HTA for Health Systems Sustantability

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

The HTA Unit of the University Hospital "Agostino Gemelli"

The HTA process, results and outputs

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Member of INAHTA

Policlinico Gemelli IMPEGNO PER L'ECCELLENZA.

Background

- HTA Unit has been involved in HTA at Meso levels for about ten years in order to support decisions making process regarding the introduction into clinical practices of new health technologies

- According to a formal procedure, the staff of UVT support hospitals management in resource allocation decisions producing recommendations using an – HTA - evidence based approach

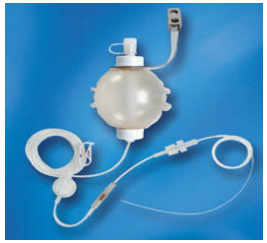
What kind of health technologies are assessed?

New Medical Device

A device available on the market but not still used at Gemelli University Hospital

- Innovative
- High unit cost
- Implantable MD (mainly)

Pain relief system



Medical equipment

- Innovative
- high impact (eg on patient safety, on organization)

Proton therapy

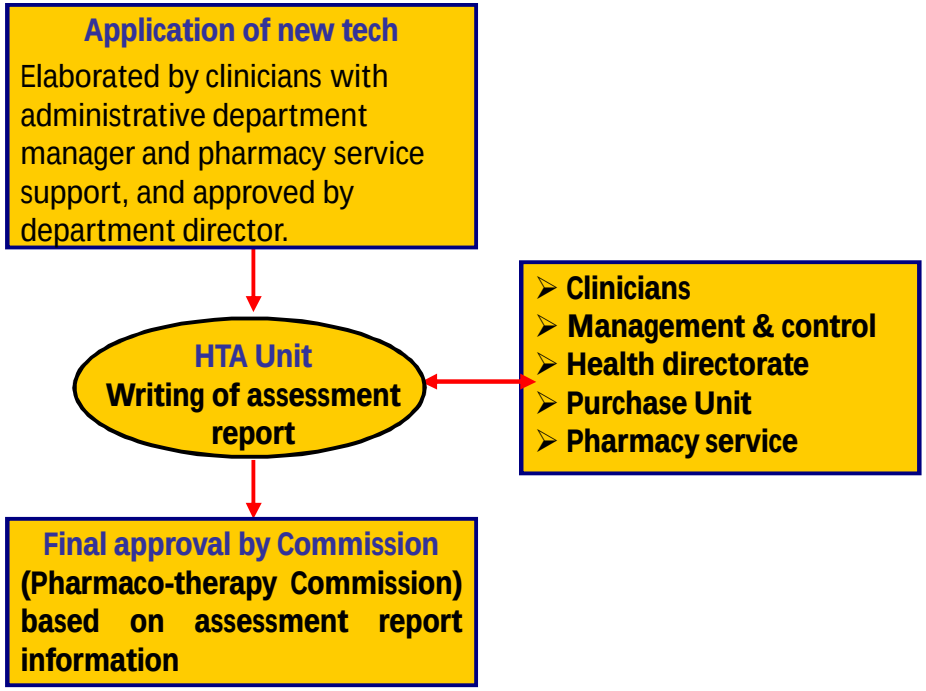
Diagnostic Test

- Innovative
- High unit cost

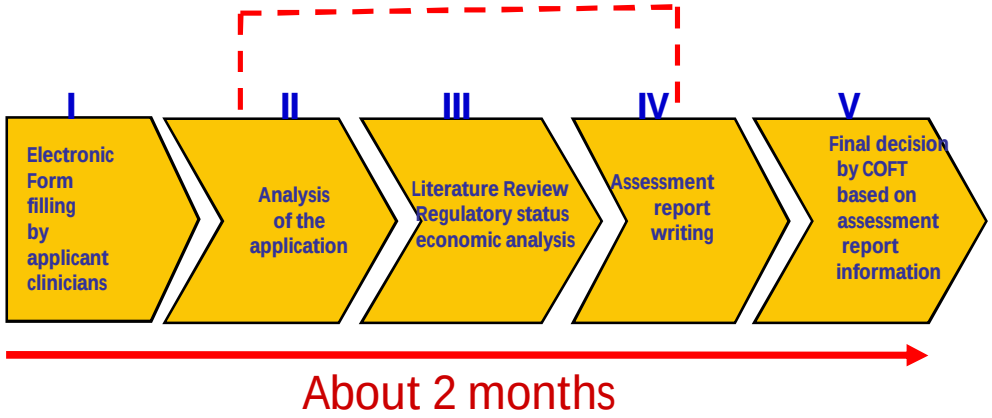
Genetic Test

The work flow

- The procedure starts from a request of a new medical technology (innovative, high cost and not yet used into hospital clinical practice) by a clinical department.
- HTA report are produced where relevant topic for an hospital context are considered
  - decryption of the technology
  - regulatory status
  - systematic review of the evidence
  - Alternatives
  - economics' issues



The Process



HTA Unit is responsible for management and coordination of the phases 1-3

In the **second** phase HTA Unit analyzes the application involving all interested units (Medical Department, Management and Control Unit, Purchase Unit) in order to complete the missing information and acquire a comprehensive view

The **third** phase is the process' core, it involves effectiveness analysis based on literature review, regulatory status (CE mark FDA approval), analysis of organizational impact (eg. additional staff needs) and financial impact (direct and indirect costs and reimbursement system)

The **fourth** phase consists of report writing

The Report

Sections

- Technology description
- Regulatory approval
- Analysis of effectiveness
- Alternatives
- Organizational and financial impact
- Conclusions

Assessment Report of Health Technologies

Required medical technology

Summary

This paragraph introduces the main elements of the report with an aim of explain all essential information for decision making process in an immediate and concise manner.

The Medical Devices

This paragraph includes technical information and ways of utilization for medical device to being evaluated. It is based on manufactures' technical brochure

Regulatory approval

This paragraph analyzes international regulatory approval. Particularly we ceck if medical devices have obtained FDA approval (USA) and the CE Mark (EU).
The aim of this analysis is to verify that the medical devices being evaluated are congruent with safety requirements foreseen by law.

Evidence of effectiveness

This part includes a systematic literature review of the medical device. We examine specialized search engines such as pubmed and Scopus and all databases available for UCSC users. Our aim is to assess if the MD being evaluated are efficient from clinical point of view. High level clinical trials have been carried out an a representative population of patients.

Alternatives

Thought a web search possible alternatives available on the market are analyzed.
Clinicians are also directly asked for this information.

Organizational and economical aspects

This paragraph looks at tow aspects.

- The organizational aspect and the
- Aspect closely connected to costs

From an organizational point of view we analyze possible changes that the introduction of the MD could bring about in terms of:

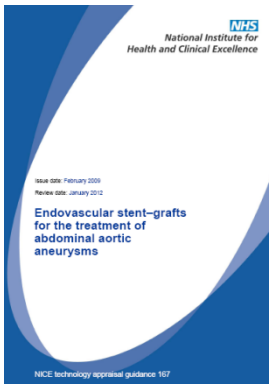
- Staff enlargement o. training.
- New organizational models (patient paths, ..)
- New working area

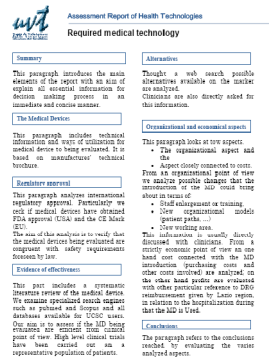
This information is usually directly discussed with clinicians. From a strictly economic point of view an one hand cost connected with the MD introduction (purchasing costs and other costs involved) are analyzed; on the other hand profits are evaluated with other particular reference to DRG reimbursement given by Lazio region, in relation to the hospitalization during that the MD is Used.

Conclusions

The paragraph refers to the conclusions reached by evaluating the varies analyzed aspects.

The Report





Economic assessment/modeling/ budget impact assessment

Expert consultation & involvement

Expert guidance on research methodology

Meta analysis

Literature search - comprehensive

RIGOUR

Cost analysis

Expert consultation

Literature search - selective

HTA full Assessment

Eg. NICE single technology appraisal

Rapid Assessment

UVT report

TIME

Days **Weeks** **1 Month** **About 9 Months**

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The report

- UVT Report contains the results of a rapid assessment on evaluated technology
- The assessment report (2-5 pages) is divided into sections
  - This reflect a multidisciplinary approach,
  - Each section is developed by staffing areas according to competencies
- Two person in charge for HTA activities:
  - 1 clinician in charge (executive manager)
  - Biomedical engineer (manager)
  - Health economist experienced in systematic review conducing (employee)

Focus on technology description

Content

- This section includes technical information and ways of utilization for technology to being evaluated.
- It contains also a brief description of clinical condition to treat trough the technology

Who is responsible? (information collecting and writing)

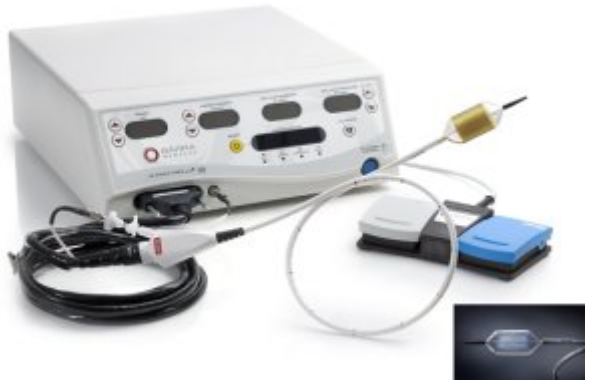
- Both biomedical engineer and health economist

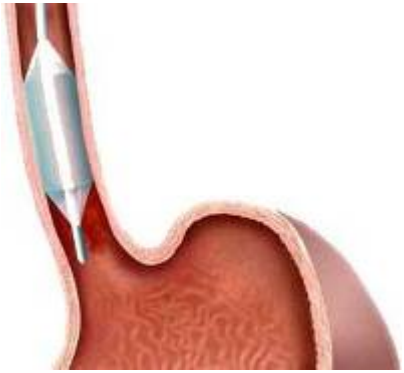
What are the information source?

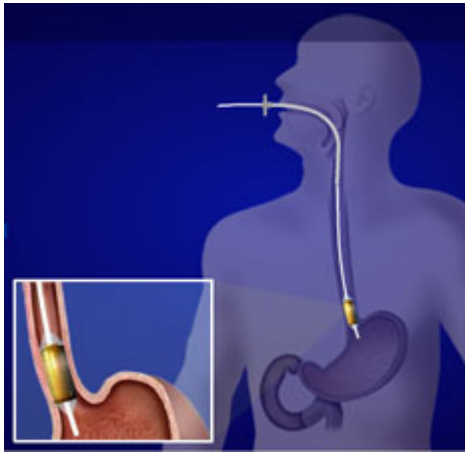
- The technical description is based on manufactures' technical brochure
- The clinical condition description is based on information resulting by internet search (Scientific Evidence, Google, Google scholar, wikipedia)

Focus on technology description: in practice…

- The gastro-endoscopic surgery required the introduction of HALO system developed to treat Barrett's esophagus disease.
- This system is a new option for removal of Barrett's esophagus







Halo system

Focus on technology description: in practice...

The device: Halo system

- Halo system allows the inner diameter of the esophagus to be ablated quickly during an outpatient procedure, with uniform removal of epithelium to a controlled ablation depth. The patient is placed under conscious sedation and a sizing balloon is used to measure the inner diameter of the esophagus. An appropriately sized radiofrequency ablation catheter is selected and introduced over a guidewire in a side-by-side manner with an endoscope. The catheter's balloon is then inflated and energy applied circumferentially ablating the epithelium to a depth of less than 1 mm. The catheter is then removed and cleaned, and reintroduced if necessary.

The condition

- Barrett's oesophagus is a condition where the normal oesophageal cells are replaced with intestinal columnar epithelium, and is commonly diagnosed in patients suffering from chronic gastroesophageal reflux disease (GERD). A normal oesophagus is lined with flat, thin squamous cells and when the oesophagus is exposed to gastric juices these cells become irritated. When untreated, a constant exposure to reflux conditions can cause metaplasia in the oesophagus resulting in the development of intestinal columnar epithelium. Once low- or high-grade dysplasia is present there is an increased likelihood of developing malignancy.

Focus on Regulatory approval

Content

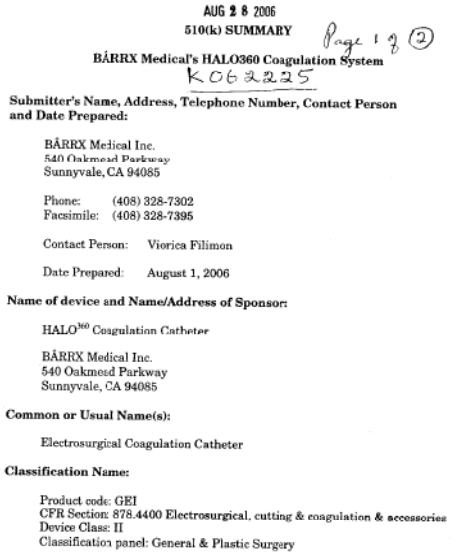
- This paragraph analyzes international regulatory approval. Particularly we check if medical devices have obtained FDA approval (USA) and the CE Mark (EU).
- The aim of this analysis is to verify that the medical devices being evaluated are congruent with safety requirements foreseen by law.

Who is responsible? (information collecting and writing)

- Both biomedical engineer and health economist

What are the information source?

- Internet search for CE mark
- FDA web site for USA regulatory status



AUG 2 8 2006

510(k) SUMMARY

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BÁRRX Medical's HALO360 Coagulation System

K062225

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

BÁRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Phone: (408) 328-7302
Facsimile: (408) 328-7395

Contact Person: Viorica Filimon

Date Prepared: August 1, 2006

Name of device and Name/Address of Sponsor:

HALO^{360} Coagulation Catheter

BÁRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Common or Usual Name(s):

Electrosurgical Coagulation Catheter

Classification Name:

Product code: GEI
CFR Section: 878.4400 Electrosurgical, cutting & coagulation & accessories
Device Class: II
Classification panel: General & Plastic Surgery

In practice...

Regulatory status

The device obtained CE Mark (EU) and FDA approval (K062225)

Focus on clinical effectiveness section

Content

- This part includes a literature review of technology.

Who is responsible? (information collecting and writing)

- health economist experienced in systematic review conducing

The literature review in hospital context shows features distinctive and different from national HTA agency

Trade of between timeless along with paucity of resources and adhesion to strict method

Research question	it refer to the specific technology to evaluate
Search strategy	❖ technology assessed (its brand) AND ❖ technology category terms AND ❖ MESH terms that identify referred procedure
Main limits	Publication date, Languages, Study design

Focus on clinical effectiveness section

Sources

- **Pubmed**
- **UCSC Health Databases (SCOPUS, CINAHL, Cochrane library, HTA, DARE)**
- **Meta databases: mRCT (meta-register of controlled trial).**
- **Grey literature (Scopus, Google and Google Scholar)**

Study identification

Database	Number of identified studies
PUBMED	
SCOPUS	
CINAHL	
mRCT	

Study selection
(title and abstract reading)

Number of studies identified	
Number of studies selected	
Studies design	• RCT • Systematic review • Observational studies • Case report • ecc

Focus on clinical effectiveness section

Summary of results

Identified study	Study design	Number of patient	Patient characteristic	Interventions	Endpoint	Results	Evidence level (GRADE)

Assessing study quality

Application of GRADE (Grades of Recommendation, Assessment, Development and Evaluation)

Grade : A systematic method of assessing the quality of studies included in a systematic review and developing recommendations or guidelines based upon the evidence

Study design is critical to judgments about the quality of evidence.

Randomized trials provide, in general, far stronger evidence than observational studies

Rigorous observational studies provide stronger evidence than uncontrolled case series.

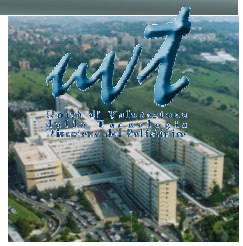
Randomized trials without important limitations provide high quality evidence

Observational studies without special strengths provide low quality evidence

Limitations or special strengths can, however, modify the quality of the evidence of both randomized trials and observational studies

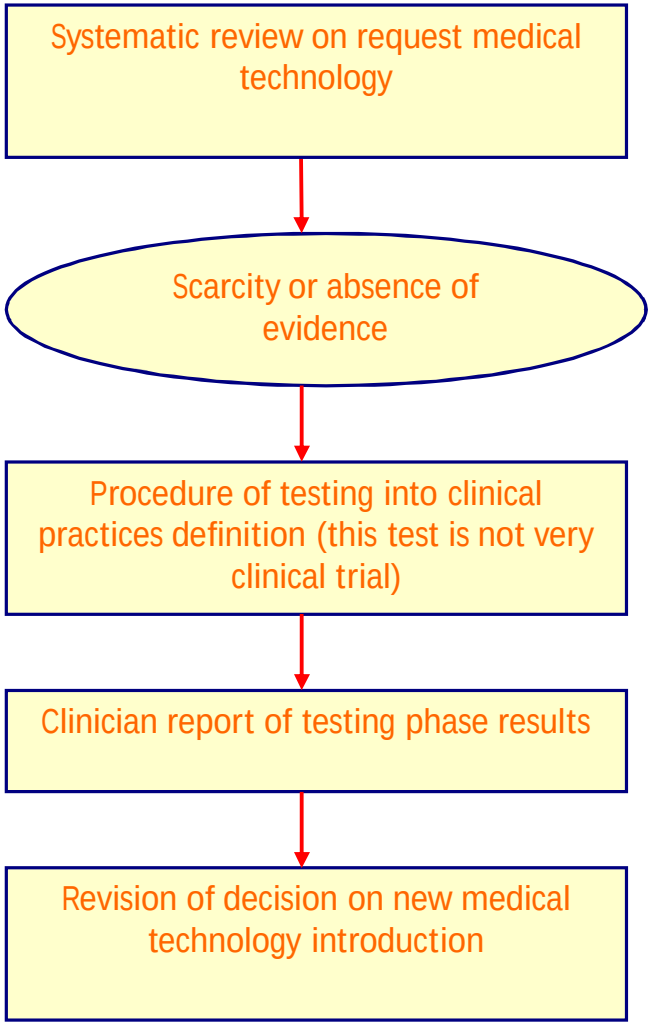
Focus on clinical effectiveness section

Main differences between comprehensive and selected review



	Systematic review (Cochrane)	UVT Rapid Review
Timetable of technology appraisal	6 mounths	One month (maximum)
❖ **Main Phases**	❖ Protocol definition ❖ Search strategies ❖ Study selection ❖ Assessment of methodological quality ❖ Data collection ❖ Analysis ❖ Reporting of reviews	Research question definition Search strategy Study selection Assessment of methodological quality Summarizing and reporting the evidence
Staff involved	**Minimum 5** ❖Clinical expert (initiates, defines, selects topics), ❖Clinical expert (partners in above process and collaborates in review to prevent bias) ❖Statistician ❖Librarian ❖Health care consumer	**1** (health economist experienced in systematic review conducing)
Expert involved in selecting studies	**Minimum 2** (Disagreements about whether a study should be included can generally be resolved by discussion)	**1** (concerns about whether a study should be included can be resolved by involvement of clinician expert in the field)

The impact on medical practices



- **Frequently, we point out scarcity of evidence on which basis to formulate a recommendation because of the evaluated technologies are very new**

- **In these cases we define and elaborate a procedure for testing the new medical technology and to implement a phase of practice trial, together with all Unit involved in the process**

Focus on clinical effectiveness section: in practice…

Search strategy per data base

Pubmed (5/10/2010)

[1] "Barrett Esophagus"[Mesh])) = 3127

[2] "radiofrequency ablation" = 1000

[3] (#2 AND # 1) =18

Limits: Humans, Clinical Trial, Meta-Analysis, Practice Guideline, Randomized Controlled Trial, Review, English, Italian, published in the last 3 years

Scopus (5/10/2010)

TITLE-ABS-KEY(Barrett Esophagus)

AND

TITLE-ABS-KEY(radiofrequency ablation)

AND

((RCT) OR (Randomized Controlled Trial) OR

(Review))

AND PUBYEAR AFT 2007

Clinicaltrial.gov (1/10/2010)

Halo Flex OR Barrx

Focus on clinical effectiveness section: in practice...

Study identification

Database	Number of identified studies
PUBMED	18
SCOPUS	12
mRCT	2

Study selection (title and abstract reading)

Number of studies identified	18
Number of studies selected	10
Studies design	• 1 RCT •2 Systematic review •3 narrative review •2 Observational studies •2 cost effectiveness studies
Level of evidence (per studies typology)	• 1 RCT (moderate) •2 Systematic review (High) •3 narrative review (low) •2 Observational studies (low) •2 cost effectiveness studies (low)
Level of evidence GRADE (mean)*	Moderate

*evidence level is expresses as mean and it is based on author opinion, that assess each studies by GRADE application.

Focus on clinical effectiveness section : in practice...

Evidences summary

A literature search of articles in English was performed using online databases of medical articles and health technology assessment reports. The identified studies listed efficacy outcomes as eradication of metaplasia and dysplasia, relapse rate and reduction in development of cancer. There is however lack of long term follow up data. Moreover from the included studies it is unclear whether circumferential radiofrequency ablation is a suitable alternative to more invasive surgical interventions as none of the studies compared treatment to the current gold standard of oesophagectomy. The patient numbers were low for all studies.

Focus on Alternatives

Content

- This section contains a general market view of technologies that show the same use of assessed technology.
- The aim is to provide a complete information

Who is responsible? (information collecting and writing)

- Both biomedical engineer and health economist

What are the information source?

- Thought a web search possible alternatives available on the marker are analyzed.
- The alternatives are also retrieved in the selected clinic studies
- Clinicians are also directly asked for this information.

Focus on Alternatives: in practice…

Alternatives

Patients with GERD (Gastroesophageal reflux disease) are usually offered:

- oesophagectomy, or
- frequent endoscopic surveillance and re-biopsy (with the aim of detecting neoplastic changes early).

Endoscopic treatments that aim to remove or ablate abnormal epithelium have also been developed, including:

- endoscopic mucosal resection and
- photodynamic therapy

Focus on economic and organizational issues

Content

- This paragraph looks at tow aspects.
  - **Organizational issues**
  - **Economic analysis (costs analysis)**

Who is responsible? (information collecting and writing)

- Both biomedical engineer and health economist with support of the other involved unit (management and Control, Purchase Unit, Pharmacy)

What are the information source?

- Organizational information is usually directly discussed with clinicians
- Costs are asked to purchase Unit

Focus on economic and organizational issues

- From an organizational point of view we analyze possible changes that the introduction of the MD could bring about in terms of:
  - Staff enlargement or training,
  - New organizational models (patient paths, …)
  - New working area
  - …

Focus on economic and organizational issues

- From a strictly **economic point of view** we performed a cost analysis in terms of:
  - direct cost' variation (cost of new technology vs cost of technology actually used)
  - staff cost' variation (if the introduction of the technology implies a variation In staff formation)
  - cost' variation linked resource utilization (if the introduction of the technology implies a variation In resource utilization, eg. Days of hospitalization, time of intervention, standard operative room vs day surgery operation theater)
- The costs are linked to profits resulting from DRG reimbursement given by Regional Government, in relation to the hospitalization during that the technology is Used.

Focus on conclusion and recommendation

- The paragraph refers to the conclusions reached by evaluating the varies analyzed aspects.
- It contains also a recommendation to decision maker. The recommendation is not mandatory for the decision makers.

In practice…

The Halo system is formed by a generator and single used devices.

Costs

- The capital cost of the generator doesn't charge because the distributor will give it in loan for use modality.
- We expect that on average patients will have 2 ablation sessions (1 circumferential and 1 focal).
- The presumed 75 session per year cost about € 175.000 yearly.
- These costs are totally extra costs because the esophagectomy, for Barrett iperplasia doesn't' performed at Gemelli University Hospital.

To these costs we had to add the other related costs of human and hospital resources.

Reimbursement

- These Actually a specific DRG for radiofrequency ablation doesn't exist in Italy, and the applicable code of oesophagus resection doesn't cover the costs of the disposable device.

Focus on conclusion and recommendation, in practice...

- The include studies confirms that RFA is an effective treatment for extensive grade esophageal dysplasia although the effectiveness proof is insufficient.
- The main problem linked to the introduction of the system is economics one.
- In the absence of increased funding for this procedure from government, about 10 procedures per year should be permitted and at the end of the year this decision must be reviewed.
- Because of the paucity of follow up data, this report should be the considered for update within approximately 1 years

Conclusion

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

- **What about the methods?**
  - Hospital Based HTA is seems even more to be a particular HTA activity that has its own peculiar characteristic
- **What about the impact?**
  - Hospital Based HTA, according to the 10 years of experiences of University Hospital Agostino Gemelli HTA Unit represents a powerful tool to support decision making process and management activities in the health care organizations
- **Future prespective**
  - A diffusion of the Hospital Based HTA is expected linked to traditional HTA activities at central level: networking is welcomed
  - Creation of a specific Hospital HTA culture seems to be necessary

Thank you for your attention

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