



Ten years of essential drugs list in Brazil using evidence-based methodology

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Coordination COMARE

Declare no conflicts of interest with the information
in this presentation

Medicines in world....

INCREASING NUMBER OF DRUGS



1% INNOVATIONS OF CLINICAL RELEVANCE



DEVELOPMENT OF FAMILIES OF ME-TOO

But.....



EMA + FDA – 2010
More drugs approved than 2009

MEDICINES IN BRAZIL - 2011

- 66.524 commercial products
- 8 000 brands of medications delivering 2 000 drugs
- Drugs registered in Anvisa - June 2009 :
 - Biological – 403
 - Homeopathic – 200
 - Herbal – 512
 - Allopathic
 - Similar – 7952
 - New – 1457
 - Generics - 2730

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MEDICINES IN BRAZIL - 2011

- High number of drugs
- Drugs unacceptable risk / benefit ratio
- Pharmaceutical industry aggressively markets products to various sectors - primarily to the prescriber

12 national strategies to promote RUD

1. Mandated multi-disciplinary body to coordinate medicine use policies
2. Evidence-based standard treatment guidelines
3. Essential Drug Lists based on treatments of choice
4. Drug & Therapeutic Committees in hospitals
5. Problem-based training in pharmacotherapy in under-grad. training
6. Continuing medical education as a licensure requirement
7. Supervision, audit and feedback
8. Independent drug information e.g bulletins, formularies
9. Public education about drugs
10. Avoidance of perverse financial incentives
11. Appropriate and enforced drug regulation
12. Sufficient govt. expenditure to ensure availability of drugs, equip, staff



LIST OF ESSENTIAL MEDICINES

- ❖ Federal essential medicines list provides guidance:
 - ✓ preparation of drug lists state and local
 - ✓ rational prescriptions
 - ✓ guide and direct pharmaceutical production
 - ✓ scientific and technological development in the country
 - ✓ mechanism of reduction of cost of medicines

CHRONOLOGY

RENAME

1973

1980

1998

1999

2002

2006

2008

2010

1st - RENAME

National Drug Policy

2nd - Review

3rd - Review

4th - Review

5th - Review

6th - Review


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graph TD; A[MINISTER OF HEALTH] --> B[Secretariat Science, Technology and Strategic Resources - SCTIE]; B --> C[DEPARTMENT OF PHARMACEUTICAL ASSISTANCE - DAF]; C --> D[COMARE];
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MINISTER OF HEALTH

Secretariat
Science, Technology and
Strategic Resources - **SCTIE**

DEPARTMENT OF
PHARMACEUTICAL ASSISTANCE -
DAF

COMARE

COMARE – 24 MEMBERS

- 8 - Universities
- 3 - Professional Associations (CFF, COFEN, and AMB)
- 2 - Scientific societies (SBMF, SOBRAVIME)
- 2 Administrative staff of the SUS (CONASS; CONASEMS)
- 1 – PAHO
- * Representatives of 8 MS (DAF / SCTIE, DECIT / SCTIE, SAS, SVS, DES, INCA, ENSP, NASS)

Requirements of members of the commission of drug selection

- WAIVER OF CONFLICT OF INTEREST
- SCIENTIFIC AND PROFESSIONAL CAPACITY

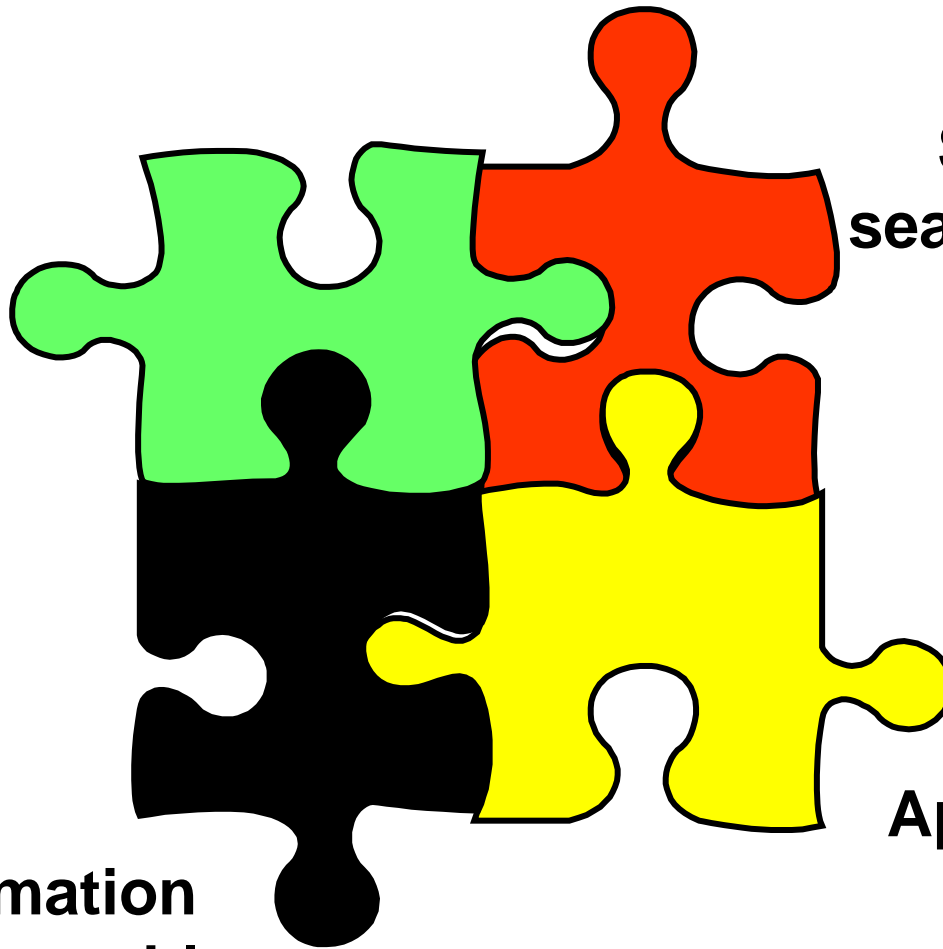


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CAPACITY SCIENTIFIC AND PROFESSIONAL

Critical appraisal

Standard search method

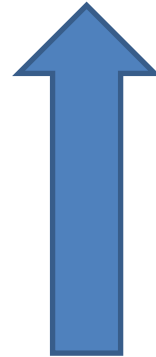


Convert information needs into answerable questions

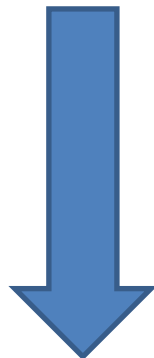
Apply evidence in context of Brasil

1st – CHALLENGE

Multiple view



- Multiprofessional
- Different way to understand the problem



- Different background
- Differing critical appraisal skills
- Lack of experience with local health service

STRATEGY ADOPTED



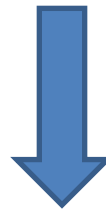
A - Workshop – Trainee



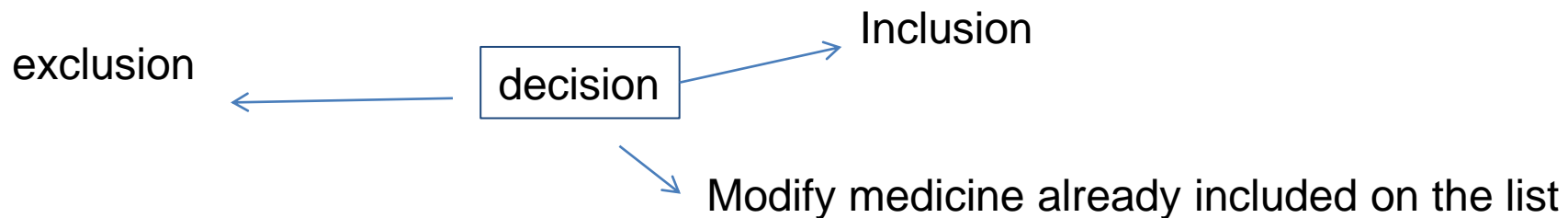
- Standardization:
 - Search methods – same database or library
 - Choose which kind of study to include to make decision
 - Report and presentation

B - Assessment of the medicines

Two members – blind



PRESENT TO ALL MEMBERS



2nd - CHALLENGE...

➤ INFORMATION OF THE DATA IS NOT AVAILIABLE OR IS NOT EASY TO GET

- ANVISA – approved indication of drugs
- DATASUS – epidemiology of disease, mortality
- DATABASE - prevalence of use of drugs or resistance from medicines

3rd CHALLENGE: inconclusive analysis

Criteria of selection

Effectiveness

Comparative assessment of several drugs that uses evidence-based evaluation

Safety

Convenience

Cost - effectiveness

Exclusion Criteria for selection

Drugs with similar efficacy and safety
(avoiding duplication)

Recent introduction in the market

Insufficient experience of using

unknown effectiveness
(no measure of clinical outcomes in trials relevant
adequately powered randomized clinical trial)



Examples

FORMOTEROL

- Effectiveness ++ ?
- Safety +?
- Convenience +
- Cost - little less
- Products (number of companies) +++++

SALMETEROL

- Effectiveness + ?
- Safety ++?
- Convenience +
- Cost – little more
- Products (number of companies) +

RENAME - BRAZIL compared to EML - WHO

Lists	Number of medicines	Number of medicines EML - WHO	Number of shared medicines
RENAME 2000	323	11 ^a (1999) – 306	198 (61%)
RENAME 2002	327	12 ^a (2002) – 326	218 (66%)
RENAME 2006	371	14 ^a (2005) – 312	220 (59%)
RENAME 2008	384	15 ^a (2007) – 340	220 (55%)
RENAME 2010	384	16 ^a (2009) - 342	220 (57%)

4th – CHALLENGE.... How to review requests from the community?

State and Municipal Secretariats

Strategic Program Ministry of Health

industries, hospitals and the community

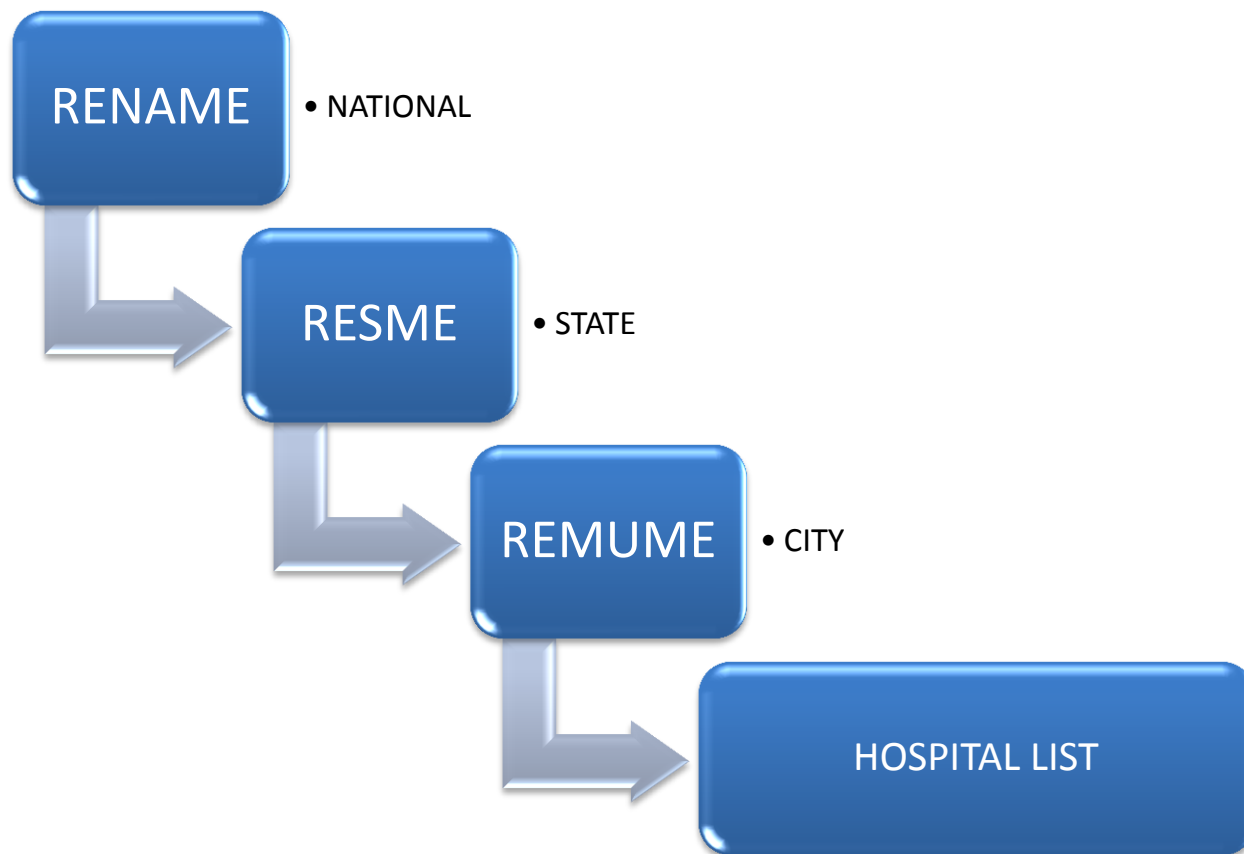
Team of Formulary Therapeutics National

In addition: Analysis not carried out in previous editions



PRIORITIZATION WORKSHOP

❖ 5th – CHALLENGE.... How to become RENAME an oriented instrument standardization ?



❖ State and municipal lists of drugs

- ✓ Variation between the 3 capitals surveyed (presence of medicines from the list in prescription)
 - 25.7% to 92.9% for REMUME
 - 45.4% to 88.2% for the RENAME
- ✓ Municipal and state lists - drugs with unacceptable risk / benefit ratio – out of essential criteria
 - cimetidine
 - celecoxib

Possible explanations for variation....

- ✓ Ignorance of the list of drugs by various management sectors of SUS
- ✓ Lack of adherence of practitioners to prescribe drugs from the list;
 - ✓ Ignorance, prejudices ingrained prescribing habits and the influence of drug advertising.
- ✓ Professionals who serve in different sectors (public, health insurance, private) have different behaviors in different roles



Obrigada!

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