEALTH SYSTEM, BRAZIL

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Objective: To analyze the route of TB patient from the first service sought to the diagnosis of the disease in the health system. Methods: This descriptive study was conducted in the municipality of Ribeirao Preto, Brazil. Data collection was conducted in two stages: first, a structured questionnaire was applied to 100 TB patients in order to recover the route of this them since they felt sick until the diagnosis and second, some secondary data were collected from the state system of TB and municipal system of electronic medical records. The analysis was performed using descriptive statistics. The route was represented by a diagram (flowchart). Results: 69% of respondents sought the emergency room as the first health service, followed by 16% who sought the Primary Health Care (PHC) and 15% specialized services. Among those who sought to PHC, it was observed that 68.5% had to search three or more services to obtain the diagnosis, and 93.8% of these diagnoses were made in specialized services, showing that the first visit to the PHC was not enough for elucidation. Of those who sought emergency care 26% experienced three or more health services until TB diagnosis , which usually was performed on Specialized Services. Only 8.7% of diagnoses were made on the first visited health facility. The specialist services showed better resolution 53.3% of cases in the first visit. Conclusion: the technological support and training of staff working in different health services can influence the speed of TB diagnosis, as well as the number of times and health services sought to solve the case.

T-215

608 – MEDICAL DEVICES PRE-QUALIFICATION MULTICENTER STUDY IN PUBLIC HEALTHCARE FACILITIES: A DISPOSABLE INFUSION SETS' SAMPLE CASE

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INTRODUCTION: Purchasing medical devices of poor quality for use in healthcare services can result in adverse events to patients and waste professional and material resources. The disposable infusion sets are among the most frequently used items and are manufactured with multiple parts assembled together. Accurate control of infusion requires dispensing the exact number of drops per minute according to physician's orders and patient's needs. Amid hospitals' strategies to promote safe and effective technology purchases, there are bids technical descriptive, specification and pre-qualification. OBJECTIVE: To report a disposable infusion sets pre-qualification experience in Brazil. METHOD: Prospective multicenter field study held in five public hospitals in Brazil, in 2008, including regulatory compliance analysis and indication's specific quality and functional requirements tests. Non-compliant devices were reported to the Techno-surveillance Unit, UTVIG-NUVIG/ANVISA's central database. Reports were classified according to the ISO 19218 revised standard and relative frequencies were estimated at aggregated levels. RESULTS: In 2008, there was an average of 26% disapproval total samples tested (95% CI: 23% to 29%). The most frequent complaints reported were mechanical failures (23%, including calibration failures, 10.3%, and mechanical obstructions,8.3%); connection failures (17%) and infusion flow (14%, dominated by improper or no flow sub-categories). Labeling problems are legal complaints and were reported in 11% of the cases, consisting of lacking, incomplete or incorrect instructions, which may lead to use errors. CONCLUSION: These results indicate a non-neglectful proportion of the devices did not meet the quality and safety standards required for its primary function, emphasizing the importance of pre-qualification in the routine of healthcare services. Indeed, pre-qualification prior acquisition is a strategy enabling to evidence problems, allowing to avoid waste of resources and to prevent healthcare risks. In addition, the pre-qualification is an important tool for techno-surveillance and it is a highly cost-effective strategy for medical devices surveillance.

T-216

610 – THE IMPORTANCE OF TECHNICAL SURVEILLANCE OF GLOVES IN THE REGULATORY PROCESS IN BRAZIL

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INTRODUCTION: Gloves are medical devices the National Health Surveillance Agency (ANVISA) regulates. Although gloves are classified low and medium risk devices, they are important barrier between potential contamination sources and professionals and patients in routine healthcare services. OBJECTIVE: To present a gloves' regulation experience in Brazil. METHOD: Descriptive study of Techno-surveillance activities in Brazil. Data (years 2003 to 2009) regarding gloves' technical complaints and adverse events reports, as well as ANVISA's printed and electronic documents were used. The reports were classified according to the revised ISO 19218 standard. Excel ™ and Access ™ - Microsoft v. 2007 software were used for database analysis. RESULTS: From 2003 to 2009, ANVISA received 2,605 reports of problems with surgical gloves, 159 adverse events reports and 90% were technical complaints, averaging 1.5 failures / report, i.e., 3,826 complaints in total. Also, amid the technical complaints, 299 additional adverse events of mild or moderate severity (dry skin, allergy, swelling, itching and peeling) were screened. Five failure modes concentrated 88% of the problems reported. Most frequent complaints consisted of fragmented or degraded material, and of manufacture process failures: torn (36%); with holes (19%); stick (8.6%); missing parts (16.4%) and with foreign body (7%). Those important reports number motivated the Brazilian gloves market's evaluation program with the National Institute of Metrology (INMETRO). Upon Certified Laboratory's tests, non-conformities were identified in all tested products, varying from packaging, labeling and/or material quality problems. ANVISA has, since, determined mandatory certification regulation including all prescribed Technical Standards' gloves physical tests. CONCLUSION: This study demonstrates the stakeholders' communication importance to achieve effective medical devices regulation. The users' continuous surveillance is a fundamental requirement and remains the central challenge.

T-217

793 – MEDICAL DEVICES FAILURE MODES: ANALYSIS OF TECHNICAL COMPLAINTS INVOLVING DISPOSABLE INFUSION SETS' REPORTED TO ANVISA IN 2007 AND 2008

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Introduction: The medical devices post-market surveillance, techno-surveillance activities in Brazil are coordinated by the National Agency for Health Surveillance (ANVISA), through its Techno-surveillance Unit, UTVIG / NUVIG, partnering with States and Municipalities Health Surveillance Departments (VISAs). ANVISA adopts several strategies and partnerships, like the Sentinel Hospitals Network and recently issued «mandatory surveillance regulations for manufacturers or legal representatives and for hospitals», to enhance field surveillance and non-compliant devices reports. Reports are collected through the centralized on-line information system, NOTIVISA. Techno-surveillance reports' investigations and trend analyses orient activities and promotion of corrective or preventive measures implementation. UTVIG constituted 5 Working Groups (WG) to support these strategies. One, the Failure Modes WG (formed by VISAs professionals) works to classify, reach consensus and to internalize national & international standardization & harmonization efforts. OBJECTIVE: Exemplify Techno-surveillance investigative and Failure Modes WG reports classification analyses through the disposable infusion sets' Failure Modes WG Consensus Report. METHOD: Descriptive study of Failure Modes WG consensus about disposable infusion sets' field reports related to NOTIVISA in 2007-08. Reports' failure modes were classified according to ISO 19218 revised standard. We used the Excel ™ and Access ™ - Microsoft v. 2007 softwares. RESULTS: In 2007-08, disposable infusion sets' field reports were 37% of the NOTIVISA's article reports total number. The predominant failures were leakage (18%), improper flow (10%), parts detachment (10%) and calibration problems (9%). Failure Modes WG analyses results indicates occurrence of manufacturing process problems (such as inappropriate material, improper assembly or structural and mechanical defects) that adversely affect the products' primary function and are associated with patients' and staff safety. ANVISA is implementing corrective and preventive measures. CONCLUSION: This systematic approach makes possible the automation of the concepts reported to NOTIVISA, easy reporting and subsidizes techno-surveillance implementation of required measures to improve products' safety and effectiveness.

T-218

139 – AVOIDABLE MORTALITY IN CHILDREN UNDER FIVE YEARS: SENTINEL EVENTS OF PRIMARY CARE QUALITY IN MARINGA-PR

Maria Jose Scochi, Universidade Estadual de Maringá, Brazil; Denise Albieri Jodas, Universidade Estadual de Maringá, Brazil

Infant mortality constitutes an important health indicator, because it contains important information about certain attributes and dimensions of health status and performance of the health system. Objective: To evaluate, in primary care, the care provided to children under five who died in the city of Maringa in 2008. Materials and methods: The study population consisted of 41 deaths under five years, residing in the city of Maringa, PR, in 2008. For investigation of death in children under one year were used the records of the Committee on the Prevention of Infant and Fetal Death. In children older than one year and less than five years, the identification took place in an active search for death certificates at Municipal Secretariat of Health were used the same criteria and methods for assessing the condition of death that the Child Death Committee, including the interview family. Results: Of 41 cases investigated, 27 (65.9%) accounted neonatal deaths, 10 (24.4%) post-neonatal deaths and 4 (9.7%) higher than a year. According to the concept of avoidability Rutstein, 37 (90.2%) deaths were considered sentinel events, 24 (64.9%) neonates, 10 (27.0%) post neonatal and 3 (8.1%) above a year. In general, the causes of death in children under five years were related to perinatal diseases, congenital malformations, respiratory system diseases and neoplasms. According to the avoidability of measures.According to the avoidability of measures, it was observed that prevention activities are most often found among the possibilities of reduction of death, leaving 22 (59.5%), followed by activities for the diagnosis and treatment with 13 (35.1%) and 2 (5.4%) other causes. Conclusions: Thus, this study demonstrates the need for better planning of prenatal care and delivery assistance for practices that are more efficient and effective by avoiding an unwanted event as it is a death in childhood.

T-219

140 – EVALUATION OF PRENATAL CARE IN PRIMARY CARE IN MARINGÁ-PARANÁ

Maria Jose Scochi, Universidade Estadual de Maringá, Brazil; Janaina Daiane Bauli, Secretaria Muncipal de Saúde de Maringa, Brazil

From the existing programs, the prenatal care is worth mentioning because it is a focus on traditional in the UBS. It is believed that by identifying strengths and difficulties in their development will be possible to make inferences about other activities in the Basic Health Units (UBS). Objective This study aimed at evaluating the prenatal care in primary care in Maringá; knowing the profile of those mothers who used prenatal service in the UBS; verifying the physical resources used in the care of pregnant women; identifying the professionals working in prenatal care; observing whether the minimum procedures recommended by the Birth and Prenatal Humanization Program (PHPN) are being followed. Similar to a study carried out in 1994, the sample consisted of 115 mothers admitted to a charity hospital, accredited to the SUS for deliveries. After the interviews, which used a structured instrument on prenatal care, we visited the twenty-two UBS (88%) where the mothers reported having their prenatal care assistance. The work process, the physical structure, and the use of the Family Health Strategy (ESF) in prenatal care were observed. Comparison with similar indicators to the previous study and the adapted Kessner index were used to analyze the data, which combined the essential criteria in prenatal care to verify the adequacy of care. Results The results, showed no significant increase in the number of health facilities in the city and that there are units with inadequate physical infrastructure for the service. However, there was an increase in the number of consultations and the start of monitoring. However, assistance was considered inadequate when the other criteria needed were combined.ConsiderationsIt was found that the prenatal care and other programs of primary care can be improved. Greater involvement of professionals with prenatal care is needed, especially by members of the ESF.

T-220

141 – EVALUATION OF QUALITY SERVICE TO HYPERTENSION PATIENTS IN PRIMARY HEALTH CARE IN MARINGÁ-PARANÁ

Maria Jose Scochi, Universidade Estadual de Maringá, Brazil; Andréia Medeiros Pires Maruiti, Secretaria Muncipal de Saúde de Maringa, Brazil

High blood pressure when diagnosed early and treated adequately it is possible to prevent harm to patients. Objective: Evaluate the quality of care given to hypertension patients in primary health care. Methodology: The sample consisted of 20 hypertension patients admitted for hypertensive crisis or heart disease, in a period of one month, in two hospitals accredited to the SUS. The patients were aged 45-65 years living in Maringá, were able to verbalize and treated in basic heath units. After the hospital interview, a search for the medical records at the health facilities was carried out to verify the presence or absence of hospital records regarding the procedures considered essential to the hypertension treatment. Results: 75% were male, 70% were married, 100% were affiliated to the SUS, although 20% also had a private health care plan of low coverage. An increase of 23.7% on hospitalized hypertension patients was observed when compared to the earlier study, with an increase in admissions at the age range over 70 years and a decline in younger age groups. The hospitalization records showed that 75% of patients were admitted with a hypertensive crisis and that others had associated diagnoses. 40% reported having been referred by the Basic Health Units (UBS) and 30% was sent by the Mobile Service of the Emergency Service (SAMU), 95% knew of their illness, 80% were in treatment, 50% followed the diet prescribed and 35% said they pursued regular physical activity. An increase in tobacco and alcohol consumption was observed in relation to the previous study and a decrease in the use of medication. Conclusion: The decrease in admissions of patients in the age groups under 70 due to hypertension may indicate that primary health care is positively contributing to the lowering of hypertension indicators.

T-221

938 – THE USE OF INFORMATION TECHNOLOGY FOR DECISION MAKING REGARDING THE OFFSET QUALITY

Maria Tereza Sanches Figueiredo, Public Clinical Hospital Foundation Gaspar Vianna, Brazil; Thaís Hetierre Abreu Monteiro, Public Clinical Hospital Foundation Gaspar Vianna, Brazil; Laena Cunha da Costa, Public Clinical Hospital Foundation Gaspar Vianna, Brazil

Products for health are aimed at the prevention, diagnosis, treatment and rehabilitation, without proper evaluation in its acquisition and its use in service may generate occurrences of adverse events that leads to risk the health of patients and professionals, and consequences of waste financial Institution. The study aims to identify the medical products classified by risk are tested in the Hospital, whose purpose is the expansion strategy with the use of technology. The method used was the green cross to be descriptive and exploratory approach to circle the quantitative magnitude of the phenomenon in the Clinical Hospital Foundation Gaspar Vianna. It was used as instrument reports of adverse events and techniques Notification System in Sanitary- NOTIVISA, data collection occurred during the twelve months and the analysis was coded into the Statistical Package for the Social Sciences (SPSS). Of the 57 notifications of technical surveillance of the articles 17.6% (10) belong to Class I is considered low risk, medium risk (class II) 75.4% (43) the absence of class III, the high-risk class IV was 7.0% (04) are mostly intrusive, with some deviation in quality, since the costs are increasing and the priorities should be is based on scientific knowledge of the adverse event. It is important to articulate the use of information technology issues compared with managers within and for the evaluation and decision making, so as not to become only records of undesirable events, and yes, safety measures and impact to be professional facilitators in the purchase and handling of medical articles. Keywords: health product, risk classification and adverse event and complaint technique

T-222
941 – THE IMPACT OF HEALTH EDUCATION IN INFORMATION TECHNOLOGY

Maria Tereza Sanches Figueiredo, Public Clinical Hospital Foundation Gaspar Vianna, Brazil; Laena Cunha da Costa, Public Clinical Hospital Foundation Gaspar Vianna, Brazil; Thaís Hetierre Abreu Monteiro, Public Clinical Hospital Foundation Gaspar Vianna, Brazil

No evaluation is only in the presentation of raw data, it is important that questions of fact in a certain context, time and space in a systematic way can bring exposure and discussion of products to health; whose aim is to propose strategy of the paradigm of health education to be applied in the acquisition of medical products through information technology; considering, be structured in educational practices in the technical understanding and administrative politic. The study was applied for the deepening and accurately describe of the phenomons of a certain reality, focusing on the organization of sectors, groups and activities to be investigated with different functions and services at the Clinical Hospital Foundation Gaspar Vianna-FHCGV. The collection comes of notifications of the FHCGV's database and analysis categorized with features in common. In the year 2010, 57 notifications were recorded and observed that the before qualification of the articles include a range of information ranging from selection to discard; and acquisition of the product by bidding process come from appropriate specific description, beyond to the testing of medical articles. During the search, it observe the fact that the professional does on a routine occurrence, without resolution, which depends on technical and legal evaluation. In this perspective, the practice of health education aimed at training professionals, as well as information of knowledge to all who participate in the process, for this, innovation of integration, through technology between the areas of management, technical and juridical, becomes essential to achieve good results from the technology assessment information effectively and efficiently. Keywords: Health education, educational strategies, Information Technology.

T-223
873 – THE USE OF GUIDELINES FOR DECIDING ON THE INCORPORATION OF TECHNOLOGIES AT THE BRAZILIAN MINISTRY OF HEALTH

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The Department of Science and Technology (DECIT) attends to the demands of the Commission for the Health Technology Incorporation (CITEC) in order to carry out studies to support decision-making on the incorporation of health technologies in the Public Health System (SUS). These studies are based on the best available scientific evidence regarding effectiveness and safety. However, in some cases, especially when dealing with rare diseases, due to a lack of evidence to support decision-making, DECIT conducts a systematized search in clinical practice guidelines (CPGs) from other countries in order to evaluate its recommendations. The search for CPGs is held in databases, such as EMBASE, PUBMED, TRIPDATABASE, CLEARINGHOUSE, PUBGLE, CRD, and in web sites of HTA agencies and institutes, such as NICE, IECS and CADTH. The search keywords were related to both technologies and diseases. In 2010, DECIT elaborated six rapid response reports on guidelines in order to attend to CITEC's demands on nine technologies (the number of guidelines found are shown in parentheses): pegvisomant for acromegaly (5); danazol for refractory thrombocytopenia in systemic lupus erythematosus (2); azathioprine (3), cyclophosphamide (3), danazol (3) and vincristine (3) for idiopathic thrombocytopenic purpura; infliximab for ulcerative colitis (5); human immunoglobulin for autoimmune hemolytic anemia (0); and pyridostigmine for myasthenia gravis (1). CITEC evaluated and decided for incorporation of seven technologies. The other two technologies will be evaluated at later meetings. Although the majority of these guidelines graded the evidence and recommendations on technology's use, it was observed that their recommendations were not always based on high-quality methodological evidence. There is often a lack of sufficient evidence for decision-makers, mainly when concerning rare diseases and new drug indications and uses. Therefore, observing the experiences adopted by other countries when using these technologies and therapeutic schemes can be a plausible alternative.

T-224

565 – INTERVENTIONS TO MODIFY EATING HABITS, PHYSICAL ACTIVITY AND SLEEP IN COMBAT OF CHILDHOOD OBESITY: SYSTEMATIC REVIEW

Mariana Figueiredo, Neuro-Sono, UNIFESP, Brazil; Vanessa Ruotolo Ferreira, Neuro-Sono UNIFESP, Brazil; Fabiana Ruotolo, Neuro-Sono UNIFESP, Brazil; Katia Yuaça, Neuro-Sono UNIFESP, Brazil; Lucila Bf Prado, Neuro-Sono UNIFESP, Brazil; Luciane Bc Carvalho, Neuro-Sono UNIFESP,Brazil; Gilmar F Prado, Neuro-Sono UNIFESP, Brazil

Introduction. There is a tendency to increased prevalence in overweight and obesity in children influenced by intake of unsuitable foods, reduction of physical activity, and reduction of sleep time. Sleep is an important modulator of neuroendocrines functions and of glucose metabolism in children. The aim of this study was to make a systematic review searching the best available evidence on educational interventions emphasizing physical activity and changes of eating habits and sleep in school children. Method. Systematic Review in MEDLINE and LILACS data bases, additional reports identified in the reference lists of the articles. There was no language or type of study restrictions. We selected educative interventions for obesity prevention; physical exercises, sleep, and feed habits changing. Data extraction was carried out independently and in duplicate. Validity assessment of the included trials was carried out at the same time as data extraction. Discrepancies were discussed and a third reviewer consulted. The author of the primary study was contacted when necessary. Results. 396 articles were found, 275 excluded (not educative intervention or age inappropriate), 121 articles were included, 41 are waiting for the complete paper. Eighty completed articles were evaluated and shown interventions as: physical activity practice (increasing of physical activity and decreasing of time spend in front of TV or sedentary), behavior modification of nutrition (workshops; fruits, vegetables, lettuces, water, and healthy snacks increase consuming; decrease of sweet drinks). One of the studies proposes changes of sleep habits as preventing childhood obesity and 11% of the studies were carried out by school teachers. Conclusion. The programs diversity, lack of efficacy evaluation, and no information about the training people who perform the intervention, demonstrate the difficulty in choosing the best evidence and led us to the necessity of further controlled studies and the inclusion of sleep. Supported by CNPq (#559187/2009-2).

T-225

689 – CONTRIBUTION OF THE HTA FOR THE BRAZILIAN NATIONAL HEALTH SYSTEM IN THE CONTEXT OF MEDICINES DEMAND THROUGH THE COURT OF LAW

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Currently in Brazil, there is a growing demand for new and high cost drugs through the Court of Law. Many products are not included in the National Health System (SUS) programs. This process has become a pressure for the incorporation of medicines by the SUS and it is happing without the use of consistent results of these drugs evaluation. It consists barriers to implementation of the practice of the rational medicine use. Studies in Minas Gerais, Rio de Janeiro and São Paulo have shown that drugs without consistent efficacy and safety evidence and some ones with no register of sale by the health authority are distributed based on court orders. This phenomenon has privileged new medicines, and drugs requested profile does not appear to meet the collective needs, as it is expected of public health policies. The Health Technology Assessment (HTA) aims to systematize the information of efficacy, effectiveness, efficiency and security of medicines to assist health managers' decision making related to assistance programs coverage. Therefore, it becomes necessary to adopt strategies for the evaluation of health technologies in order to be more efficient in resources allocating and to assist in decision making regarding the inclusion of new technologies. Also, the HTA results must be used to keep up their drug programs and clinical protocols updated, adding new knowledge about drugs that are already incorporated and the new ones. This may decrease the long-term health and economic impacts in the SUS due to the practice of requesting medicines through the Court of Law.

T- 226

316 – USING HTA TO SUPPORT DECISIONS IN A SUPERREGIONAL PERSPECTIVE: EXPERIENCE OF THE LAVAL UNIVERSITY INTEGRATED HEALTH NETWORK

Martin Coulombe, UETMIS/ Centre Hospitalier Universitaire de Québec - CHUQ; Marc Rhainds, UETMIS/CHUQ

To optimize their performance, every health centres and regional health agencies must manage and implement changes and innovations to face the evolution of the healthcare system and of population's needs and expectations. To optimize their impacts, clinical and administrative decisions must be evidence-based and take into account the expertise of clinical and administrative teams at the local level. Health technology assessment (HTA) is an important tool to support evidence-based management and evidence-based clinical practice. The province of Quebec, Canada, is divided in four integrated health university network regrouped around the four Medical Faculties of the province. The Laval University integrated health network regroups six regions (population: 1.7 million). The network was implemented to coordinate specialized care, teaching, research and HTA and share the expertise of university health centers with smaller hospitals and the regional health agencies. Panels of representatives of the regions and of the university centers were recruited to act as the coordination bodies at the superregional level for different healthcare priorities. The HTA Panel mandates are to prioritize HTA questions of common interest, enhance knowledge transfer and use of HTA reports in decision-making at the local and regional levels, and promote the implementation of a culture of evidence-based management and clinical practice in the university network. HTA specialized resources being rare and state of the art HTA processes requiring teams of reviewers, they are mainly concentrated in the bigger university health centers. The HTA unit of the Quebec University Health Center leads the HTA projects within the network and offers coordination, mentoring, and knowledge transfer. In this presentation, the model will be described focusing on the first two integrated projects (negative pressure wound therapy and alternatives to seclusion and restraint). Its benefits and the implementation barriers and facilitators will be discussed.

T-227

414 – EVALUATING PHARMACEUTICALS FOR REIMBURSEMENT DECISIONS: A SYSTEMATIC REVIEW OF EVALUATION FACTORS CONSIDERED IN OECD COUNTRIES

Matthew Bending, University of York, United Kingdom; John Hutton, University of York, United Kingdom; Clare Mcgrath, Pfizer, United Kingdom; Julie Glanville, University of York, United Kingdom

Objective: There are many factors in the evaluation of pharmaceuticals for reimbursement decisions. This study aims to identify the elements of formal evaluation of pharmaceuticals included in empirical studies assessing the influence of factors on reimbursement decisions in OECD countries. Methods: A search of MEDLINE, EMBASE, EconLit, Health Management Information Consortium, NHS EED and REPEC Economic working papers until July 2010 was conducted to identify studies considering factors in the evaluation of pharmaceuticals. A hand search of the International Journal of Technology Assessment in Health Care was undertaken (1990-2010). The following study designs were eligible: experimental, quasi-experimental, retrospective, prospective, case series and surveys or questionnaires. Eligible studies were those that considered the influence of factors (clinical considerations, economic considerations and other considerations) on reimbursement decisions. The factors identified were grouped by type and reimbursement agency. Findings: The search identified 35 studies that met the inclusion criteria. Forty percent of studies explored factors considered for decisions in England. Other studies focused on Australia, Belgium, Canada, Finland, Netherlands, Sweden and the USA. Clinical study factors included clinical effect size, uncertainty, quantity and quality of evidence and disease prevalence. Economic considerations identified were cost-effectiveness estimate, uncertainty, type of economic evaluation, quality of life measurement, budget impact, price and quality of the economic model. The other considerations included severity of disease, decision history, stakeholder involvement and lobbying, decision process, lack of alternative therapies and end of life. The factors identified varied across countries and predominantly focused on the characteristics of the technology assessment rather than factors relating to process of reimbursement decision-making. Conclusions: The majority of identified empirical studies consider clinical, economic and other considerations for England, Australia and Canada. There is very limited evidence of the components considered in decision-making for other OECD countries.

T-228

416 – WHAT INFLUENCES PHARMACEUTICAL REIMBURSEMENT DECISIONS? A SYSTEMATIC REVIEW OF FACTORS REPORTED TO INFLUENCE DECISIONS IN OECD COUNTRIES

Matthew Bending, University of York, United Kingdom; John Hutton, University of York, United Kingdom; Clare Mcgrath, Pfizer, United Kingdom; Julie Glanville, University of York, United Kingdom

Objective: Many factors influence pharmaceutical reimbursement decisions. This study aims to determine the influence of factors considered in the evaluation of pharmaceuticals on the reimbursement decisions of government funded bodies in OECD countries. Methods: A search of MEDLINE, EMBASE, EconLit, Health Management Information Consortium, NHS EED and REPEC Economic working papers until July 2010 was conducted. A hand search of the International Journal of Technology Assessment in Health Care was undertaken (1990-2010). The following study designs were eligible: experimental, quasi-experimental, retrospective, prospective, case series and surveys or questionnaires design. The influential factors were reviewed across and within OECD countries. Findings: The search identified 12 quantitative studies and 23 qualitative studies. The quantitative studies considered the correlation between factors and decisions either through regression analysis of retrospective decisions or discrete choice experiments. Cost-effectiveness was found to be consistently influential for reimbursement decision-making in Australia, England, Canada and the Netherlands. There was variation in the definition of clinical considerations and other factors in studies conducted in countries. This limited comparability within and across countries. Studies reported mixed evidence of the influence of the quality, quantity and type of clinical evidence, robustness of economic models, sensitivity analysis, budget impact, lack of alternative therapy and severity of disease on reimbursement decisions. Qualitative studies reported narrative descriptions, case studies and interviews with decision-makers. These studies supported the influence of cost-effectiveness found in the quantitative evidence. They additionally described the influence of the composition of the decision panel, committee deliberations, stakeholder involvement and lobbying on decisions. Conclusions: There is limited evidence on the influence of evaluation factors on reimbursement decisions in a few OECD countries with established reimbursement processes. Wider investigation of the factors influential in other countries would allow comparison of the similarities and differences across OECD countries.

T-229

418 – WIDER CONSULTATION IN HEALTH TECHNOLOGY ASSESSMENT (HTA) DECISIONS: BETTER UNDERSTANDING OR A LOBBYING OPPORTUNITY?

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Objective: HTA agencies worldwide have varying processes that allow consultation with stakeholders during decision-making. The objective of this study is to determine the impact of the National Institute for Health and Clinical Excellence (NICE) Single Technology Appraisal (STA) consultation stage on reimbursement decisions of pharmaceuticals. Methods: Documentation was accessed from the NICE website for all STA's conducted between 2006 and August 2010. Details of the first Appraisal Consultation Document (ACD) draft decision, subsequent ACDs, Final Appraisal Determination (FAD) and final guidance decision were extracted. The decisions were categorised with respect to the licensed indication (recommended, restricted, not recommended, only in research). Details of the further analysis and evidence submitted by the manufacturer as a result of consultation were extracted. These data were analysed for the different stages of decision-making. Findings: The website search identified 55 NICE appraisals of which over fifty percent were for cancer medicines. Final decisions (draft first provisional decision) included 36% (13%) recommended, 36% (20%) restricted decision, 16% (56%) not recommended decision and 11% (11%) terminated decision. One appraisal contained only in research recommendations in addition for use in routine practice. An ACD was produced in 42 appraisals, followed by the manufacturer providing further economic analysis in 26 appraisals, a patient access scheme in 5 appraisals and new clinical evidence in 2 appraisals. Types of further economic analysis provided were analysed for other treatments/strategies; different modelling assumptions; alternative survival distributions; further sensitivity analysis; and other. Conclusions: NICE's iterative consultation process allows consideration of evidence and wide consultation with stakeholders. This results in evidence that is more appropriate for the evaluation of pharmaceutical's and partly explains the higher recommendation rate when compared with similar international reimbursement agencies. There is a need for further research to understand the impact of the different processes employed across countries' decision-making.

T-230

493 – THE EXPERIENCE OF INCREASING THE UTILIZATION OF ADULT HEALTH EXAMINATION IN THE REMOTE AREA

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OBJECT:Erlin branch of Changhua Christian Hospital is located in the central Taiwan, near the Taiwan Strait. The number of residents age over 65 years are about 25,640. However, there are just 1,849 people came to this hospital to get health examination service in 2009. It is only 7.2% of the number of eligible residents. To double the utilization of adult health examination become one of our goals in 2010. METHODS:We use the following methods to remind people to get the health examination services. (1) To remind patient the day before appointment by telephone, (2)To send postcards, (3)Monthly community newsletter, (4)Poster, (5)Community health education activities, (6) Electronic public broadcasting system, (7) when patient is in clinic, physicians can use the outpatient prescription system to check and printout health examination notice. FINDINGS:At first people came to get he health examination services is so much that we need additional staff and change service line. There are 3,837 people came to our hospital to get health examination service in 2010. This service volume is more than twice the volume of service in 2009. After all,we reach the goal. CONCLUSIONS:The main reasons that we can success be summarized as follows.(1) The use of Information systems to assist in identifying people eligible. (2)Take the initiative to invite people eligible. (3) From physician to administrative staff hospital-wide mobilization. Even if the eligible residents got the message, they are so old that they can not come to hospital to get health examination. The transport between their home and hospital will be the next barrier to break through.

T-231

685 – FROM EFFICACY TO EQUITY: REVIEW OF DECISION CRITERIA USED IN RESOURCE ALLOCATION AND HEALTHCARE DECISIONMAKING

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Objectives: Fair and efficient allocation of resources, essential to healthcare system sustainability, requires consideration of many factors and diverse streams of information. Objectives of this study are to identify criteria used in healthcare decisionmaking and priority setting around the world. Method: An extensive literature search was performed in Medline and EMBASE to identify articles reporting decision criteria. Bibliographies of relevant articles were also searched. Studies conducted with healthcare decisionmakers (e.g., empirical studies, field-testing of decisionmaking tools, focus groups, questionnaires, interviews), conceptual and review articles as well as articles describing decisionmaking tools were included. Criteria reported were extracted and organized using a classification system derived from the EVIDEM framework. Results: A total of 2903 records were identified through database searching and 243 additional records were identified through bibliographic hand searching; of these 2790 were excluded. 356 articles were assessed for eligibility and 40 articles were included in the study. Large variations in terminology used to define criteria were observed and 338 different terms were identified. These were assigned to 58 unique criteria which were classified in 9 different categories including: 1) health outcomes and benefits of intervention, 2) types of health benefit, 3) impact of disease targeted by intervention, 4) therapeutic context of intervention, 5) economic impact of intervention, 6) quality/uncertainty of evidence, 7) implementation complexity of intervention, 8) priority, fairness and ethics, 9) overall context. The most frequently mentioned criteria were: equity/fairness (33 times), efficacy/effectiveness (28), healthcare stakeholder interests and pressures (28), cost-effectiveness (23), strength of evidence (20), safety (19), mission and mandate of health system (17), need (16), organizational requirements and capacity (17) and patient reported outcomes (16). Conclusion: A wide range of criteria are used by decisionmakers highlighting the importance of comprehensive HTA approaches to facilitate consideration of these criteria for optimized resource allocation.

T-232

548 – THE INFLUENCE OF LAWSUITS IN PHARMACEUTICAL ASSISTANCE AND THE USE OF NEW HEALTH TECHNOLOGIES

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Objective: Study the phenomenon of medicines demand via the Court of Law to the State of Minas Gerais Health Office (SES/MG), from the perspective of "new" medicines and the relationship between lawyers and prescribers. Methodology: It has been built a database with 6,184 lawsuits against the SES/MG related to 10,096 drug requests, between 1999 and 2009. It was analyzed data from lawsuits, such as legal patient representative, prescribers and data regarding the profile of "new" medicines. The drugs selected were the ones with the highest frequency in the lawsuits under the responsibility of few lawyers and prescribers. Results: The frequency of lawsuits (n=1680) related to the more representative 'new' drugs and percentage of the top three lawyers are: adalimumab (n=365), 44.4%, 19.5%, 18.9%; etanercept, (n=292), 30.5%, 25.7%, 17.1%; infliximab, (n=143); 32.9%, 14.7%, 11.9%; aripiprazole, (n=117); 41.0%, 29.9%, 19.7%; teriparatide (n = 86) 22.1%, 17.4%, 16.3%, respectively. The percentage of doctors associated with each drug is: adalimumab, 15.1%, 4.1%, 2.7%; etanercept, 9.2%, 3.8%, 2.7%; infliximab, 4.9%, 3,5%, 2.8%; aripiprazole, 14.5%, 6.8%, 5.1%; teriparatide, 12.8%, 4.7%, 3.5%, respectively. Conclusion: These results indicate that the lawsuits of some drugs have the participation of few lawyers. It was found no such relationship about the doctors. The concentration of lawyers in demand for "new" drugs through the lawsuits may point towards shady relations with the pharmaceutical industry, suggesting that there is a prevalence of economic interests instead of the application of clinical protocols.

T-233

306 – CRITERIA FOR INCORPORATION OF NEW MEDICINES TO TREAT HEMATOLOGICAL CANCER (HC) IN THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM (SUS): IS THERE AN INFORMAL COST-EFFECTIVENESS (CE) THRESHOLD?

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Introduction: International agencies, such as NICE or CADTH, have clear criteria that guide new drug incorporations. In SUS the process to apply for the incorporation of new medicines is well documented. However, there is no clear statement about the criteria that will be used to decide for or against it. Recently, some new high-cost drugs (HCD) were incorporated, taking us to the point to study if a CE pattern can be identified. Objectives: To identify the incremental cost effectiveness ratio (ICER) of the drugs recently incorporated by SUS to treat HC and to identify how and if these criteria can be applied to other drugs not yet incorporated. Methods: Through research of different sources and databases, we identified HCD that were approved and incorporated in the last 10 years for the treatment of HC by SUS. For all HCD, Brazilian CE studies were used to identify the ICER of each drug, and this result was compared against the incorporation decision. Results: Three HC drugs were incorporated by SUS: Dasatinib for Chronic Myelogenous Leukemia (CML) ICER – US$ 68,333 Blastic Phase; US$ 50,556 Accelerated Phase; US$ 44,444 Chronic Phase. Imatinib for CML 1stline – ICER US$ 5,752. Rituximab for BLarge Cell Lymphoma - ICER US$ 27,251. Three other drugs have regulatory approval but have yet to be incorporated: Bortezomib for Multiple Myeloma(MM)- ICER US$ 14,816 1stline; 29,087 2ndline; 31,824 3rdline. Rituximab for Chronic Lymphocitic Leukemia (CLL) - ICER US$ 24,119; Rituxumab for Maintainance of Follicular Lymphoma (FL) - ICER US$ 17,909; Alemtuzumab for CLL – Potentially cost saving. Conclusion: In Brazil, there is no clear cost-effectiveness threshold for the adoption of new HC drugs in SUS. Bortezomib for MM, Rituximab for FL and CLL and Alemtuzumab present ICERs below other adopted drugs, and would thus be considered cost-effective, but have not been incorporated yet.

T-234

671 – ELABORATION PROCESS OFF AN EXPLICIT PACKAGE IN HEALTH BENEFITS, IN URUGUAY (COMPREHENSIVE PLAN FOR HEALTH CARE - PIAS)

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IAbstract Introduction: In the context of the Health System Reform in Uruguay, was raised as one of the tools for change in the care model, the development of an explicit package of benefits, mandatory coverage, entitled “Comprehensive Plan for Health Care – PIAS”. The entry into force of PIAS, by Executive Order in October 2008, said universal and equitable access to cost-effective services that respond to demographic and epidemiological profile of the population. Objectives: To describe the process of preparing the package of benefits in health in Uruguay (specifically diagnostic studies and therapeutic procedures) Methods: It was used a methodology that combines several sources, from a pragmatic criteria based on consensus: a history of previous working groups, analysis of available evidence, current legislation, and the opinion of experts through a modified Delphi-like consensus method (experts in the health system in macro and middle management positions.) The work was carried out in several consecutive stages: a) Preparation of Base List of PIAS, b) Selection of practices to be considered in the Delphi study, c) Delphi and analysis of the results, d) Definition of final list PIAS, e) Definition of mechanisms of additions and withdrawals of technology or changes in their indications. The variables analyzed in the Delphi were: level evidence of effectiveness, cost effectiveness, budgetary impact, need / benefit of standardization, availability of technology in Uruguay, socio-political feasibility, potential cover-equity. Practices without agreement or inadequate assessments were subjected to consensus by the interagency working group (Ministry of Public Health, National Resource Fund, Social Insurance Bank from Uruguay and Health Institute on Clinical Effectiveness from Argentina). Keywords: Health reform, Health benefits, Delphi method.

T-235

164 – PROFILE OF LAWSUITS DEMANDING MEDICINES AGAINST THE STATE HEALTH SECRETARIAT OF ESPÍRITO SANTO, BRAZIL: AN EXPLORATORY STUDY

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This work focuses on lawsuits demanding medicines from the state of Espírito Santo-Brazil. Individual lawsuits may be an important means of obtaining medicines when there is no access through normal administrative channels. Nonetheless, the increase in numbers of lawsuits has turned this situation into a problem. The state is obliged to supply expensive medicines devoid of adequate evidence of efficacy or safety, even when a therapeutic substitute is available. Our objective is to profile lawsuits against the State Health Secretariat, to investigate demanded medicines in regard to their safety and efficacy, according to published scientific evidence and to thus help contribute to strategies that may approach and confront the problem. An exploratory sectional study, characterized by descriptive and analytical components, was formulated, using the State Pharmaceutical Services Management data bank. The investigation covered December/2008 to May/2009. Information on 203 lawsuits was collected, which demanded 283 medicines, projecting yearly expenditures of $1,477,573.34. The Public Defender´s Office was council in 79% of lawsuits. The private health sector originated 64.2% of prescriptions and 68.6% of medicines were absent from the State Essential Medicines List (EML). There were therapeutic alternatives in the EML for 76.6% of these medicines. Medicines for diabetes were the most frequent (17.3%); 50.2% of the expenditure was related to anticancer drugs (8.1% of the demands). A specific city concentrated lawsuits while a small group of physicians prescribed many demanded medicines. The greater part of medicines (65.0%) was approved by the FDA for the indications present in the suits. Some rulings are made and demand of medicines granted without proof of safety or of efficacy. This causes undue risk to users, with unlikely benefit, as well as high expenditures with a small number of plaintiffs, as opposed to a possible collective benefit and to the upholding of the right to health.

T-236

893 – EVIDENCE-BASED AUDITING OF ONCOLOGY TREATMENTS IN A PRIVATE HEALTHCARE SYSTEM: A BRAZILIAN EXPERIENCE

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Background: The quest for sustainability is critical. Healthcare providers (HcP) must find effective strategies to avoid excessive costs without compromising quality of treatment. Chemotherapy has major role in Brazilian healthcare system expenses. Evidence-based auditing (EBA) helps HcP to assure their clients receive treatments with strong scientific support, avoiding experimental treatments and minimizing the effect of conflicts of interest in the prescription. Objective: To identify, using EBA, if there are significant differences between approved and denied chemotherapy claims (general profile and drug costs) Methods: All chemotherapy claims from a group of private HcP were submitted to EBA from January 2009 to November 2010. Total cost with drugs were calculated based on SIMPRO (Brazilian official list). Coverage approval was suggested if the claims had strong scientific evidence of benefit for the patient and fulfilled inclusion criteria of mandatory coverage according to HcP regulation. We adopt a random sample of approved claims extracted by a table of random numbers. Claims were classified according to ICD-10 and separate analyses were performed using 3 most frequent tumors. Results: 9,042 chemotherapy claims were analyzed, 1,202 received suggestion for coverage denial (15,33%). Average cost of approved claims was R$4,534.20 and for denied claims, R$7,947.01 ($p<0.05$). Reasons for denial were: experimental treatment (62%), off-label use of drug (19%), disease progression with the same treatment (9%), oral medication (9%) and others (1%). The most frequent ICD-10 were: breast (25%), lung (9%) and colorectal (8%) cancers. Average drug costs for breast cancer were significantly different for approved and denied claims (R$3,263.08 vs. R$7,371.71; $p<0.05$). For lung and colorectal cancers there were no significant differences. Conclusions: EBA was able to identify 15% of claims that lacked strong evidence of benefit and/or mandatory coverage, avoiding unnecessary costs for HcP. Denied claims were significantly more expensive specially for breast cancers

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T-237

440 – MANAGEMENT OF PATIENTS WITH HIGH RISK (GPAR)

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1. Key Words: Health Management; Monitoring; Risk 2. Objective: Prospection, Classification, Allocation and Monitoring of High Risk Patients. 3. Methods: GPAR has nine Flows: Aging (above of 60 years, with health problems); Cardiovascular (cardiopathies or risks for cardiovascular illnesses); Pregnancy (prevention of illnesses and prematurity with pregnant); Mammography (risk to develop breast cancer); Diabetes (risk or diabetes already installed); Red Flag (high cost and high complexity user); VIP (user with specific and personalized necessities of attendance); Osteomuscular (risk or Osteomuscular illnesses); and Effector (to follow distant patients). It works with automatic or manual prospection, in the data base, after manager parameterization, or for health professionals' interview, signaling escapes of rules. 4. Findings: With 260.000 identified risks' users, and more than 160,000 monitored users, was possible the creation of the Program of Osteomuscular Prevention, to prevent surgeries of column through other less invasive treatments with users' satisfaction, the reduction of the hospitalization index and prevents the complex locomotion for the examinations and procedures execution, for some kind of users. 5. Conclusion: With GPAR, the health professionals know if the users did the indicated exams, in the correct amount and regularity, if they had been at the consultation or had visited other doctors. If it will have escapes in these rules, the professional will be setting, by alert (SMS, email), to verify occurrences and to assist him, making the most efficiently and viability health system. 6. References: Protocols of the Federal and Regional of Medicine Council, Universities, Societies and Associations of Medicine, Framingham, American Diabetes Association, National Committee of Quality Assurance

T-238

452 – NATIONAL CENTRAL OF TECHNICAL EVALUATION IN ONCOLOGY (CENATO)

Claudio Tafla, Amil, Brazil; Paulo Cesar Souza, Amil, Brazil; Antonio Felipe Sanjuliani, Amil, Brazil; Andre Luis, Amil, Brazil; Carlos Alexandre Sydow, Amil, Brazil; Clovis Marcos Andrade, Amil, Brazil; Lucianno Henrique Pereira, Amil, Brazil; Antonio Jorge Kropf, Amil, Brazil

1. Key Words: Health Management; Monitoring; Risk 2. Objective: Prospection, Classification, Allocation and Monitoring of Oncology Patients. 3. Methods: CENATO centralize the oncologists' prescription and uniformize the protocols and guidelines with them. All of prescriptions came for the Health Care Company by web, with formatted screens in the prescription's site. It works, too, with automatic or manual prospection, in the data base, searching users who may be with cancer diseases. Patients will be follow by the system and the oncologist and health company will be alert for the parameterization, signaling escapes of rules. 4. Findings: This Flow work with case management in Oncology and every high cost treatment in health care. We found 160.000 identified risks' users, who represent 2 - 6% of health care costs. This Flow controls the best treatment for the specific patient, and signaling abuse, fraud and waste in this case. We do the accompaniment of the outcomes in this population, since the initial diagnosis. Moreover we know some index, like: global survival, survival analysis without progression, survival without disease return, mobility, mortality, etc. 5. Conclusion: With CENATO, the health professionals know if the users did the indicated exams, in the correct amount and regularity, if they had been at the consultation or had visited other doctors. They could know which drugs, number of cycles, hospitalization and the explanation for this, by the oncologist. If it will have escapes in these rules, the professional will be setting, by alert (SMS, email), to verify occurrences and to assist him, making the most efficiently and viability health system. 6. References: Protocols of the Federal and Regional of Medicine Council, Universities, Societies and Associations of Medicine, WHO, American Society of Clinical Oncology, National Committee of Quality Assurance.

T-239

871 – THE USE OF HTA IN THE PROCESS OF DEVELOPING CLINICAL PRACTICE GUIDELINES IN THE BRAZILIAN MINISTRY OF HEALTH

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The Clinical Practice Guidelines (CPG) of the Brazilian Ministry of Health (MoH) aim to ensure the quality management of diseases in the Brazilian Public Health System (SUS), providing recommendations to health care managers and professionals on diagnosis, treatment, control and monitoring of diseases and verification of results. The HTA area of Department of Science and Technology (DECIT) of MoH is part of a working group, consisting of 21 participants, established to critically appraise these CPGs, before its publication, ensuring the development of guidelines based on best available scientific evidence. To develop new CPGs and review the old ones, a multidisciplinary developer team (composed of health care professionals, experts in each disease, and researchers from educational institutions) was defined by this working group. This team was responsible for developing and reviewing the CPGs according to a pre-established methodology, based on HTA principles: search, review and appraise the scientific literature and formulate recommendations based on the best available evidence. The patient's values and preferences aren't considered at the moment of CPGs' elaboration, but their suggestions are collected and evaluated by the developer team after a public consultation of finished CPGs, before its publication. In 2009 and 2010, the HTA area of DECIT attended 45 meetings and produced 32 HTA studies about new technologies to support the formulation of CPGs recommendations. To date, 49 CPGs for treatment of various diseases have been published, including alzheimer's disease, parkinson's disease , crohn's disease, endometriosis, myasthenia gravis, epilepsy, asthma, hyperprolactinemia and celiac's disease. As all the interventions recommended by the CPGs must be reimbursed by SUS, HTA is the only effective strategy known to maximize health benefits, optimizing the use of available resources and ensuring people's equal access to effective and safe technologies.

T-240

19 – ORGANIZATION OF PHARMACEUTICAL SERVICES IN THE STATE OF RIO DE JANEIRO: ACTION PLAN FOR SELETION ESSENTIAL MEDICINES

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The List of Essential Medicines is a tool for guiding the clinical and administrative proceedings on medicines. Its adoption promotes access and contributes to rational use, to the extent that only essential medicines with verified efficacy, safety and lower cost of treatment/day are included. The study aimed to build a drafting process for the List of Essential Medicines of the State of Rio de Janeiro - Brazil. These medicines should be available in the State of Rio de Janeiro and include those for all levels of health care. The first stage was a historical review of the actions related to medicines selection in the State of Rio de Janeiro. Legal documents and meeting minutes were consulted. Other methods of data collection included participant observation and meetings with the responsible departments. Simultaneously, the review process of the Brazilian List of Essential Medicines was analyzed. A plan of action for preparation of the final product, the list of medicines, was designed. Under the scope of health services evaluation, the plan was organized in three parts. It began by structuring necessary planning activities for the review process, followed by the actual evidence-based review of medicines, seen as the core of the selection process. Finally, the results were worked upon, represented by the actions of promoting and monitoring adherence to the list. Intended objectives, goals and actions for each step were drafted, totaling objectives, eight goals and 16 sequential and coordinated actions. Every action was detailed in regard to its contribution to the objective, to its implementation methodology and required resources, the estimated period for implementation and indicators to measure whether the objectives were achieved. It is estimated that the action plan can support regular reviews of the list, as well as the selection processes in municipalities and state health units.

T-241

728 – AVAILABILITY OF SELECTED MEDICAL TECHNOLOGIES IN URUGUAY IN 2004 AND 2007

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Introduction: In the context of the implementation of National Integrated Health System, assessment of high cost health technology was prioritized. In 2007, a specific regulation promoted that Health Care Services requested authorization to install new equipment .This study describes the baseline situation for future comparison. Objective: To compare the distribution, availability, operating condition and uses of some selected health technologies in 2004 and 2007. Methods: Descriptive study. A customized questionnaire was sent by mail to all nationwide health care services in 2004 and 2007 in order to collect data about technology availability and use. Nine types of medical equipment were studied: linear accelerators (ALE), angiography (ANG), tomography (TAC), bone densitometry (DO), magnetic resonance imaging (RM), lithotripsy (LE), , gammacamera (GAM), cobalt bomb (BCO), extracorporeal circulation (BCE). Results: A total of 154 units in 2004 and 167 in 2007 were registered; 69% in the capital city in 2004 versus 66% in 2007. Only 20% of the registered medical equipments were installed in public institutions in 2004 and 25% in 2007, even though half of the population is beneficiary of this sector. The average equipment availability nationwide was 47.5 equipments by million inhabitants in 2004 vs 51.5 in 2007 , 80.7 vrs 83.7 in the capital city and 24.5 vrs 28.2 in the rest of the country. The acquisition of equipments in this period was based in non second-hand ones. An increase in TAC, LE, ALE, RM and a decrease in BCE, BCO, DO was registered. Conclusions: No great changes in the total numbers of selected technologies. Important increase in TAC, RM, LE and ALE installation was detected. Obsolescence of the equipments should be considered in future analysis.

T-242

644 – APPROACH ECO-BIO-SOCIAL CONTEXT OF DENGUE: WHAT HEALTH OFFICERS ARE SAYING?

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Dengue is the higher incidence of arbovirus in the world, being endemic in all continents except Europe. In Brazil all 27 states have cases of the disease and is considered a serious public health problem. The Northeast is the one that presents the greatest number of cases reported by multiplicity of factors that favor the proliferation of mosquito. In the city of Fortaleza, the initiatives to implement the program are trying to involve the community, intersectoral covering the issue of preventing and controlling dengue generating conflicts between population and professionals. The aim of the study, which is a research Masters in Public Health, will know the perspective of health workers within the context of dengue from the ecology and bio-social during the years 2012 to 2013, as well as understanding, analyze and explore the vision of health workers on the scene of dengue in the city of Fortaleza. This is the first phase of a multicenter study conducted in partnership with six Latin American countries, with support from the Foundation of the United Nations Children, International Center for Research and Development, Program Development of the United Nations, World Bank, World Health and Special Program for Research and Training in Tropical Diseases (TDR). The research will be characterized as a qualitative and ethnographic study, to have as a research field based clusters drawn in endemic areas in the city of Fortaleza. The instruments for data collection are: in-depth open interviews, participant observation, field diary, in addition to record visual, photographic and audio recorder. It is hoped that the results may contribute to the quality of care and training of health workers, but also lead to the awareness of population as the missing link between the people and creates barriers to staff jobs prevention and control of dengue.

T-243

557 – LITIGATION AND HEALTH TECHNOLOGY ASSESMENT: THE EXAMPLE OF LARONIDASE FOR THE TREATMENT OF MPSI

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Mucopolysaccharidosis type I (MPSI) is a rare lysosomal disease whose treatment involves the use of laronidase, a high-cost orphan drug, approved by international regulatory agencies (FDA and EMA) since 2003, and ANVISA, Brazil, since 2005. Once it is not included in any special program of the Ministry of Health (MH), access to this medication is predominantly guaranteed through lawsuits. AIMS:To characterize requests of laronidase in the two states of Brazil, as well as related lawsuits and judicial decisions.METHODS:Observational, cross-sectional, and retrospective study, approved by competent ethical committees. The data were collected and analyzed using a specific tool.RESULTS: 16 lawsuits, proposed between May 2004 and Sept 2007, were analyzed: 6 from federal government and 10 from Brazilian states (7 from RS and 3 from RJ). Except for one, all lawsuits had only one plaintiff in litigation (17/16) and were instituted either by private counselors (10/16) or by the Public Ministry (06/16). Profile of the plaintiffs: under 18 (15/17); former participant of a clinical trial (08/17).The majority of prescriptions were provided by physicians of the public health services (13/16). In all cases there was a preliminary injunction granting a mandate (16/16). Main arguments for granting it: the right to health (12/13) and medical reports (12/16).Answers of the defendants(12/16): prevision of impact on the public budget (08/12);ethics applied to scarce resources allocation(08/12) and participation in Research Protocols (06/12). Medical expertise counseling (03/16) ratified the need of the medication. CONCLUSIONS: The Brazilian Constitution reinforces the right to treatment with high-cost medications. Although this represents a strong effort for developing countries, the creation of long-term mechanisms of sustainability for the treatment of orphan diseases, such as MPS I, ought to be encouraged.Ethic aspects of research in human beings need to be discussed. Special treatment for orphan conditions in health technology assessment remains an open question.Support: MCT/CNPq/MS-SCTIE-DECIT 033/2007.

T-244

865 – PERFORMANCE OF FIRST HEALTH CARE IN THE DIAGNOSIS OF TUBERCULOSIS IN A BORDER TOWN OF TRIPLE – BRAZIL

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Objective: Analyze the performance of the first health service sought by the patient in Foz do Iguacu, Brazil for the diagnosis of tuberculosis. Methods: This is a descriptive epidemiological study. We interviewed patients in treatment of tuberculosis in the months from July to November 2009 using a questionnaire based on “The Primary Care Assessment Tool (PCAT) adapted to assess the diagnosis of tuberculosis in Brazil (VILLA, RUFFINO-NETTO, 2009). We applied the technique of descriptive statistics (frequency analysis), measures of location (median) and the measure of reason (odds) to explore the association between delay in diagnosis of tuberculosis and the independent variables. The study groups were, the Tuberculosis Control Program, Primary Health Care, Emergency Assistance, Clinic/Polyclinic, a Private Practice and Hospital. Results: The median delay in the health service was 14 days. Among the services, units of Primary Health Care were the most delayed in diagnosis (45.7%). It is noteworthy that 59.1% of professionals did not suspect tuberculosis at the first consultation. The request for smear only occurred in 50.5% triggering diagnosis in less time. 33.3% of patients were over 3 times to health services for diagnosis, presented to more delayed diagnosis. The failure to obtain the first appointment within 24 hours contributed to the health service within the case diagnosed in more than 14 days (median). When the health worker referred the patient to perform diagnostic tests for other health services the time delay was reduced by 17%. Only 30.1% achieved diagnosis in the 1st health services sought. Conclusion: The study demonstrated the need for implementation in the diagnostic capacity of health services to obtain timely diagnosis of TB. If the diagnostic system of tuberculosis run seamlessly, ensuring the performance of sputum smear microscopy and chest radiography results readily available this goal would be achieved.

T-245

724 – BRAZIL’S MEDICAL DEVICE PRICE DATABASE: AN INITIATIVE TO REDUCE ASYMMETRY OF INFORMATION AND SUPPORT DECISION MAKING

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The Brazilian Health Surveillance Agency (ANVISA) has been using Health Technology Assessment (HTA) to support pricing decisions for new drugs since 2004. The Agency approved on October 2006 a Resolution (RDC 185/2006) with the expectation of using HTA in the area of Medical Devices, and with the objective of reducing information asymmetry in this market. This Government regulation stipulates that suppliers of medical devices should send economic information of some medical devices, from the following categories: cardiology, ophthalmology, orthopedics, in vitro diagnostics, hemotherapy, electronic hearing devices and renal replacement therapy. The lack of price transparency of medical devices is an important barrier to implement efficient economic and health policies. One of the tasks of the Office of Economic Regulation (NUREM/ANVISA) is to monitor the market of medical devices in order to detect possible distortions which may difficult the implementation of national health programs. Therefore, since the end of 2006, Nurem has been evaluating information received through the RDC 185/2006, and has recently published a list of prices of some cardiologic and orthopedic devices. As a result of this, an information system was developed to increase the price transparency on medical devices market. It contains data from different sources of information: health publications; health regulation information; RDC 185/2006; prices paid by Health Private Sector, directly informed by this sector or surveyed by a medical auditing company. The lack of information about the costs of medical devices and about comparative effectiveness doesn’t allow health care professionals and payers to select the most cost-effective products. The information system aims to support decisions of different stakeholders about medical devices, increasing transparency in this market and improving efficient acquisition of the Brazilian Universal Healthcare System (SUS).

T-246

906 – THE POWER OF SOCIAL RELATIONS IN THE INCORPORATION OF PEGYLATED INTERFERON IN BRAZIL

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Introduction: For over thirty years, medical sociology studies the phenomena of new technologies incorporation in the health care sector. In Brazil, this subject became important in recent years for health system, mainly due to ambivalence of the Sistema Único de Saúde (SUS), at the same time the system ought to provide integral access to the available technology. On the other hand, has not guaranteed the source of resources to finance such access. Objective: On the basis of the mapping the network of relationships between the actors, we critically analyzed the process that took the decision of incorporation of Pegylated interferon the medicine list of the SUS. Methods: Concepts of social networks under the perspective of analytical structure of the relations between the involved actors in the process of incorporation of Pegylated interferon in Brazil had been used, mapping the connections between academic, professional practice, governmental management and industry dimension. The data had been collected by means of semi-structuralized interviews and of public sources of data, such as platform lattes and communications in events. Results: The entailing of the interests became clear between analyzed environments, as well as the positioning of the involved ones in the consensus regarding the interest. The effect of the weak ties was also noticed as a help in the process of transmission and diffusion of the common interest and as the institutional structure of the educational system and of the SUS served of support to reach the objective to incorporate the medicine to the list of obligator coverings. Conclusion: We conclude that the recognition of the social networks and its use as a analytical tool allows the society better understand the phenomenon of the incorporation of new technologies in health.

T-247

637 – INTEGRATING HTA INITIATIVES FOR INNOVATIVE MEDICINES IN BRAZILIAN UNIVERSITY HOSPITALS

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University hospitals (UHs) play a key role in implementation and dissemination of innovations related to healthcare, such as medicines. Use of these technologies may be influenced by institutional characteristics. Our work discusses the importance of HTA initiatives and their possibilities of working together for medicines selection in UHs in Brazil. Medicines selection involves the establishment of Drug and Therapeutics Committees (DTCs) which base their work process on evidences of efficacy, safety and on economic evaluation. These, in turn, must be done in the perspective of each health system or setting. Studies on DTCs carried out in developed countries stress difficulties rrelated to lack of technical knowledge in the undertaking of pharmacoeconomic evaluations. In Brazil, DTCs are not mandatory and when present in hospitals or local systems do not usually comply with international requirements. Networks in Brazil have been set up for evaluation and rational use of health technologies in UHs and in complex-care institutions. The Sentinnel Network (National Drug Regulation Agency - Anvisa), created in 2001, involves 250 Risk-management centers (RMC). In 2008, the Brazilian HTA Network (REBRATS) was launched to help the decision-making process in the public sector, and in 2009 24 HTA Nuclei (NATS) were created in teaching hospitals. The NATS train professionals and prepare institutions for REBRATS, give support to evidence-based research projects, review clinical guidelines and promote integration between teaching and practice in HTA. Joint work between NATS, DTCs and RMCs in Brazilian UHs could associate these initiatives to foment comprehensive and coordinated HTA, especially in relation to medicines, which account for a large portion of hospital and health-system expenditures, while being keenly associated to health risks. This integration may also result in better-trained health personnel and enhance production of pharmacoeconomic research in Brazil.

T-248

1008 – DESIGNING A SUSTAINABILITY PLAN FOR A HEALTH CORPORATION

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Objective: To develop a sustainability plan of action for a public health corporation (Parc de Salut Mar of Barcelona), with more than 900 beds, several hospitals and different lines of activity (hospital care, long term care and mental care). The objectives aimed by the PSMar are the reinforcement of the leadership image of the PSMar as one of the main institutions in sustainable health policies. Methodology: The first action for the project is interviewing key personnel who own responsibility in the management of areas related to sustainability. The examined areas are: Sustainability Policies and Organization, Healthcare, Consumptions (energy and natural resources), Purchasing, Wastes and Logistics. Afterwards, it began a process of data gathering and analysis, in order to perform a diagnostic that evaluated the status of the management in the analyzed areas related to sustainable development at the Parc de Salut Mar. Once the status is determined, improvement areas are detected and a plan of action is designed. In order to follow the effects and evolution of the measures included in the plan, the firm provides a list of indicators which allow the PSMar to monitor the outcoming results. Findings: The Sutainability Plan is a Instrument that allows the management to prioritize the main actions to carry out in the sustainable development, both in the short and medium term. At the end of the project, the Hospital will have a list of indicators which will allow the managers to monitor of the impact and the evolution of the sustainability plan of action. Conclusions: Explaining an experience of the development of a sustainability plan of action for a public health institution, how to gather information, analyze it and create an action itinerary in order to achieve the defined objectives.

T-249

1009 – CHANGES IN HEALTH CULTURE TO SUPPORT SUSTAINABILITY: ANALYSIS OF THE STATUS OF SUSTAINABILITY IN 37 SPANISH HOSPITALS

Manel Jovells, Uch - Unió Catalana D'hospitals, President, Spain; Roser Vicente, Gesaworld, S.A., General Director, Spain

Objective: To perform a situational diagnosis and to analyze the sustainable measures applied by 37 Spanish hospitals (8601 acute care beds), in order to detect areas of improvement in the social and health sector. Through the answers, a global vision of the status of sustainable development will be obtained (not just environmental, but also social and economical) in each hospital and in the whole region. Methodology: Designing three surveys involving different fields of action (sustainable policies and organization; assistant practice; general and support services), validate them in a pilot test with 4 hospitals (1730 acute care beds), tracking responses, operating the collected data and analyzing the results. These were presented in a workshop which ended in a discussion with the participation of several experts. The survey is designed to be annually renewed in order to follow the applied measures, their effects and evolution. Finding: 80 percent of the hospitals have taken steps to reduce the use of electricity, paper, water and air conditioning. These initiatives represent savings of 7 percent. 52 percent of professionals consider that daily practice already includes sustainability criteria. 30 percent of hospitals have deployed initiatives to integrate sustainability in healthcare practice. 25 percent of hospitals already have or are in the process of obtaining an environmental certification. 69 percent of the centers confirm they have indicators to measure sustainability actions. However, only 36 percent have them included in their balanced scorecard. Respondents consider sustainable development is best achieved in relation to physical resources (consumption, infrastructures, waste), while mobility, personnel expenses and care provision offer more obstacles. Conclusions: The challenge is to implement the concept of sustainable development in governance and organization and to integrate it in healthcare services. Quality, efficiency and professionals must be change catalysts by means of a plural commitment including all the stakeholders.

T-250

673 – HISTORICAL AND FUTURE DRIVERS FOR HTA IN REIMBURSEMENT SYSTEMS IN POLAND AND BRAZIL

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Objectives: Although HTA is well established in healthcare systems like the England & Wales National Health Service (NHS), it is increasingly used more formally in developing countries such as Poland and Brazil. They were selected as examples of centralized and decentralized developing healthcare systems. The objectives of this research were to understand the drivers of decision-making and future trends in these HTA systems in relation to market access for pharmaceuticals. Methods: Secondary research and structured telephone interviews with 6 key stakeholders in Poland and Brazil was carried out. The research evaluated trends in the following aspects of the systems: impact of HTA in final reimbursement decisions, positioning of HTA in the healthcare system and future trends. A comparison of the impact of HTA in Brazil and Poland was then made on a rating scale devised to account for these influencing factors. Findings: HTA in Brazil is positioned within a highly decentralised healthcare system, although centralised economic evaluation is crucial in determining price and access for pharmaceuticals. HTA decisions apply not only to the public healthcare system (SUS) as 65-70% of the market is private and the economic dimension is thought to be increasingly important (n=5) in the regulatory framework. The Polish HTA body, AHTAPol, works closely with the reimbursement process at the central level, but its ultimate influence on price and reimbursement is moderate; the majority of respondents (n=4) regarded HTA as more of a negotiating tool, as decision-making balances multiple diverse interests. Conclusions: The Polish system, despite being centralised, is seen to use HTA to a lesser extent that Brazil, which has a decentralised health system and a large private sector. In addition to HTA, historical development of the healthcare system, external influences and financial resources are equally important drivers of access decisions.

T-251

925 – HTA AS A DECISION TOOL IN INDIA: REASONS FOR IT'S NON-EVOLUTION

Sahil Kirpekar, Double Helix Consulting, United Kingdom; Ben Shankland, Double Helix Consulting, United Kingdom; Henry Dummett, Double Helix Consulting, United Kingdom

Objective: Despite a large part of the healthcare system in India being funded out-of-pocket, payers like State governments, Railways and Armed Forces form a significantly sized institutionally reimbursed part. Unlike other countries with similarly financed healthcare systems, HTA is not seen to be a greatly developed tool for decision making by these bodies. The objectives of this research involved developing an understanding of the reasons behind this non-evolution of HTA and potential for increased adoption of HTA techniques. Methods: Secondary research to understand the reimbursement systems publicly available information about recent reimbursement decisions was done. Primary research involved discussions with decision makers in important reimbursement bodies. Eight in-depth interviews were conducted covering individuals from a variety of backgrounds. Information was collected under headings covering current drivers, historical influences, existing issues, reasons for non-evolution of HTA and expected changes. Data was analysed qualitatively to develop results. Results: HTA was considered a foreign concept in general (n=4). The private market was considered the early adopter of new technologies, from where successful ones were added to the formulary of institutional payers. Majority of the market being out-of-pocket is considered the key driver where both industry and doctors are thought to generally oppose any formal technology appraisals (n=3). Fierce competition in drug retail and "non-ethical" drivers of drug preference were also considered important reasons (n=4). Evolution of any formal HTA process in the immediate future was considered unlikely although increasing development of government sponsored insurance schemes like that seen in the state of Andhra Pradesh is expected to lead to some "HTA-like" filtering process. Conclusions: India lags behind in the HTA evolution scale due to internal resistance, general ignorance regarding HTA and the fragmented healthcare reimbursement system. Increased use of high cost drugs in by some reimbursement authorities might change this trend in future

T-252

195 – VACCINE WASTAGE: CAUSES AND PREVALENCE IN FOUR BRAZILIAN STATES

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Introduction: Systematic evaluation of the prevalence of vaccine wastage in the National Immunization Program (PNI) is necessary for management of vaccine supplies in the country. For this reason, an information system to track vaccine utilization (SI-AIU) was developed to calculate vaccine wastage in individual vaccination posts. As part of the pilot implementation of the vaccine management system in four Brazilian states, data were analyzed to estimate prevalence of vaccine wastage and causes of wastage at all levels in the immunization program. Objective: Calculate the prevalence of wastage and causes for four vaccines (BCG, diphtheria-tetanus-pertussus-Hib [DTP-Hib], oral rotavirus and measles-mumps-rubella [MMR]) in routine immunizaiton programs in four states. Results: Wastage rates averaged 75.1% (range, 69.1% – 80.3%) for BCG; 25.1% (range, 15.6% – 37.9%) for DTP+Hib; 64.1% (50.0% – 76.0%) for MMR and 3.6% (2.2% – 5.7%) for rotavirus. Multi-dose vial practices were responsible for more than 90% of all wastage for all vaccines except rotavirus. Conclusion: Wastage rates were highest for multi-dose vials with short shelf lives after opening (BCG and MMR vaccines). Vaccine utilization requires close monitoring to identify alternative production and distribution options to reduce wastage without sacrificing vaccination opportunities. Key words: Prevalence, vaccine utilization, doses administered, wastage, causes of wastage.

T-253

87 – SOCIAL-SPATIAL INEQUALITIES AND ACCESS TO MEDIUM COMPLEXITY SERVICES IN THE CURITIBA METROPOLITAN AREA

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Objective: Identify and analyze inequalities in the access to medium complexity services in the municipalities composing the Curitiba Metropolitan Area (CMA). METHODS: this is a quantitative, ecological, descriptive and cross section research. In its preparatory stage, this paper focused on the socioeconomic and epidemiologic profile of the healthcare and sector financing networks in the 26 municipalities composing the CMA. Primary data was collected in 24 municipalities, regarding the capacity allowed by their installations, directed demand and the repressed demand of medium complexity healthcare services. RESULTS: The context analysis revealed accentuated social-spatial inequalities and the synthetic index allowed the classification of the municipalities in four groups, relatively homogeneous regarding its living and health conditions. The municipalities located in Vale do Ribeira obtained worse outcomes for Living Conditions and Health Situation Index, and had higher repressed demand for medium complexity healthcare services. CONCLUSIONS: As the geographic distance from the city of Curitiba increased, worse living and health conditions were found and there were greater inequalities in access to healthcare services.

T-254

88 – ACESS TO MEDIUM COMPLEXITY HEALTHCARE SERVICES IN THE CURITIBA METROPOLITAN AREA: A REPORT BY THE ADMINISTRATORS

Sandra Lúcia Vieira Ulinski Aguilera, Pontifícia Universidade Católica do Paraná, Brazil; Beatriz Helena Sotille França, Pontifícia Universidade Católica do Paraná, Brazil; Simone Tetu Moysés, Pontifícia Universidade Católica do Paraná, Brazil; Edeny Terra Loyola, Pontifícia Universidade Católica do Paraná, Brazil; Samuel Jorge Moysés, Pontifícia Universidade Católica do Paraná, Brazil

The access to medium complexity healthcare services represents a difficulty due to its costs and/or the technological density involved in many Brazilian municipalities. This study aimed to understand an administrator's perception of the access by the population to medium complexity healthcare services in the Curitiba Metropolitan Area (CMA). An exploratory study was conducted with seventeen health administrators in the CMA. The data were obtained in semi-structured interviews, which were evaluated through speech analysis. The analysis has shown that the municipalities are in different stages regarding basic healthcare, where the difficulty in access to medium complexity healthcare services promotes interruptions to healthcare lines. The regionalization of medium complexity and health services is deemed necessary, once this area is as complex as the differences in reality of some of the municipalities studied here.

T-255

347 – CURRENT STATUS AND ISSUES OF CONDITIONAL DECISION MAKING FOR COVERAGE IN SOUTH KOREA

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Even though the concept of evidence-based decision making has been accepted in healthcare system globally, there still have been many practical barriers applying evidences in reimbursement decisions. One of the barriers is uncertainty of evidence. If we only have evidence-based decision making without a method to deal with uncertainty, decision making would be done in a rigid way or uncontrollable diffusion of healthcare technology uncertain both in terms of benefits and harms. Methods to deal with uncertainty include 1) encouraging clinical research including pragmatic clinical trials and high quality outcomes research to reduce uncertainty and 2) establishing a system like coverage with evidence development (CED) to allow time for research before making a final decision. Korea had several CED-like decision makings in the past: conditional approval of off-label use of anticancer chemotherapeutic drugs, off-label drug uses other than chemotherapeutic drugs and a couple of cases of medical and surgical interventions. These decisions makings intended as a solution for conflicts between policy makers and healthcare providers by mitigating uncertainties; however, there were many obstacles. The main ones are from poor institutionalization, subsequent absence of rule of game, misunderstanding of stakeholders, low motivation of policy makers and nonsystematic link between decision making and research. To achieve the goal of conditional decision making, we need institutionalization of CED and well organized system to link decision makings with research.

T-256

257 – A MACRO ECOLOGICAL EXAMINATION OF CORRELATES OF HEALTH TECHNOLOGY DIFFUSION IN THE ASIA PACIFIC REGION: IMPLANTABLE CARDIAC RHYTHM THERAPY DEVICES AS AN EXAMPLE

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Background: We were curious about the macro jurisdictional level determinants of technology diffusion in the Asia Pacific region following observations of widely differing technology adoption rates in apparently similar countries. This has implications for policy driven technology adoption in emerging economies. We conducted a simple macro-ecological analysis to identify correlates of technology adoption, using Implantable Cardiac Rhythm Therapy (CRT) devices as the exemplars. Methods: We reviewed available data (Mond 2008) on national rates of new CRT implantation rates, concurrent economic (The Economist World in Figures) and clinical data: GDP/head, GDP Health/head, GDP growth, implanting capacity, AMI death rates (surrogate for disease prevalence). Countries examined were Australia, New Zealand, Singapore, Thailand, India, South Korea, China, and Japan. Results: New implantation rates were strongly correlated with GDP health/head (r = 0.92) GDP/head (R = 0.79) and implants per centre (r = 0.75). Weaker correlation was with % of population > 65 years (r = 0.42), implantation centers per million (r = 0.42) and AMI rate (r = 0.39). Recent GDP growth was negatively correlated with new implantation rates (r = 0.47). Total implants performed per centre were highly correlated with GDP/head. However, there were wide spreads in rates of implantation in spite of similar correlating factors e.g. GDPhealth/H – Korea vs. Singapore. Conclusions: Economic development and implantable directed resources are strong predictors of CRT adoption. The disparities between apparently similar countries indicate policy and other influences affect adoption. Data suggests that appropriate adoption of high acquisition cost technologies can be modified by policy, but should be informed by need, total cost perspective and ability to pay. Caution is needed in interpreting these univariate analyses; multivariate analyses would be informative. Additionally the analytical unit is a country and correlation does not necessarily imply causality. These analyses can inform active management of technology adoption.

T-257

423 – BONE DENSITOMETRY –HOW MUCH DOES IT COST AND WHAT IS THE REAL BENEFIT?

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Background: Bone densitometry (BD) has been largely used to asses osteoporosis, a chronic progressive disease. The positive predictive value of BD for fractures is low - about 36% (1 SD) and 56% (2 SD). For every 10,000 women aged from 65 to 69 years old, screened with BD and submitted to proper treatment, 14 hip and 40 vertebral fractures would be avoided. Cost-effectiveness studies in Brazil showed that, with appropriate management of osteoporosis, BD does not interfere with clinical outcomes. Objectives: To evaluate the expenditures with bone densitometry at Unimed BH and the potential savings if the exams were performed according to protocols. Methods: From October 2008 to September 2010 all BD recorded on Unimed BH database were analyzed. Indications of BD were considered appropriate according to the following criteria: 1) BD biannually for all women aged from 65 to 75 years old and all men aged from 70 to 75 years old; 2) BD biannually for both genders aged from 55 to 65 years old (female gender) or 70 years old (male gender), considering that 40% of the population has risk factors. Results: There were 60,279 BD performed on 56,563 patients; 95.8% were female. The total cost was R$6.2 million (U$3.7million). Using first criterion, 12,559 exams were considered appropriate and cost R$1.3 million (U$ 0.8 million). Using second criterion, 5,848 exams were considered appropriate and cost R$0.9 million (U$0.5 million). Overall, 18,407 (35%) BD were considered appropriate. The total cost of appropriate BD would be R$ 2.2 million (U$1.3 million), which represents a potential saving of R$4 million (U$2.4) in two years if inappropriate indications of BD were avoided. However, even according to protocols, patients' benefit from BD screening for osteoporosis is a matter of debate worldwide.

T-258

683 – COST-EFFECTIVENESS OF BEVACIZUMAB IN THE TREATMENT OF METASTATIC COLON RECTAL CARCINOMA USING DATA FROM THE ITALIAN MONITORING REGISTER

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OBJECTIVES: The treatment of bevacizumab (BV) in patients with metastatic colorectal cancer (mCCR) in combination with fluoropyrimidine-based-chemotherapy is reimbursed by the Italian Health Service on the basis of a cost-sharing-agreement which includes patient enrollement in the Register of oncology medicines, set up by the Italian Medicines Agency (AIFA). This study is aimed at the evaluation of cost effectiveness of BV treatment in comparison with the primary standard treatments using literature data and evidences collected by the Registry. METHODS: The assessment of effectiveness of the BV treatment was performed in comparison with the primary standard therapy regimens, by selecting the main outcome measures from clinical trials protocols and the more recent literature. The evaluation of ICER values were conducted by considering life-year gained (LYG) available in other HTA reports and economic models, derived for both OS and PFS. A comparison with data from the AIFA Register was carried out using the median duration of treatment based only on patients progressing as resulting from the Register. The analysis also reported information on BV clinical use and financial impact of the AIFA monitoring Register. RESULTS: The main results of study showed very high ICER (85.000-290.000€ for LYG) resulting from the addition of BV to standard chemotherapy in the treatment of mCCR, produced by both BV high costs and overall relatively modest health gains, which are synthesized in a slowing of disease progression. The median duration time of the BV treatment was of 160 days, mitigating the high cost of therapy. The financial model produced a median discount of 12,2% of the costs reimbursed by NHS. CONCLUSIONS: The cost-sharing scheme supported early patient access to the treatment, introducing BV in Italy at global reference-price, with an effective overall discount produced essentially by the cost-sharing model, linked to dosage and number of total doses required.

T-259

5 – ENVIRONMENTAL HEALTH MONITORING TECHNOLOGIES IN THE MINING INDUSTRY

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Objective: This was a cross sectional study that determined occupational and environmental health and safety conditions in a mining area in the Philippines. The objective was to determine the appropriate health methodology assessment tools for mining industries. Methods: Environmental monitoring was done in water samples for cyanide and mercury determination. Survey questionnaires were given to 124 respondent, and 15 were interviewed on mining hazards and related issues. Findings: A workplace inspection was done to assess the working conditions, work hazards, environmental waste management, and work practices of the miners. 38 samples were found to be positive with cyanide residues; however, all were within the limits set for cyanide (as free cyanides), based on EPA standards at 0.2 mg/liter. Of 50 samples of mercury, 60% exceeded the EPA maximum mercury level at 0.002 mg/liter. 49% reported being sick in the last twelve months because of work. The workplace inspection of the underground tunnels and pits was far beyond the standard requirements for safety. There were also issues related to environmental hazards, occupational health and safety, and local government regulation of small scale mining. Conclusion: There is prevalent health and safety issues among mining workers in the Philippines. There is also widespread use of mercury and cyanide that pollutes the environment. The study proposes appropriate technologies for assessing environmental contamination, as well as appropriate medical services for mining workers in the Phiilippines and abroad. Keywords: mining heath services, environmental hazards, occupational safety and health, mercury, cyanide monitoring

T-260

655 – IMPROVING THE QUALITY OF CARE BY SUPPORTING DISINVESTMENT FROM INEFFECTIVE PRACTICES: LESSONS LEARNT FROM NICE

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Background: The current financial climate has increased pressure on healthcare systems to provide quality and cost-effective service. NICE has always produced some disinvestment recommendations in its guidance but these were not easily accessible. NICE has introduced a range of initiatives to improve their visibility and identify further disinvestment opportunities including inappropriate referrals to resource-intensive secondary care. Methods: The first initiative, the NICE 'do not do' recommendations database, presents published NICE guidance that recommends complete discontinuation or stopping routine use of clinical practices/interventions. The second, identifies opportunities from Cochrane reviews and translates them into mini-reports highlighting improvements in quality of care and potential productivity savings. The NICE 'referral advice' recommendations database is the third initiative and contains all referral recommendations from NICE clinical guidelines, cancer service guidance and public health guidance. An evaluation is in progress including a review of web-page usage. Results: We have now collected 868 examples of 'do not do' recommendations that have had 27,965 web-page requests and 28 Cochrane mini-reports with 6,007 page requests since they launched in July and August 2010 respectively. There are now 496 examples of 'referral advice' recommendations that have received 16,311 page requests since their launch in October 2010. Preliminary qualitative feedback from the field suggests support for disinvestment products from NICE and a user workshop will further evaluate these products later this year. Discussion: NICE has seized the challenge to improve the quality of care while also saving money and resources. It has always used HTAs to provide such guidance for the NHS, but is working towards improving identification and increasing accessibility and usefulness. Individual examples may not lead to huge savings but combined these initiatives will support the NHS in responding to the current economic climate.

T-261

797 – COCHRANE REVIEWS TO SUPPORT DISINVESTMENT: PERSPECTIVES FROM NICE

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Background: Cochrane reviews provide high quality assessments of RCT evidence supporting healthcare interventions. A proportion of reviews conclude that an intervention is unproven and should be used only in research, or is ineffective or harmful and should not be used. In response to financial pressures facing the NHS, NICE and the Cochrane Collaboration undertook a project to explore the potential of using Cochrane reviews to identify disinvestment candidates. Methods: Over five months all newly published Cochrane reviews concluding that an intervention could not be recommended were identified by Cochrane and evaluated by NICE. The potential impact of stopping the intervention was assessed against four domains: quality of care; patient and carer experience; patient safety; and productivity savings. Reviews were excluded if the intervention: a) was not relevant to UK practice; b) required additional investigation; c) unlikely to achieve gains in any domains. Evaluated topics were published on the NHS Evidence QIPP website as suggested disinvestment opportunities for local healthcare providers. Feedback was sought. Results: Of the 65 reviews appraised, 43% provided candidate interventions for local disinvestment. Quantification of potential productivity savings was difficult (non quantifiable to) by the absence of NHS usage data. Most could not be quantified, but one (minocycline for acne) suggested £2 million savings. Most interventions were found to no longer be used, or have insufficient evidence for their efficacy, making a disinvestment recommendation inappropriate in the absence of a robust national decision-making process. Discussion: Using existing systematic reviews to identifying disinvestment candidates is an attractive proposition. NICE found that additional work/evidence is generally required which needs infrastructure, resources and robust national processes. Few interventions identified as ineffective were in regular use in the NHS suggesting alternative disinvestment strategies may be required to achieve productivity savings.

T-262

562 – SUSTAINABILITY CONSIDERATIONS IN HEALTH SURVEILLANCE: A SURVEY OF SITUATIONS AND ACTIVITIES IMPACT ON HEALTH FROM ENVIRONMENTAL SANITATION IN ISOLATED COMMUNITIES, QUILOMBOLAS AND SOME INDIGENOUS COMMUNITIES IN THE STATE OF SÃO PAULO AND BAHIA / BRAZIL

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Brazil, like all world society widens in urbanization.But still has numerous isolated communities, with special features that need to be adjusted to specific environmental health. This study seeks to identify, through surveys, specific situations in two major Brazilian states: Sao Paulo and Bahia. It presents analysis of studies in maroon communities, indigenous settlements and small isolated communities.This survey was conducted by a medical sanitary, a sanitary engineer and analyzed by the comparative view of a lawyer.The revision of literature was made with the participation of university students in the state of Bahia and São Paulo, in the specialties: Social Service (BA), Psychology (UFBA), History (UFBA), Biology (UNICAMP), Medicine (USP).This analysis aims to generate legal referrals so that this population can be identified and in some way benefited

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T-263

709 – HEALTH AND ECONOMICS REPORT – COMPARISON OF TREATMENT COST FOR HYPERTENSION

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According to the pharmaceutical price regulation theory, the pharmaceutical market has failures, which means that the production of health goods and services by the market are not efficient. One of the most important failures is information asymmetry, affecting medicine users and even health professionals. The Health and Economy Report, a Brazilian Health Surveillance National Agency (Anvisa) bulletin on economic assessment of health care technologies, is a strategy to deal with information asymmetry. The 4th edition is about hypertension, which is a risk factor for cardiovascular, cerebrovascular and renal diseases, being asymptomatic in most cases. In 2004, around 35% of Brazilian citizens, above 40 years, were hypertensives. Among them, 75% appealed to Brazilian public health system to be assisted by primary attention care network. Five classes of antihypertensive drugs with equivalent efficacy were compared against each other: diuretics, beta-receptor blockers, calcium-channel blockers, ACE inhibitors (angiotensin-converting enzyme inhibitors) and angiotensin-II receptor antagonists. The medicines, for which the treatment cost was calculated, were chosen because they were the bestsellers in 2009 in Brazil, at their respective classes. The following drugs were selected: hydroclorothiazide (diuretic), atenolol (beta-receptor blocker), amlodipine (calcium-channel blocker), enalapril (ACE inhibitor) and losartan (angiotensin-II receptor antagonist). The comparisons of treatment costs were made between the branded and generics drugs with the same substances. Despite the same efficacy, the differences from the treatment costs achieved 1811% between the less expensive generic drug and reference branded drug, in this case, Norvasc. To determine the treatment costs, it was considered the maximum initial doses and the maximum price to consumers (PMC) including tax.

T-264

714 – INTERNATIONAL COOPERATION AS A PROCESS OF BUILDING HTA CULTURE IN BRAZIL

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The sharp escalation in health care technology is characterized by increasing flow of new drugs and medical devices, which has significant budget impact on the health systems and promises of great therapeutic advantage, very often not achieved. In order to strengthen development of HTA within Government, it was developed from 2006 to 2010 the Integrated Project for Health Technology Assessment (HTA) under the Cooperation Agreement between Anvisa (Brazilian Health Surveillance Agency) and Pan American Health Organization (PAHO). The objective of this paper is to present the results of this strategy to develop HTA in Brazil. The project was developed with the expectation of improving knowledge of HTA and building a network of institutions dealing with health technology assessment, seeking an increasing use of information based on evidence. In order to spread HTA culture, a set of activities was conducted in three strategic lines: continuing education, international technical cooperation and dissemination. Among the achievements, it can be highlighted the conduction of six studies of economic evaluation, as result of a partnership between Anvisa and the Institute of Clinical Effectiveness and Health of Argentina. The publications Brazilian Health Technology Assessment Bulletin (BRATS) and the Health & Economy Report are other results of continuing education and dissemination. With regard to network building, units of HTA in teaching hospitals are promoted in association with the Ministry of Health of Brazil. Finally, the HTA Project achieved its goals having developed national capacity, established HTA networking and disseminated information. In 2011, considering the results achieved, Anvisa has established a new cooperation with PAHO, targeted to activities covering Evidence-Based Medicine, Economic Regulation and Economic Evaluation of Health Technologies in the Region of the Americas.

T-265

741 – EFFECTIVE DECISIONS ON THE USE OF HEALTH TECHNOLOGY ASSESSMENT IN THE REPUBLIC OF KAZAKHSTAN

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Ministry of Health Republic of Kazakhstan, clinicians and hospital managers are faced with choosing between alternative medical technologies and services. Such decisions require careful analysis of existing data and demonstrate the need for a systematic, objective and transparent assessment methodology. This qualitative analysis is based on research evidence on the introduction and dissemination the health technology assessment in clinical practice in the Republic of Kazakhstan. Qualitative semi-structured interviews were conducted with twenty respondents holding various positions in the Ministry of Health Republic of Kazakhstan, Health Development Institute Republic of Kazakhstan, Astana Medical University, Medical Information-Analytical Center Republic of Kazakhstan, as well as several research institutes of medical specialization. The data was analyzed using the framework approach. In the absence of regulated order of evaluation of medical technology raises a number of challenges for managing the process in funding procedures for assessing medical technology. An important aspect is that when there is insufficient regulation of this process can occur out of control conflicts of interest. Therefore, in conditions of introduction into the health system Republic of Kazakhstan a mechanism for evaluating medical technologies necessary to implement the following steps: first - by law regulate the procedure for health technology assessment, secondly - to develop financing procedures mechanisms for assessing health technologies in accordance with applicable law, and thirdly - develop processes to identify and manage conflicts of interest at different levels of health technology assessments. There is a need for clear regulatory approaches and mechanisms of health technology assessment. And the results should be used by managers of health decision-making aimed at improving the diagnosis and treatment of diseases. For this reason, there is also necessary to optimize the educational system at all levels of functioning in order to effectively adaptation modern health technology in the Republic of Kazakhstan.

T-266

15 – USER'S SATISFACTION TO TUBERCULOSIS TREATMENT IN A CITY AT SAO PAULO STATE, BRAZIL

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Objective: To analyze user's satisfaction to health services which conduct treatment of tuberculosis (TB). Methods: A descriptive study was conducted at a large city in southeastern Brazil. To collect data a structured questionnaire adapted to analyze patients' satisfaction to TB treatment was used. Open questions were also included during interviews in order to identify patients' perspectives related to assistance received at health services. Results: All indicators showed a satisfactory standard of responses. The best score was obtained for the indicator related to patients relationship with the professional who administer the directly observed therapy (DOT), allowing therapeutic bond. However, distance to the health service is identified as a barrier, resulting in financial barriers and changes of patient´s routine, such as loss of time and dependence on others for displacement. Some patient´s statements also showed lack of flexibility in health services' organization aspects regarding to DOT, mainly on negotiation of schedules, frequency of supervision and stigma related to home visits. Conclusions: Satisfactory results could be due performance of specialized health professionals, who focused their care to Tb control. Low expectations from users of public health services, or even the feeling of gratitude could prevent users to critically evaluate the services. Further in depth studies on DOT are necessary, considering aspects related to human rights and health policy; as well as the need for trained human resources to work with TB control at primary care services. Keywords: Tuberculosis; User's Satisfaction, Primary Health Care, Health Care Evaluation

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T-267

18 – TUBERCULOSIS TREATMENT IN BRAZILIAN CITIES: ASSESSMENT OF HEALTH SERVICES' PERFORMANCE

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Objective: To assess the performance of health services to treat tuberculosis. Methods: This was a cross-sectional study conducted in five priority municipalities for TB control: Itaboraí (ITA), Ribeirão Preto (RP), Sao Jose do Rio Preto (SJRP), Campina Grande (CG) and Feira de Santana (FS). Between July and December 2007, 514 TB patients in treatment were interviewed using the Primary Care Assessment Tool (PCAT) adapted to assess TB care in Brazil. The statistical tests used were ANOVA and Tukey's test. Results: The best PHC performance was identified in the dimensions: treatment access, offered services (comprehensiveness) and family focus, and in the TB Reference Centers (TRC), the best performance was identified in the dimensions bond (longitudinality) and coordination reflecting the better training of the TRC team, access to patient information and interaction between users and TRC team. The indicators of the dimensions were statistically different between municipalities. The municipalities RR and SJRP showed indicators superior in all dimensions when compared with the other municipalities, ITA, FS and CG. Conclusion: The performance of health services in TB treatment faces the following challenges: to address the family as the core of the care process, to perform Directly Observed Therapy (DOT) in PHC services near the area which patients live or in the users domiciles, to provide incentives and benefits, to focus efforts on training of teams and to strengthen the structure of the services network with financial, technical and political investments. Keywords: Primary Healthcare; Tuberculosis, prevention & control; Healthcare; Health Services Accessibility; Health Services Evaluation.

T-268

799 – EVALUATIVE STUDY OF THE PROVISION OF HEALTH SERVICES IN THE BRAZILIAN PRIVATE SECTOR: THE CASE OF CANCER FROM THE PERSPECTIVE OF INTEGRALITY OF CARE

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This study presents an innovative approach for evaluating health care performance. Cancer's impact on healthcare in Brazil has resulted in a significant investment by the government and the private insurances to improve the quality of care to these patients. Previous studies (Franco et al, 2007;Silva Junior et al,2010) point out the existence of a fragmented healthcare attention to cancer patients within the private healthcare sector in Brazil.Additionally these studies have shown the lack of coordination of care by the operators.We aim to evaluate the provision of cancer services from a qualitatively perspective,from the looks of Integrality of care,and comparing this information with the patients' therapeutic trajectories.Researchers have advanced beyond the original concepts attributed to Integrality(comprehensiveness),taking it as a kind of image-building goal in health policy and practice,inseparable from the equality and universality,thus considering it a right of every citizen.The methodology takes into account the following categories for analysis of the patients' trajectories: Host, bond-accountability, timeliness(opportunity) and coordination of care.According to Silva Junior et al.(2007),studied from a case of a small healthcare insurance company. Information was raised by the health insurance and personal and semi-structured interviews were conducted.Eight cancer patients from a total population of diagnosed people were included.Profile of respondents: 4 women and 4 men, 62.5% over 65 years, 37.5% affected by breast cancer, 25% by lung cancer and 37.5% for different cancers types. Results:satisfactory reception from providers,but poorly with the service plan,a bond-accountability are inadequate.Timeliness was in some cases detrimental to treatment.Fragmentation of care,disarticulation between providers,lack of provision of medical references and knowledge of the practices of providers by the operator,the operator has little influence on the trajectories therapies(75% of the interviewed patients sought medical non-accredited).Conclusion: Even the easier access to health technologies in the private sector,the care offered is little effective when it deals to aspects of Integrality.

T-269

923 – HEALTH LITIGATION AND NEW CHALLENGES IN THE MANAGEMENT OF PHARMACEUTICAL SERVICES

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Problem Statement: Health litigation spurs many challenges in the management of pharmaceutical services. Performance of health managers and decision-makers must be adjusted to new administrative and legal boundaries. Their actions must also be efficient in responding to ongoing lawsuits, as well as in avoiding additional litigation and in upholding principles and directives of the Brazilian Health System (SUS). Objectives: This paper proposes to better understand one of the aspects of health litigation, namely the growing use of lawsuits demanding medicines, and the relationship between this phenomenon and pharmaceutical services management in SUS. Design and Setting: A review of management and technical procedures related to health litigation of medicines in Brazil was carried out. Through the analysis of available published research on the subject the main elements of medicines litigation are presented and examined in light of their interference on the activities of the pharmaceutical services cycle. Results: Three possible negative effects of judicialization were found: problems with the principles of universal access, difficulties in the management of pharmaceutical services and risks to patient safety, due to misguided prescribing of listed and public-funded medicines, and also of new, innovative medicines without solid established evidence. Moreover, unregistered, not market-authorized medicines, or off label indications may be the target of demands. All technical and operational phases of the pharmaceutical services cycle may suffer disruption by judicial demands. A model flow for the analysis of judicial demands in light of the need for evidence-based decision-making was obtained. Conclusions: The analysis points to possible mechanisms to be adopted by decision-makers in management and in the Judicial System, since the right to health can only be effectively established when management and Justice are predominantly aware and committed to

the safety and the protection of patients and users.

T-271

420 – EVALUATION OF BODY PRACTICES SUCH AS CARE TECHNOLOGIES IN PRIMARY HEALTH CARE: AN EVALUATION IN BASIC HEALTH UNITS AND PARK THE DISTRICT OF BUTANTAN, SÃO PAULO, BRAZIL

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Considering the appeals focused on physical activity, governments and researchers, and recent health sector policys, assess bodily practices implemented in the Basic Health Units -Vila Dalva and São Jorge and the Previdência Park located at Butantã, São Paulo, Brazil, to contribute to the improvement and management of these initiatives in the National Health System of Brazil (SUS) as technologies related to production of care for individuals and communities. Methods: Qualitative research consists of literature research and camp. Data were collected from the users of the SUS, participants and non-participants of bodily practices. Initially a questionnaire was administered to identify the profile of the population and issues relating to participation in programs. Subsequent interviews were conducted for exploration of issues relating to bodily practices, the SUS and the body care. And the observations were systematized in a diary. Results: 1090 questionnaires and 196 interviews revealed that the significance of body care for participants and non-participants to bodily practices is related mainly to the procedures (cosmetic, preventive or curative), showing that the bodily practices implemented not emphasize the body care in view of production autonomy, co-responsibility and co-host of the interests and needs of the population. Conclusion: Despite advances on the provision of bodily practices is urgent the necessity to explore the themes “health education” and “quality of interventions”, considering the singular context of individuals and communities and also the workers, and thus, contribute to the expansion of the modes of thinking and acting within the scope of primary health care.

T-272

823 – FUTURE CHALLENGES OF HEALTH TECHNOLOGY ASSESSMENT IN KOREA

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Objective: Korea implemented the health technology assessment (HTA) by the requirements of national health insurance (NHI) from 2007. The study provides an overview of the health technology assessment (HTA) in Korea. We mainly review the process of reimbursement decision making for new health technology. We suggest the future framework for the improved conduct of HTA for resource allocation decisions in Korea. Methods: We systematically collected and reviewed relevant information to describe the HTA process and reimbursement systems. Results: HTA in Korea has been driven by the requirements of the NHI. Medical procedures should be reviewed for safety and effectiveness by the HTA committee to be listed on the schedule. The committee member comprises nine from the field of academics, healthcare professionals, consumer representatives, governmental staff. The expert committee also consists of five subcommittees: internal medicine, surgery, other medicine, dental medicine, and Korean traditional medicine. The subcommittees are responsible for systematic literature reviews and draft reports. From 2007 to 2008, a total of 414 applications were submitted and 146(35.3%) were eligible to be assessed for HTA. The main technology type was from medical technologies (388 cases, 93.7%). The current criteria for NHI decision making were cost effectiveness and benefit appropriateness by the expert committee. For the transparency of the decision making for HTA, firstly, we will need to consider improving the involvement system of the patient and citizen such as NICE. Secondly, developing the explicit cost effectiveness evaluation method. Lastly, setting the disinvestment system from potentially obsolete technologies in terms of rational use of health care resources. Conclusions: HTA in Korea has future challenges with accumulated experiences for the long-term plans. The focused area was the engagement of stakeholders, development of economic evaluation method and setting the disinvestment system.

T-273

403 – APPLICATION OF THE MODEL OF HEALTH BELIEFS IN THE WORKER'S ADHERENCE TO HYPERTENSION TREATMENT

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Objective: Analysed the behavioral changes in hypertensive workers in the treatment adherence after application of a technology in health based on the Health Belief Model. Methods: Qualitative and descriptive study realized in philanthropic institution, and after the proposal of health education, the participants were interviewed and we selected the following thematic categories: perception of the severity of hypertension, awareness of the benefits of adherence, awareness of change costs, identification of the changes aiming the adherence and motivation for the establishment of objectives for the change. The interviews were recorded after focalgroup participants and lasted for sixty minutes. We used a field diary to record information necessary for the process of analysis and inference. Data were organized by the method of content analysis. Findings: In the application of TS, we observed behavioral changes in subjects, especially regarding the acceptance of hypertension, the drug regimen, and the adoption of healthy eating habits, there is still resistance to adherence of exercise. The data obtained reinforce the health education of hypertensive worker as a changing strategy of habits and values for the acquisition of new knowledge and adoption of positive attitudes to health, through a critical and transformative education, in which the subject takes active participation in the process of learning. Conclusions: The study provided an understanding of patients with SAH regarding adherence to treatment through the application of TS based on MCS. The TS has raised among workers to expand their perception of vulnerability and severity of hypertension, the benefits of adherence to treatment, eliminate and / or control barriers impeding behavioral changes, the stimulus for action and developing strategies to control Hypertension, preventing complications, promoting their health and wellness, encouraging them to experience quality of life. Key-words: Arterial hypertension; occupational health; treatment adherence.

T-274

405 – PREVENTION OF THE RISK OF THE GESTATIONAL HYPERTENSION SYNDROME IN TEENAGERS – A TECHNOLOGY IN HEALTH

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Objective: To evaluate the behavioral changes in twenty-five pregnant teenagers in the prevention and/or control of the risk factors of the Gestational Hypertension Syndrome (GHS). Methods: Participative research with application of an educational technology in health (ETH) based in Health Belief Model (HBM), realized in a Basic Unit of Family Health in Fortaleza-CE. The ETH was composed of ten educational meetings, thus promoting individual and collective construction of knowledge about the conduct of prevention and control of risk factors of GHS, and the incorporation of these in the daily conduct of pregnant women. It is worth mentioning that we use these moments as a facilitator to ETH. Findings: With the application of ETH, we observed significant changes in the habits that can contribute to the pregnants' health. We also noticed that several of them took on the role of change implementers and multiplying agents of educational actions in the social context in which they were. However, we noticed that there were difficulties in the change process, but most of them seemed motivated to adopt habits of prevention and/or control of the risk factors of GHS. Conclusions: The ETH shows itself as efficient, because it contributed to significant behavioral changes, besides keeping the pregnant women motivated to continue adopting behaviors that do not expose the life of the mother-child pair to risks. We consider the application of ETH in the group studied, as the natural expiration, thus making it necessary to insert it in the context of health education for prevention and / or control of situations that pose a risk to put life of the mother and her son, and that should be included in routine practice in health education in the basic units with an approach to promoting humane care, providing prenatal care, more humane and wholesome.

T-275

364 – SURVEILLANCE OF THE ADR

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ADR Reporting system in Mongolia Part II Ch. Amarjargal /MOH/ Sh. Enkhzaya /DOH/ Z.Zuzaan / DOH / Objectives: To define and analyze the strengths and weakness of the current reporting system in connecting reported ADR cases /Part I/ . Methodology: The questionnaire survey consisted of 11-23 questions, on knowledge and attitude of health professionals and general public about ADR. They were involved in the questionnaire survey from the 7 selected health facilities /3 central clinics, 1 district hospital and 3 aimag hospitals/. Results: In patients: A questionnaire was filled by 70 urban and rural citizens. 94.2% of participants did not have sufficient knowledge on ADR and 5.8% replied that they have little knowledge to limited extend. Regarding to the survey participants view about questionnaire's importance of ADR reporting, 38.5% considered that this could be used to exclude medicines causing ADRs from medical practice. To the question asking about the importance of the guideline for filling the questionnaire, 38 patients (54.2%) considered that this guideline is needed to fill yellow page. In health professionals: It was conducted among 140 health professionals. To the question asking about the procedure of ADR reporting, 38 /27,1%/ has chosen yellow page and 24/17,1%/ has answered that there is no reporting system. In the field of difficulties in filling forms, 53.6% did not understand information sharing system of ADR. Regarding to the ADR information in hospitals, 130 /92,9%/ has answered very often, often, sometimes, occasionally and never. Conclusion: Result shows that the general public does not have enough knowledge and understanding about importance of ADR registration and reporting. The most of health professionals do not know the correct way of ADR reporting either. In the future it is needed to change the questionnaire of the yellow page, more understandable and simpler format and include guideline for

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T-267

990 – HOSPITAL RISK MANAGEMENT (HRM) IN HEMOTHERAPY

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Introduction: Managing healthcare risks involves hospital comprehensive actions from identification of risk factors, planning of measures for intervention and prevention. Among the greatest challenges of HRM is the process of blood transfusion, since clinical indication to installation and infusion. This process must be evaluated for any adverse reactions. Objective: This research aims to evaluate the transfusion process in a public hospital for trauma reference in São Paulo city for promoting safety and quality. Methodology: Analysis of records of blood components dispensing from hospital's transfusion department from July to October of 2010 and entire attendance on the transfusion process in 20 patients. And analysis of all patient's hemoglobin levels before transfusion. Results: In this period were transfused 2.132 units of blood and blood components in 558 patients: 74.5% were packed red blood cells, 14.4% of plasma and 9.9% of platelets. From surgical departments were 312 patients and 246 were from clinics. Adult Intensive Care Unit and Adult Emergency Department received 44.2% of all transfusion. Patients with 61 to 90 years old are 43.9% and male are 57.1%. The laboratory hemoglobin level before transfusion: <7.0 mg% in 20.6% of patients, but >10.9 mg% were in 17.9%. In attendance of the transfusion process for checking the application of Brazilian's Surveillance Agency blood transfusion standard was noted that the nursing did not record the vital signs or complications. And sometimes there was no medical filling for ordering blood transfusion and nor there was medical records of adverse events. Conclusion: This study point out the lack of professional knowledge about hemotherapy and identified opportunities for improving this process. Educational campaigns to physicians, residents and nursing aims for implementation in routine checking of vital signs, correct filling of medical orders and strengthening surveillance of adverse events in the transfusion process are paramount for every healthcare service.

T-277

212 – EVIDENCE-BASED MEDICINE JOINT PROJECT: BRAZILIAN COCHRANE CENTRE, ATTORNEY GENERAL´S OFFICE, NATIONAL COUNCIL OF JUSTICE AND NATIONAL COUNCIL OF PUBLIC PROSECUTION

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Background: It is known that judicial activism can cause damage to health policy, due to budget issues and lack of scientific reasoning in judicial decisions, endangering plaintiffs and the all community. Its main cause refers to lack of information available to judges, prosecutors and lawyers, as well as the peculiarities inherent to legal science. In fact, the great majority of Brazilian jurists have no access to evidence-based medicine. Aim: This papers aims to describe the institutional joint research project of Brazilian Cochrane Centre, the Attorney General´s Office (AGU), the National Council of Justice (CNJ) and the National Council of Public Prosecution (CNMP), which intends to spread through the judicial system the Evidence-Based Medicine as a foundation for decision-making, regarding the phenomenon of judicialization of health policies. Discussion: The initial idea of the project emerged in PhD studies taken at Federal University of São Paulo, which has the scientific support of the Brazilian Cochrane Centre. Based on the methodologies of evidence-based medicine (EBM), the project aims to create its own methods and adapt them to law, so legal decision-making can also be based on scientific evidence. This proposal meets health policies needs, especially considering judicial activism, which often is represented by ungrounded decisions. Thus, relevant social actors (AGU, CNJ and CNMP) would join the Brazilian Cochrane Centre, so that systematic reviews can be made available to all jurists, scientifically subsidizing decision-making for judges, lawyers and prosecutors. Conclusion: The described joint project is just one of the repercussions of the unprecedented legal discipline called Evidence-Based Law, whose characteristics prioritize pragmatism and science as a basis for making complex judicial decisions. In fact, evidence-based decisions tend to reduce lawsuits and ensure, on those perhaps filed, the scientific quality of the decision, ensuring the plaintiffs rights and the sustainability of the health system.

T-278

595 – METHODOLOGICAL GUIDELINES: EVALUATING THE PURCHASING OF MEDICAL DEVICES FOR THE BRAZILIAN MINISTRY OF HEALTH

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Objective: To describe the development of the proposal “Methodological guidelines: medical devices evaluation for purchasing by the Brazilian Ministry of Health (MoH)” (MDE). Methods: In 2010, the MoH, in partnership with the Brazilian Health Surveillance Agency (ANVISA) and PAHO/WHO, established a Medical Devices Working Group (MDWG) to discuss issues on the management (acquisition and reimbursement) and the life cycle of medical devices. To minimize asymmetrical information and fragmented activities, the MDWG is composed of several areas from the MoH and from ANVISA, such as: marketing approval; economic evaluation of health technologies; purchasing of medical devices for services networks; technovigilance (surveillance of medical devices); health research; and development of the health-industrial complex. Initially, a mapping of all measures and activities was carried out in order to identify any weaknesses and possible improvements. The MDWG suggested the development of the MDE to explain the purchasing process for medical devices for therapeutics or diagnostics, which are of non-individual use. Results: There were nine meetings of the MDWG during the year 2010. The analysis of the merits of new medical device purchasing and the outdated current legislation were identified as two key challenges. The following MDE topics were agreed upon: introduction (presentation, history and purpose); clinical evidence of efficacy and safety; analysis recommendations; economic considerations, and presentation format. Two universities (UNICAMP and UFSC) with expertise in clinical engineering were contacted for a written elaboration. The first version is expected for the first half of 2011. There will be several revision stages with the MDWG and a public consultation. Approximately US$ 25,000 is being invested for the MDE development. Conclusions: It is expected that the MDE assist in the analysis of the merits of new medical device purchasing in the Brazilian Public Health System.

T-279

962 – HTA UNIT OF GETÚLIO VARGAS UNIVERSITY HOSPITAL: IMPLEMENTING PROCESS IN MANAUS, AMAZONAS, NORTHERN BRAZIL

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OBJECTIVES: To describe the implementing process an HTA unit at Getúlio Vargas University Hospital (NATS/HUGV), and the current institutional perspectives related to Brazilian Network for Health Technology Assessment (REBRATS). HISTORY AND STRUCTURE: The Department of Science and Technology of Ministry of Health and the National Health Surveillance Agency launched a public call for proposals for HTA units in university hospitals. NATS/HUGV was one of the 24 projects supported. NATS/HUGV is subordinate to risk management coordination, which has six people in its staff, and also improves other activities HTA-related: pharmacovigilance, technical surveillance, haemovigilance, environmental management and capacity building for evidence-based medicine. MISSION: To promote the HTA culture in the hospital, strengthening its capacity of decision-making related to health technologies, health care, teaching and research. HOW NATS/HUGV WORKS: The HTA reports are the main products. These reports are based in the rapid HTA standardized by the Ministry of Health and REBRATS. Health professionals and regional managers are invited to make requests. ONGOING ACTIVITIES: Nuss procedure for pectus excavatum; magnetic resonance imaging in neurology; hemodynamics in neurology; digital radiography; support surfaces for pressure ulcer prevention; and laser therapy for mucositis. FUTURE PLANS: To support the hospital restructuring process. This involves very expensive medical devices purchasing and more fixed beds. Increase collaboration with the internal audience and REBRATS.

T-280

537 – CENTRALIZATION OF STERILIZATION PROCESSES IN THE CEARÁ'S STATE HEALTH DEPARTMENT HEALTHCARE FACILITIES NETWORK

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Introduction: Most Rapid Growing Mycobacteria infections are linked to medical devices cleaning and sterilization failures, particularly amid those classified as "critical". "Critical devices" are defined as articles or equipments used in invasive procedures with skin or mucous membranes penetration into the adjacent tissues or into the vascular system, as well as all items directly connected with these systems. Objective: To introduce the Standardized Guidance Protocol of sterilization processes, as well as to describe the centralization of these services into one of the Ceará's State Health Department (SESA-CE) healthcare facilities network. Methods: Descriptive study of a consensus process involving decision makers and of guidelines participative construction. Results: The Protocol for the centralization of sterilization processes was made collectively by the Supplies and Sterilization Centers' Coordinators and Health Technology Assessment Commission (CATS, of the SESA-CE) representatives. The necessity to optimize the installed capacity motivated the project initiation. A consensus was negotiated to centralize the sterilization processes for the entire network at one of the hospitals possessing underutilized resources, including three hydrogen peroxide plasma (HPP) and saturated steam autoclaves. Moreover, the remainder SESA-CE's healthcare facilities outsourced this service to a private company, resulting in costs burden, besides the difficulty to assess the process effectiveness. This project begun staged, with a systematic review of the relevant literature, discussing the required protocol chapters and then the content drafting, including: description of existing guidelines, newest scientific evidences review, algorithm and the flowchart diagram with their detailed description, glossary and annotated references. The algorithms included all important steps for quality control, from cleaning, critical products preparation, the sterilization process controls and criteria for products liberation for use. Conclusion: The centralization decision and the Standardized Procedures Sterilization Guidelines were evidence based. We can already observe considerable financial savings; however, validation of the process is a dynamic challenge.

T-281

901 – HEALTH DISORDERS: OVERWEIGHT AMONG PUBLIC SCHOOLS EMPLOYEES

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The concern with the increasing rate of obesity is rising among educators, public managers and scientists. According to the World Health Organization, more than 700 million will be obese by 2015. It is known that obesity can be related to the appearance of diseases such as arterial hypertension, dyslipidemia, and diabetes mellitus type 2 affecting an adult's life. In this perspective, the purpose of this study was to evaluate the nutritional status of the schools deans, collaborators, secretaries and elementary school teachers, and to apply a nutritional educational intervention. In a cross sectional design, 179 individuals were invited to participate, however by different reasons 128 agreed to participate (71.5%). Anthropometric measurements of the weight and stature were obtained to the corporal mass index (IMC) calculations, classified accordingly to the World Health Organization. Dietetic counseling took place in the period of three months, with one session every week. From the total group of the participants, 11.7% (n=15) were schools dean, 53.1% (n=68) were elementary school teachers, 12.5% (n=16) collaborators and 29% (n=22.7) secretaries. Also, the results showed that 95.3% (n= 122) of the participants were women. The ages of the individuals varied from 24 to 64 years (DP=8.6) in which the average age was 44. The majority (58.6%) earns about US$ 600.00 dollars monthly and 43% had a college degree. The IMC median was of overweight (25.1kg/m2; DP=4.8). The correlation between IMC and the age was (r=0.188; p<0.05), meaning that level of overweight is higher on older individuals. The intervention did not result in significant changes in the median IMC (r=0,988; p<0.01) of the participants. In conclusion, the lack of a reduction of the IMC suggests a need for longer periods of counseling and additional approaches such as, physical activities, to create positive impact in the nutritional status of the participants.

T-282

907 – EFFECTS OF NUTRITIONAL INTERVENTION IN SCHOOL CHILDREN TO PREVENT OBESITY

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Objectives: The objective of this study was to analyze the effects of nutritional education intervention among school children from public and private schools in Brazil focusing on the reduction of obesity among infants. Methods: The educational intervention was based on the Theory of Social Cognition. It consisted of six meetings, during three months, dealing with nutritional guidelines and physical activities. The weight and the height of school children were measured to verify their nutritional status. To measure the self-efficacy of the school children in relation to their capacity of fruit consumption, an adapted questionnaire was used, applied before and after intervention. Information about eating habits and life style of the students, as well as socio-economic aspects of the responsible parents of the students were also collected through another adapted questionnaire. The data were analyzed by the software SPSS, being conducted a descriptive statistics and the qui-squared test of Spermanrho. Findings: It was found that the dominant weight excess, overweight and obesity occurred in the school children attending private schools (n=23; 31,94); that had as responsible parent an individual with a higher education levels (n=18; 33,96%) and that also had better socio-economic level (n=18; 33,96). These differences in the findings of the factors mentioned were statistically significant (p< 0,05). It was observed the increase in the self-efficacy of the school children in relation to the consumption of fruits, since the mean of the total score initially calculated changed from 15,23 to 18,02 after the intervention, the difference also presented significant statistic (p<0,05). The reduction of the children's weight was not significant. Conclusion: The modification of the body weight among school children still is a special challenge in private schools settings. The increase in the children's self-efficacy by eating fruits could be considered the first step.

T-283

808 – ATTENDANCE IN TRADITIONAL HEALTH BASIC UNITIES AND FAMILY HEALTH CARE STRATEGIES UNDER THE USERS' VIEW

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Introduction: The implantation of Family Health Care Strategy (FHCS) has been gradually taking place, although many municipalities still use the Traditional Health Basic Unity Modality (THBUM). In its development, there are some challenges to be identified and faced. This work intends to consider in what aspects this strategy is contributing to attend people's real necessities, and to construct a new logic of health attention. Objective: In this study, we propose to analyze the attendance in FHCS and THBUM under the users' view, taking into account all dimensions in the basic attention evaluation proposed by Starfield (2002). Method: 32 interviews were achieved, being 16 with FHCS users and 16 with THBUM users. The analysis was based on an hermeneutic-dialectic perspective. Results: In both FHCS and THBUM, the access was considered facilitated because of the unit location, and difficult due to the lack of schedule to appointment. In both modalities, the users have understood basic attention reference entry system either as beneficial for the patient or as a result of his/her lack of choice. Although FHCS users have had easy contact with all the health team, Community Health Agents are the main bond in both modalities. Regarding the cast of services and their connection, the two modalities users point a minimum offer in medical specialities and specific exams, besides the poor organization between services. Only FHCS users have asserted to receive familiar assistance, whereas the two modalities users have not identified any community guidance. However, FHCS users pointed lack of medical experts, whereas THBUM users consider professional background adequate.Conclusion: Improvement is necessary in the whole attendance net, and changes are to be made in focusing patients' care attention, mainly in the supposedly structural-organized distinctive attendance FHCS.

T-284

810 – STRENGTHS AND FRAGILITIES OF FAMILY HEALTH CARE STRATEGY UNDER THE HEALTH TEAM'S VIEW

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INTRODUCTION: Family Health Care Strategy (FHCS) is a modality of health attention based on the creation of entailing, sheltering and organizing health care actions. In its development, there are some challenges to be identified and faced. This work intends to consider in what aspects this strategy is contributing to attend people's real necessities, and to construct a new logic of health attention. OBJECTIVE: Based on interviews with different professional categories, we intend, in this study, to analyze FHCS strengths and fragilities. METHOD: It was made a qualitative study based on interviews with Family Health Unit professionals of a municipality in São Paulo State. Twelve professionals were interviewed, being four Community Health Agents (CHA), three Nursing Assistants (NA), two physicians, two nurses and a dentist. Data analysis was achieved by the elaboration of sense-nuclei in the hermeneutic-dialectic perspective. RESULTS: FHCS strengthning points were: facilitated access, humanizing shelter to the users, and a patient's social and familiar approach. As fragile points, professionals have pointed people's poor engagement in health promotion actions, difficulty to access more complex levels of health attention, insufficiency in counter reference system, disconnection between physical structure of the unit and the strategy proposed, and excessive health care demand in the unities. CONCLUSION: Based on FHCS strenghts and fragilities, it can be inferred that much more struggle is needed in order to develop a model of health care attention which emphasizes health promotion actions and the patient's whole care.

T-285

602 – PIONEERISM AND EFFECTIVENESS OF A DISTANCE-LEARNING CLINICAL RESEARCH PROGRAM

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Introduction: Technical advances are essential to improve health care in the Brazilian National Health System (SUS). With this goal in mind, the National Network of Clinical Research (NNCR) was launched in 2005 with the aim of integrating research centers linked to public academic institutions. Through a pioneering public-private partnership in Health Sciences Education, the Hospital Alemão Oswaldo Cruz (HAOC) and the Brazilian Ministry of Health (MS) have developed this program to fulfill NNCR needs in technical training for health professionals in clinical research. Methods: Between September 2009 and July 2010, twelve institutions in 8 states were enrolled in the course. A commercially available connection software was used and all centers had, or were provided, the minimum required hardware. The course program included forty real-time lectures broadcasted to remote centers, monitored online chats and student forums, links for questions to speakers, and tutorial support (www.capacitacaopesquisaclinica.com.br). Weekly required readings were also available at the site. Final grades were calculated based on online exams and essays, as well as class participation though live connection after lectures. Results: Eighty eight students completed the course (21.4% dropout rate, 88/112), and 86 were approved (97.7%, 86/88). The average passing grade was 8.59 for a maximum of 10.0. Conclusion: The dropout rate for online non-sponsored courses varies in the literature (14 to 70%). Lack of familiarity with e-learning and information technologies, different backgrounds among participants, as well as changes in professional status may have impacted our dropout rate, even after the selection process. The internet has enabled the dissemination of knowledge simultaneously to multiple remote points of our vast territory, overcoming logistics and economics difficulties. Trained tutors, good course design, technical support, stratification according participants' competencies and the use of motivational and leadership strategies can minimize dropout and increase adherence rates.

T-286

500 – KNOWLEDGE GAPS – THE SWEDISH COUNCIL ON HEALTH TECHNOLOGY ASSESSMENT (SBU) WORKING WITH TREATMENT UNCERTAINTY

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The Swedish Government has assigned SBU to identify healthcare methods where the scientific evidence on treatment effects is uncertain. Identifying and actively disseminating information on inadequately assessed interventions in health care is intended, eg, to draw attention to important issues that could be addressed by clinical trials and to secure evidence for setting priorities in health care. Treatment uncertainty is defined as: a substantial gap in knowledge concerning the effects of a treatment method. Treatment uncertainties can be classified into two different levels of uncertainty. The first refers to the absence of reliable studies addressing the matter (or that available studies show substantial uncertainty), ie, scientific evidence is insufficient or absent. The second refers to the absence of well-executed, updated systematic literature reviews addressing the matter, ie, the evidence has not been fully appraised. In the first case, further primary research is needed to fill the knowledge gaps. In the second case, a systematic literature review is needed to clarify the evidence. SBU is constructing a database to systematically compile information on treatment uncertainties. The work process is described and its relation to research funding. It is essential to establish channels for collecting information from professionals, from the county councils' (ie, providers') knowledge-based organizations, and from other actors in the field. A major survey was conducted to collect suggestions on possible treatment uncertainties. In the future, this effort could include areas of responsibility involving other agencies, eg, the Swedish Social Insurance Agency, the National Food Administration, the Prison and Probation Service, and the Swedish National Institute of Public Health. Several ethical and moral aspects can arise when it is shown that the evidence supporting a particular treatment method is insufficient or completely absent.

T-287

598 – DENGUE: HOW PROFESSIONALS THE FAMILY HEALTH PROGRAM (FHP) THINK IN FORTALEZA-CE

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Dengue, in actuality, became a recurrent problem in the scenario of public health, since it has as determining factors for their proliferation, rapid urbanization, the irregularity in water supply and consumption of disposable products, among others. Therefore, it is clear that there is a full understanding of the complexity of their derterminants. It is known that the Family Health Program has an importance in dengue control, since it works as a gateway to the population, and constitutes a model of care focused on disease prevention and health promotion. The objective was to examine the perceptions of professionals in the Family Health Program in Fortaleza, capital of Ceará, in relation to dengue. This was the first phase of a multicenter study conducted in six Latin American countries, with support from the International Development and Research, Development Programme, United Nations, World Bank and World Health Organization Special Programme for Research and Training in Tropical Diseases (TDR). This research was qualitative, with descriptive approach, where were interviewed on the subject in question with five family health teams, whose clusters were randomly selected. In total we interviewed 20 professionals, including managers, nurses, dentists, community health workers and agents of endemic diseases. The data revealed that there are no financial resources for vector control directed to the PSF; people know about dengue fever, but not change their behavior, and that the irregularity in water supply, violence in the community and lack of education this hamper the work of professionals. Therefore, it is necessary that these services seek linkages with other sectors than health, since the control of dengue based on an integrated and that studies be undertaken to understand the reason for not changing people's behavior in order to decrease the number of hospitalizations, overcrowding health services and raising the political costs and social.

T-288

580 – THE EVALUATION OF CARE PATHWAYS AS A COMPLEX INTERVENTION: APPLICATION OF A METHODOLOGICAL FRAMEWORK

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Objective: To assess the extent to which the development steps of the evaluation of care pathways (CP) can be represented in the framework for the design and evaluation of complex interventions. Methods: The framework is composed by 5 phases: theoretical (pre-clinical), identification of components of the intervention (phase I), definition of trial and intervention design (phase II), main trial execution (phase III), promoting effective implementation (phase IV). Results: The framework was applied to the evaluation of CP for strokes. Pre-clinical phase was aimed in synthesizing the evidences: 3 reviews were selected and showed that CP are theoretically applicable in stroke care and that mortality should be the main outcome to be analyzed. Phase I was done through a descriptive pilot. 253 consecutive patients admitted for strokes in 29 hospitals were analyzed. Overall in-hospital stroke mortality was 19.76%. Stroke teams (OR=0.25; p=0.025), antithrombotic therapy (OR=0.26; p=0.009) and complications (OR=6.40; p<0.001) were independent predictors of in-hospital mortality. Therefore these variables were selected as components of CP or treated as covariates. Because CP are active both on organizational (units) and individual (patients) level, a two-arm cluster Randomized Controlled Trial with hospitals and long-term rehabilitation facilities as randomization units was designed in phase II. 14 units were randomized either to arm 1 (CP) or to arm 2 (usual care) including 238 patients per group. The primary outcome measure was mortality, the CP were also analyzed with key quality indicators. The trial has been successfully performed (phase III) and in-hospital mortality has been reduced (OR=0.10; p=0.04). Because the adjusted results are not available yet, it was not possible to identify the active components of the CP and therefore phase IV has not been performed. Conclusions: Even if the results are still partial, it seems possible to apply this framework to the study of CP.

T-289

582 – A MODEL FOR EVALUATING DIAGNOSTIC ERRORS FROM AUTOPSY DATABASE

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Objective Patient safety and reducing health inequalities are becoming priorities for healthcare systems worldwide. While the impact of socioeconomic factors on health has largely been demonstrated, the relationship between social status and medical errors has been explored only partially. The aim of this study was to determine whether socioeconomic factors can be associated with diagnostic errors in subjects who died in hospital. Methods An historical cohort was analyzed through 2003-2008, including all the consecutive in-hospital deaths followed by autopsy. Diagnostic errors were defined as the presence of clinically missed diagnosis involving a principal underlying disease or primary cause of death. The discrepancy between clinical and postmortem diagnosis gave the measure of diagnostic error for each patient. The clinical and socioeconomic information was collected for each patient (length of stay, reason for admission and death, comorbidity, age, sex, educational level, marital status, occupational status, deprivation level according to the Italian deprivation index). Univariate and multivariate stepwise forward logistic regression models were used in order to determine the independent association between diagnostic errors and socioeconomic variables. Results The sample included 397 cases. The rate of diagnostic errors was 45.6% (95%CI 40.5-50.5), with 58.6% (95%CI 51.3-65.8) of unexpected findings contributing to patient's death. Diagnostic error rate increased in patients of deprived/very deprived areas, even after adjusting for confounding factors (OR 1.8, 95%CI 1.1-3.2; p=0.047). Conclusion The results showed that errors can be related to living in a deprived area. Despite the possible limitations (small sample size, single centre study, etc.), these findings suggest that social factors and errors are not independent. Moreover these results emerged in a context where advanced diagnostic technologies, academic competence and social policies are available. Therefore new integrated healthcare strategies could be necessary to face both problems.

T-290

615 – SURVIVAL IN CORONARY ANGIOPLASTY AND CORONARY ARTERY BYPASS GRAFT SUPPORTED BY HEALTH INSURANCE AND PRIVATE IN RIO DE JANEIRO STATE

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Objective: Study survival in patients undergoing coronary angioplasty (CA) or coronary artery bypass graft (CABG) in Rio de Janeiro State (RJS), paid for health insurance and private, from 2000 to 2007. Method: Information about CA and CABG comes from Database Hospital Admission Communications (CIH) and deaths from Database Death Certificates issued by the Rio de Janeiro State Health Bureau, from 2000 to 2007. It was carried out probabilistic relationship between these databases with RecLink ® program to identify individuals who died after CA or CABG. Findings: Only 980 procedures were reported in eight years in 937 individuals living in the RJS. It were identified 428 individuals with CA, 71.7% was outside of the city capital of Rio de Janeiro (RJ) and the others were identified in other states, 22.8% in São Paulo (SP). With regard to CABG, 32.4% of 509 patients undergoing the procedure were outside of the capital of RJ, while the others were detected in other states, 66.6% in SP. Survival for CA at 7 years was 86.9% and 88.0% in CA. Conclusion: The performance, as assessed by survival after CA or CABG supported by the supplementary health system in RJS, from 2000 to 2007, was unsatisfactory and resembled that seen in the public system, according to records available from CIH.

T-291

613 – CASE FATALITY IN CORONARY ARTERY BYPASS GRAFT IN-HOSPITAL AND IN THE FIRST YEAR AFTER HOSPITAL DISCHARGE SUPPORTED BY BRAZIL'S NATIONAL HEALTH SYSTEM IN RIO DE JANEIRO

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Objective: Estimate case fatality and identify the percentage of deaths related to the Circulatory System Diseases (CSD), from admission to hospital up to the first year after hospital discharge, in patients undergoing coronary artery bypass graft surgery (CABG), through Brazil's National Health System (SUS) in Rio de Janeiro State (RJS) between 1999 and 2003. Method: Information on CABG comes from the Hospital Admission Authorisations (HAA) and Death Certificates databases issued by the RJS Health Bureau. Probabilistic relationship between databases was drawn up through the RecLink® programme, excluding CABG with valve replacements. Four periods were taken into consideration: in-hospital, up to 30 days, 31 - 180 days and 181 - 365 days after hospital discharge. Percentage estimates were drawn up of deaths and case fatality rates by CSD related causes and periods. Findings: There were found 5.180 patients with CABG and 675 individuals who died within up to one year after hospital discharge. In-hospital case fatality reached 8.0%, according to the HAA. The accumulated case fatality rates for 0-30 days, 31-180 days and 181-365 days after hospital discharge were respectively 10.2%, 11.9% and 13.0%. The basic cause of some 89.0% of the deaths consisted of CSD related diseases. Conclusion: The in-hospital case fatality rates for CABG underwritten by the SUS in RJS were high and remained high up to one year after hospital discharge. The CABG seems have not modified the mortality by circulatory system diseases as long as 89% of patients died from those causes until one year after the proceeding.

T-292

614 – CASE FATALITY IN CORONARY ANGIOPLASTY DURING THE FIRST YEAR AFTER HOSPITAL DISCHARGE THROUGH BRAZIL'S NATIONAL HEALTH SYSTEM IN RIO DE JANEIRO STATE

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Objective: Estimate case fatality from admission to hospital up to the first year after discharge from hospital, in patients undergoing coronary angioplasty (CA) supported by Brazil's National Health System (SUS) in Rio de Janeiro State (RJS) between 1999 and 2003. Method: Information on CA comes from the Hospital Admission Authorisations (HAA) Databases and Death Certificates issued by the Rio de Janeiro State Health Bureau. In order to identify persons dying after CA, the probabilistic relationship between the Databases was drawn up through the RecLink® programme. Four periods were taken into consideration: in-hospital, up to 30 days, 31-180 days and 181-365 days after discharge from hospital. Percentage estimates were drawn up of deaths and case fatality rates by Circulatory System Diseases (CSD) related causes and period. Findings: 475 pairs of individuals were found who died within up to one year after discharge from hospital. In-hospital case fatality reached 2.2%, according to the HAA. The accumulated case fatality rates for 0-30 days, 31-180 days and 181-365 days after discharge from hospital were respectively 3.2%, 5.2% and 6.9%. The basic cause of almost 85% of the deaths consisted of CSD related diseases. Conclusion: The case fatality noted during the first year in RJS was higher than that noted in other follow-up studies of patients with clinical treatment or through CA. The death risk for those undergoing CA remained high, compared with the risk for the population of individuals of the same gender and in the same age bracket in this study.

T-293

38 – COMMUNITY SURVEILLANCE SYSTEM BASED ON TELEPHONE CALL NOTIFICATION FOR FEBRILE SYNDROME AND INFLUENZA LIKE ILLNESS

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BACKGROUND: The term e-health is used to encompass the terms telemedicine and telehealth, and it is characterized by the combined use of electronic communication and information technology in the health field. OBJECTIVES: To describe the system named Bonis, which uses Information and Communication Technology to prevent, warn, monitor and control the spread of febrile syndromes and influenza like illness at the community level. METHODS: The developed system, Bonis, has a kernel free software application; Asterisk, a phone center with VoIP service, PHP as Script language and Mysql as data base management. The system was implemented in an area of the Hospital Barrio Obrero, in a primary health Care Unit (UAPS), named Mutual Aid Centre and Health for All (CAMSAT) and is monitored by the National Centre for IHR (DGVS/MSPBS). CAMSAT has 10 community health agents, each responsible of monthly visits to 150 households. RESULTS: The developed system has the ability to record, classify, and prioritize automatically through the IVR (Interactive Voice Response) the suspected cases of syndromic fever and influenza like illness.The system, to which the users access from a mobile or fixed telephone, automatically receives the call with 9 questions on signs and symptoms such as fever, pain, shortness of breath, diarrhea and vomiting. It also has a database of identity cards associated to the person`s address and capable of registration by a voice message for user not in the system, in order to locate the person who called into the system. CONCLUSION: The developed system is allowing the community to notify and register events that require surveillance, and the community health agents is prioritizing visits to those homes from where fever cases are reported for sooner and more appropriate interventions.

T-294

222 – TELE-ULTRASOUND SYSTEM FOR DIAGNOSIS OF ABDOMINAL AND REPRODUCTIVE PATHOLOGIES IN REMOTE POPULATIONS

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Clinical background: Biomedical Informatics developed by multidisciplinary groups to facilitate the use of communication technologies and Informatics (TICs) have made easier the implementation of telemedicine systems to improve health services from scattered and remote populations. According to the UN statement in Alma Ata, nowadays health systems are focused towards a greater equity in rendering service and they present more concern in relation to effectiveness and the use of health technologies. The new technological tools TICs and its wide territorial spreading in the country offer important possibilities to improve ultrasound diagnosis services coverage for abdominal and gynaeco-obstetric pathologies in remote populations in the country. The potential benefits of this technology (5) are the notarization of ultrasound diagnosis service, standardization diagnosis services in the country, and it improves the quality and effectiveness of ultrasound diagnosis for abdominal and gynaeco-obstetric pathologies. Technology: Tele-ultrasound consists of an architectural software stand alone to catch images from the ultrasound device. The computer integrates ActiveX controls to handle the video capture card and subsequent digital image processing. For transmission of images through the Web to “remote specialist” for further diagnosis and medical report delivery/patient, diagnosis/treatment physician, it is used the technique “store & forward”. Objective: To determine the utility of a Tele-ultrasound system for abdominal and gynaeco-obstetric pathologies in remote populations. Results: 25.238 articles were used mainly from Trip Data base, Pub Med and some journals of identified scientific publications, but not all of them were used.Most of the analyzed texts in this report were part of multicenter descriptive observational studies which were most prominent in rural or remote areas. The main studied population consisted of pregnant women with maternal or fetal risk factors. A second line were applied to a general population for abdominal ultrasound. In general, the chosen studies agree that Tele-ultrasound offers a reliable

T-295

333 – ECONOMIC EVIDENCE IN THE CONTEXT OF HTA: THE CHALLENGE OF PALLIATIVE CARE

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Objective: To identify and evaluate the evidence available for the costs of palliative care and how this evidence is applied in submissions and appraisals made by NICE. Methods: NICE technology appraisals and associated assessment group reports, across all diseases, were searched for the word “palliative” or related terms. A detailed review of these documents and published systematic reviews in palliative care concluded that the research question needed to be focused on a specific disease area, otherwise the scope of the project would become impractical. Metastatic renal cell carcinoma (mRCC) was selected and a systematic search (using the Cochrane library, Medline, Embase, and Econlit) was developed to identify cost studies relevant to palliative care in mRCC, in September 2010. In both reviews, results were filtered using pre-specified selection criteria and data extracted into a pre-defined template. Findings: At first pass a total of 56 NICE appraisals were identified that made reference to palliative care; only 20 reported detailed information. The mRCC searches identified over 1172 citations. Forty eight studies were retrieved in full, but only 17 were ultimately included. Conclusions: There was interchangeable and inconsistent use of the terms ‘best supportive care’, active supportive care or active symptom control or similar. The systematic review highlighted the methodological issues of applying systematic methods to the palliative care question and demonstrated that there was little costing data relevant to palliative care specifically in mRCC. The description of care was universally vague and treatment assumptions in the mRCC differed, resulting in the failure to compare ‘like with like’. The clinical/ social model of provision was also inconsistent with national and regional variations. The review suggests that palliative care cannot be generalised, as it is specific to local/country practice and warrants careful consideration when part of HTA appraisals.

T-296

934 – EVALUATING INDICATORS OF UNAVAILABILITY OF PULMONARY RESPIRATORS REFLECTING ON THE REDUCTION OF HOSPITAL BEDS OF INTENSIVE CARE UNIT (ICU) ON A PUBLIC HOSPITAL OF RIO DE JANEIRO

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Goals: There is a great shortage of ICU beds on Rio de Janeiro state hospitals, thus creating a cruel waiting line for patients with life threatening diseases. According to the state central that regulates beds distribution in Rio de Janeiro hospitals there are 131 patients waiting in line for an ICU bed. By a law of the Brazilian Ministry of Health (Portaria Nº 2.918), an ICU must have one respiratory blender per bed. In this work the authors intend to evaluate the indicators of unavailability of pulmonary respirators on the ICU of a public hospital and the reflection on the reduction of available beds. Methodology: Survey of all respirators on the ICU and identification of each equipment by a code previously defined by the authors. Creation of a database containing the brand, model, serial number and other relevant information of the respirators. Monthly visits were made to the ICU from December 2009 to December 2010 to gather information on the status of each equipment. Results: During the surveyed period four respirators were withdrawn from the unit for corrective maintenance, without replacement. These were unavailable for 293 days, 311 days, 76 days and 32 days, respectively, which resulted in the blockage of 3 beds for 5 months, 2 beds for 5 months and 1 bed for the remaining 2 months. The ICU has 13 beds with the occupancy rate being of 2 patients per bed per month. Hence the unavailable beds amount to 54 untreated patients that year. Conclusion: The authors propose the creation of a central to manage the mechanical ventilators in order to organize the resources, thus optimizing the use of these equipments in the hospital, as well as to control the preventive and corrective maintenance.

T-297

640 – MEASURING QUALITY OF LIFE IN PSORIASIS: THE CALIPSO QUESTIONNAIRE

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In dermatology, several instruments are available to measure health-related quality of life (HRQoL) of patients. They vary in content emphasis and in the extent to which their measurement properties have been investigated and reported. In this study, we summarized five dermatology- and psoriasis- specific HRQoL questionnaires into a new psoriasis-specific questionnaire, the Comprehensive Appraisal of Life Impact of PSOriasis (CALIPSO). The questionnaires were completed by 936 patients with diagnosis of psoriasis. Rasch's unidimensional measurement model was used to verify the construct validity and the operational characteristics of each instrument separately. The items with the best performance according to the Rasch model were selected. The final 30 items constitute the CALIPSO. Responses are given on a 3-point scale: never, sometimes/quite frequently, often/ oll the time. The properties of the CALIPSO now need to be verified through the analysis of new data from different population of people with psoriasis: In future, clinicians may use it without having decided amongst several competing scales, to evaluate HRQoL in patients with psoriasis.

T- 298

389 – THE APPLICATION OF MICROSIMULATION METHODS IN HTA FOR PERSONALIZED MEDICINE STRATEGIES

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Purpose: Personalized medicine (PM) takes into account that diagnostic and therapeutic health technologies should be based on individual characteristics of patients such as risk profile and treatment response. Economic evaluations of PM and HTA that summarize economic findings require adequate methods to incorporate multiple characteristics (e.g., genotypes, blood markers). Microsimulation is a technique to evaluate health technologies, policies and interventions based on individual characteristics. Our goal was to identify and contrast different microsimulation approaches using well known health policy models (e.g., POHEM, UKPDS) and discuss the applicability of these approaches in the evaluation of PM. Methods: We performed a review on microsimulation and applications in social sciences, health care and politics. Assessment criteria include the modeling of patient characteristics/patient history/prior events, the way events or transitions between health states are modeled, the inclusion of life years/utilities/costs, open/closed cohort approach, and the way time is modeled. Results: Identified approaches range from state-transition models, discrete-event simulation models to equation-based models. Individual characteristics relevant for PM include individual risk factors, clinical properties, patient history, severity of disease, number of repeated events. Different approaches were used to link risk factors and predictors to prognosis and treatment decisions and success. E.g., POHEM is one of the leading comprehensive Canadian microsimulation models for health care policies. Applications range from lung cancer treatment, breast cancer prevention to the evaluation of cardiovascular diseases. POHEM is a continuous time, open cohort model, in which actors and their characteristics are modeled. Overall microsimulation has been successfully applied e.g., in cancer research, for chronic diseases or screening and prevention. Conclusion: Microsimulation techniques are broadly applied but still underrepresented in health sciences. Microsimulation is a powerful tool for evaluating strategies in PM, because it can be used to incorporate the genetic and clinical heterogeneity of individuals as well as personalized decision algorithms.

T-299

213 – THE ROLE OF TECHNOLOGY IN THE EDUCATION OF HEALTH PROFESSIONALS: MEANNNINGS, DILEMMAS, AND POSSIBILITIES

Walter Ferreira de Oliveira, Universidade Federal de Santa Catarina, Brazil

The unprecedented technological boom testified from the second half of the XXth century throughout our present days has propitiated revolutions in all fields of human existence. Clones, genetically modified organisms, communications, robots, organ transplants, distance education, and many newly invented products tantalize our societies, everywhere. More technology has always been considered as a synonym of a better life which, to a great extent, seems to be true. However, one question, for which we have not yet a final answer, continues to puzzle our information and technological societies: does technology by itself guarantee the well being of our populations? The answer seems to be simple and obvious but the question stirs important discussions including in regards to the education of health professionals. Deeply affected by various technically advanced products, by the internet, and by last generation computers and media, education of health professionals continues to face, as always, enormous dilemmas. What is the nature and the role of technology in the construction of efficient, efficacious, and effective health care systems? How do we contextualize technology against the background of ethics, reflexive and critical thinking, which constitute foundations and goals of education in a democratic society? How can we offer proper guidance for decision-making in the path to a healthy and sustainable future? This presentation aims to deepen these and other related questions, putting into perspective historical analyses, based upon the works of authors who, in their time, have focused on the continuous impact of technology, such as Eric Fromm, Norbert Wiener, and MarshallMcLUhan; and contemporary social criticism, analyzing the works of authos such as Boaventura Souza Santos, Paulo Freire, Baumann, and Maffesoli. We aim to contextualize these analyses in the education of health professionals and in the development of health care systems.

T- 300

411 – ADHESION OF THE HYPERTENSIVE PERSON AT THE PHYSICAL EXERCISE - A TECHNOLOGY EDUCATIVE IN HEALTH

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Objective: To evaluate the occured modifications with the implementation of a educative technology for adhesion of the hypertensive subject to the physical exercise. Methods: Participant research with 15 hypertensive subjects followed by the LHAHM, with the application of the educative technology, elaborated with basis in the theoretical referencial of health promotion, stages of change, during six months. The results had been collected through the half-estrutturada interview, organized in categories, and analyzed with basis of the experiences of the subjects, in the theoretical referencil, underlying premises in health education and effective literature. Findings: The walked one was the elect modality of physical exercise. In the first meeting, the subjects had disclosed previous knowledge on the benefits of the physical exercise. Among the subjects, tres was in the contemplation, five in the preparation, two in the action, tres in the maintenance and excessively in the termination. After implementation of the technology, eight participants had initiated the walked one. Passed four months of the application of the proposal, we evidence that the group evolved of distinct forms, disclosing stages of training diverse of changes. Conclusions: The Model of Stages of Behavioral Change as a basis for intervention strategies in order to promote adherence in hypertensive patients to exercise, allowed us to identify characteristics of the group, facilitating the encouragement to re-inclusion of physical exercise between the approach control hypertension, and other preventive health. In this context, the educative technology based in the Model of Stages of behavior change if showed efficient, a time that had the awareness of the subjects on the control of the illness, including the practical of the physical exercise. Keywords: Health education, Exercise, Hypertension.

T-301

413 – PARENTS HELPING TO PREVENT HYPERTENSION – A EDUCATIVE TECHNOLOGY IN HEALTH BASED ON MCS

Francisco Getúlio Alves Moreira, Faculdade do Nordeste /FANOR, Brazil; Zélia Maria de Sousa Araújo Santos, CGTES/SESA-CE - Universidade de Fortaleza -UNIFOR, Brazil; Rodolfo Gondim Costa, Universidade de Fortaleza - UNIFOR, Brazil; Jamily Silva Vieira, Universidade de Fortaleza - UNIFOR, Brazil

Objective: To evaluate the behavioral changes in fifteen parents of students from pre-school, in the prevention of risk factors of HAS from the application of educational technology in health (ETH), based on the Model Beliefs. Methods: Search participant in a private school in Fortaleza-CE. Study participants were parents of fifteen students from preschool (3-6 years) of that school, regardless of gender, education, family income, who have physical and emotional conditions to answer the questions and agreed to participate.The field research activities conducted through educational workshops and collecting data through questionnaires and interviews. The data organized into categories, and the analysis based in the assumptions of education in health. Findings: With the implementation of the ETH, presented significant changes in the habits of parents, in addition to the papers made-agent of change and educational multiplier stock in the family. But there were difficulties in the process of change, but the parents were motivated for the prevention of risk factors for HAS itself and the children. Conclusions: The ETH based in MCS shown to be effective because significant behavioral changes, in addition to motivate parents to prevent HAS through a healthy lifestyle. The ETH has enabled the country since the reflection on the need for changes in themselves and in children, as the performance of the roles of agents of change and multipliers. Given the results, consider the ETH valid and should be included in routine practice in health education in schools, in partnership with parents or guardians. Keywords: Hypertension; Lifestyle; Risk Factors.

T-302

415 – THE LIFESTYLE OF THE HIPERTENSIVE ELDERLY – AN ANALYSIS OF THE REPERCUSSION OF EDUCATIONAL HEALTH TECHNOLOGY BASED ON THE BELIEF MODEL

Juliana Ls, FAECE, Brazil; Zélia Maria de Sousa Araújo Santos, CGTES/SESA-CE, Brazil; Joselany Afio Caetano, Universidade Federal do Ceará - UFC, Brazil; Maria Clara Gonçalves de Castro e Silva, Universidade de Fortaleza - UNIFOR, Brazil

Objective: To evaluate the changes in the lifestyle of hypertensive elderly attending a daycare center for older people, called Lar da Melhor Idade, sited in Aquiraz - Ceará. Methods: This study reports a participative research, which aimed The research was done through the implementation of educational health technology, based on the Health Belief Model. Participated in this study, initially, 21 elderly hypertensive patients of both sexes who had physical and emotional conditions to answer the questions and who agreed to participate. During the application of Educational Technology in Health (ETH), four elderly group were absent due to illness, leaving 17 participants. The field research was done through educational workshops, and data collection was done though questionnaires and interviews. The data were organized in empirical categories and was based on the educational presuppositions about health and the pertinent literature. Findings: With the implementation of the educational health technology, significant changes were found in the lifestyle of the majority of the elderly participating in this research, even though a few of them focused only on the susceptibility and severity to which they had been exposed, and were, consequently, unable to accomplish the objectives established by themselves during this research. It is believed that the application of ETH has allowed the elderly to become peer educators, making them capable of promoting self-care and empowering them to promote individual and collective health. Conclusions: We observed changes in lifestyle of some elderly people, who joined the healthy behaviors by participating from ETH, as the practice of physical exercise and regular use of antihypertensive medication, among other measures. So, we considered the implementation of Educational Health Technology efficient, for it allowed significant behavioral changes in the subjects' lifestyle, and also motivated them to prevent and control Arterial Systemic Hypertension and its complications. Keywords: Arterial Systemic Hypertension.

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