

**Evidenced-based medicine (EBM) program  
for a Health Plan in Brazil**  
coverage criteria for new technology-based interventions: an update

**13<sup>th</sup> Cochrane Colloquium**

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# UNIMED - Brazil

- 25% of Private Health Care
- Cooperative of physicians
  - 96.000 members – all share holdings
  - 11.000.000 patients
  - 3.600 hospitals
  - Divided in regions (381)

Region 1	Region 2
2.100.000 inhabitants	400.000 inhabitants
10 cities	11 cities
2.627 physicians	524 physicians
26 hospitals	14 hospitals
420.000 patients	105.000 patients

# Health Plans

- Regulated by Brazilian laws
  - How much the patients pay
  - Reimbursement
  - Coverage of medical procedures/treatments
    - Exclusion of “experimental treatments”
- Challenges
  - Inclusion of new technologies
  - Lack of clear definition of “experimental” treatments
  - Limited financial resources

# Pressure for New Technologies

- Financial interests
- Personal interests
- Lobby influences
- Expert opinions
- Administrative criteria

# Inclusion of New Technologies

- Pressure for incorporation into clinical practice
  - Pharmaceutical industry
  - Medical equipment industry
  - Media
  - Patients
  - Colleagues

# How do a regular Health Plan manage new technologies in Brazil?

- Lack of EBM knowledge
  - Subjective criteria
- Lobby influences – interests
  - Expert opinions
  - Administrative opinions
  - Patients / media demands
- Evaluation of ‘price’
  - Lack of economic evaluation

# Consequences

Lack of the best care

- Patients
  - Hazardous or ineffective treatments
- Management
  - Waste of resources
  - Open to law suits
- Physicians
  - Continuity of errors
  - Open to law suits



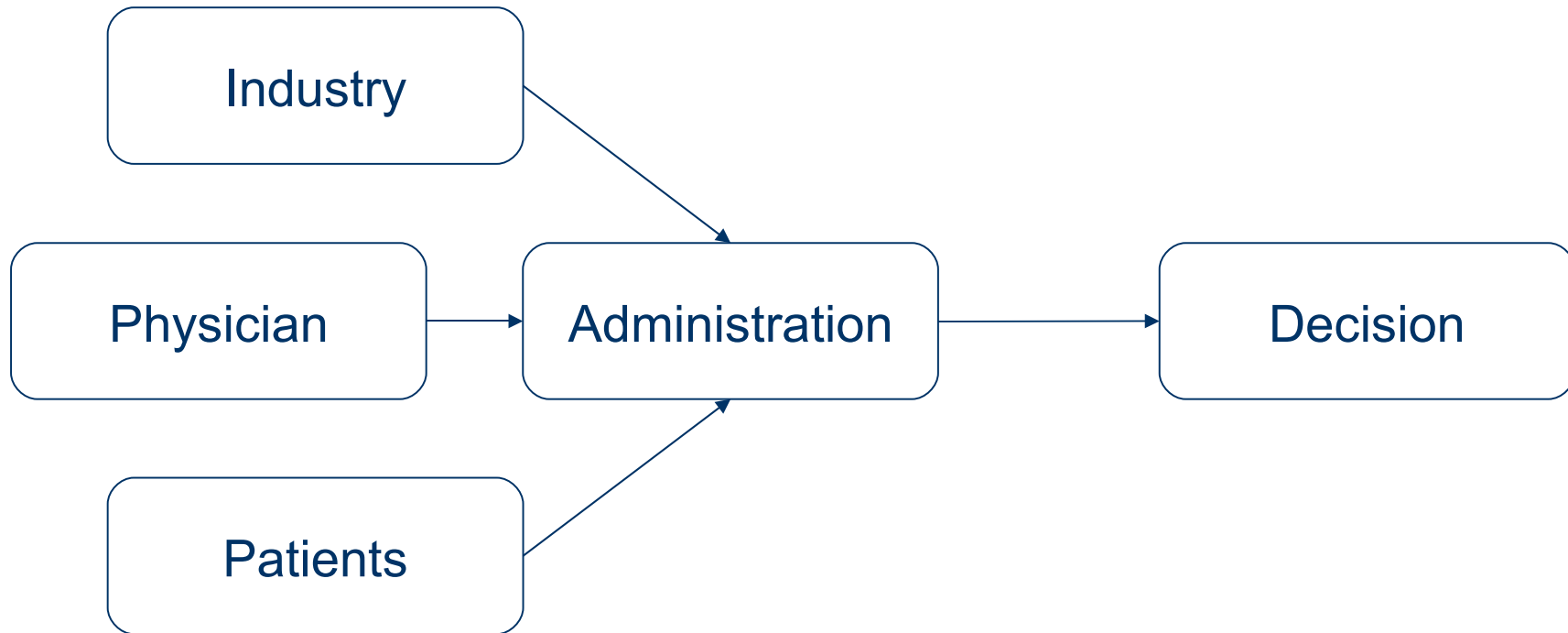
# Evidence-based program: How to adopt new procedures

- Evaluation
  - Science based
  - Provide best care to patients
  - Avoid experimental treatments
  - Safety to physicians and health plans
  - Makes audit easier

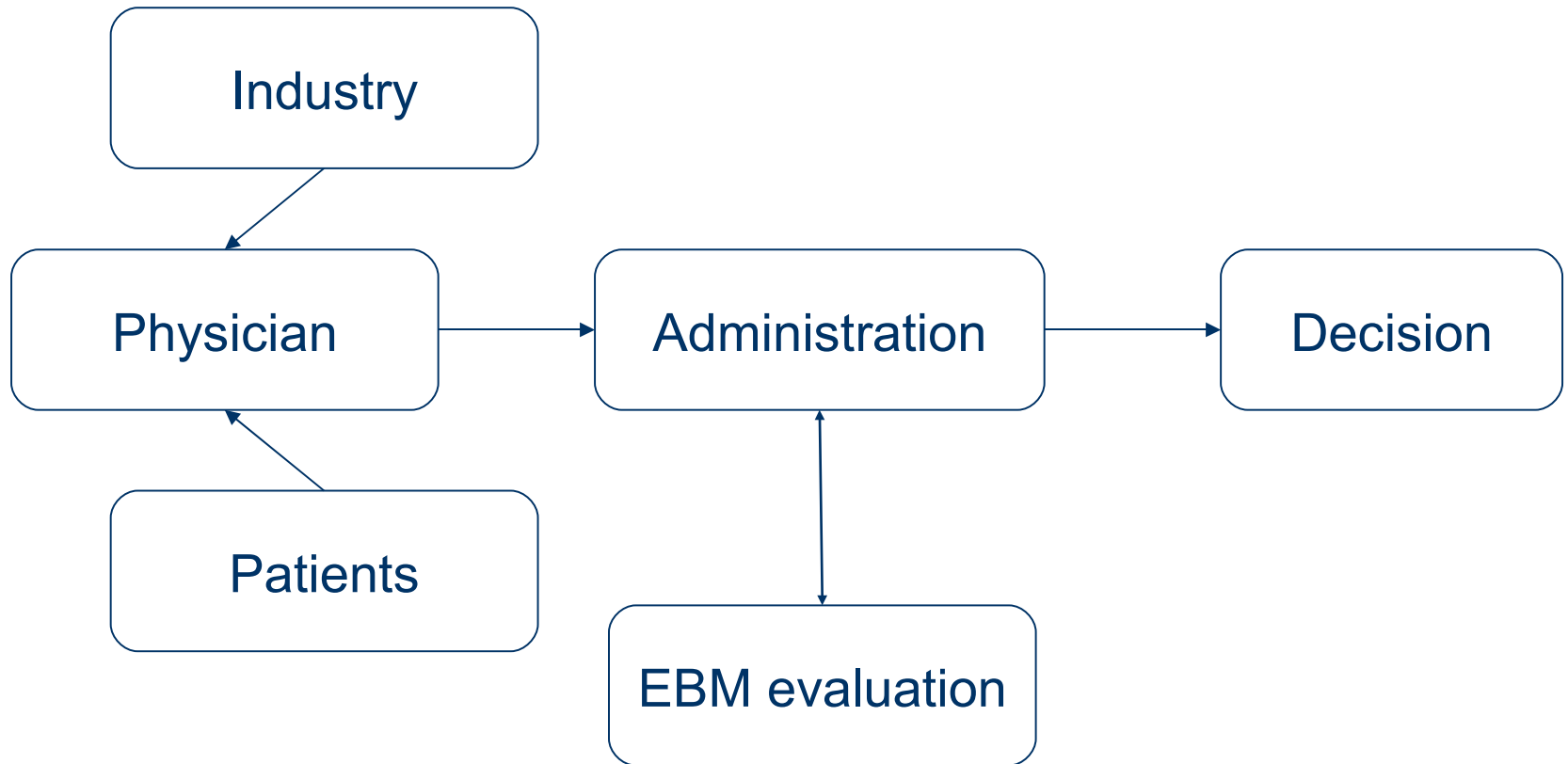
# EBM Program

- Group of EBM trained physicians
  - with knowledge in SR (publications)
- EBM teaching experience
- Access to administrative board

# Decision to incorporate new procedures (before)



# Decision to incorporate new procedures (nowadays)



# EBM program

- Evaluate physicians' applications and arguments
- Evaluate initial position of administration
- Search literature
- Written report of best evidences found with recommendation for or against coverage

# EBM Research

- Computerized literature databases
  - MEDLINE
  - LILACS
  - DARE
  - CENTRAL
  - MD Consult
  - Clinical Evidence
  - HTAi
  - EBM Online
- Clinical Guidelines
  - AMB (Brazilian Medical Association)
  - National Guidelines Clearinghouse
  - International regulatory entities (FDA)

# Methods

- Evaluation period: 21 months  
(07/2003 to 03/2005)
- 149 applications
- Individual analysis of each one

# Critical evaluation of literature

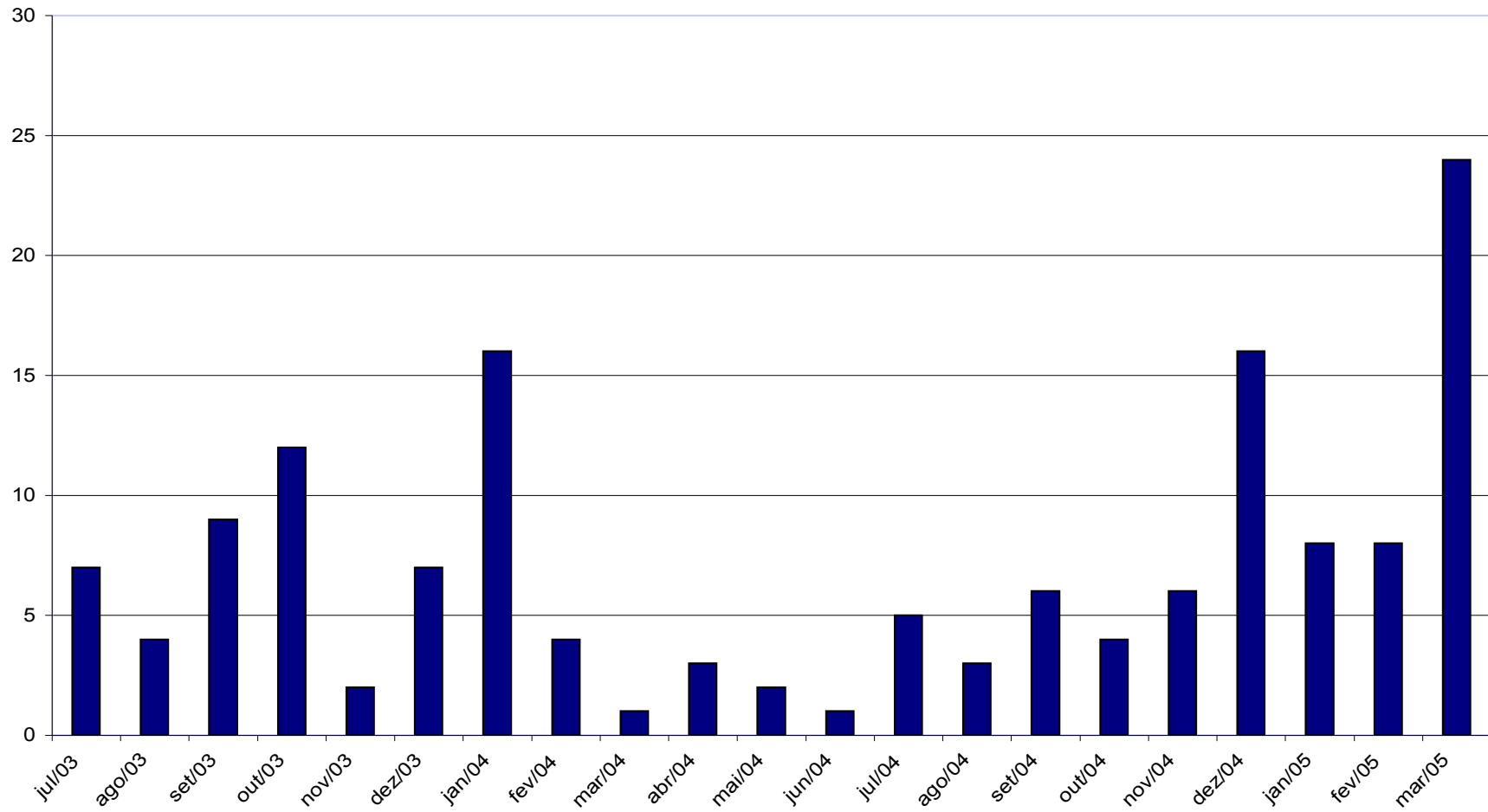
- Are the results valid?
- Are the results important?
- Are the results applicable to our patients?



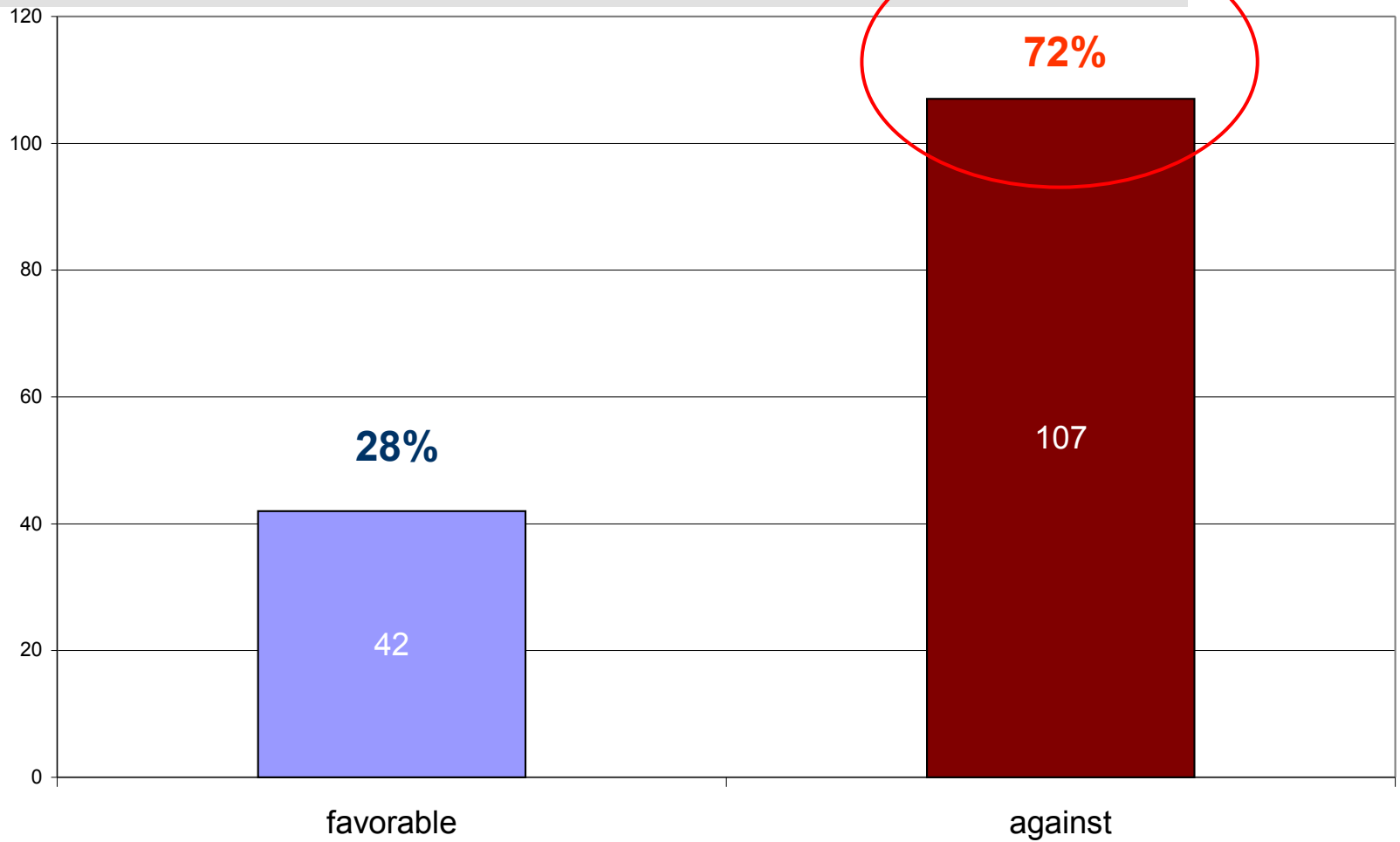
# Analysis

- Final EBM report
  - Experimental
  - Ineffective
  - Effective
  - Same effect as standard

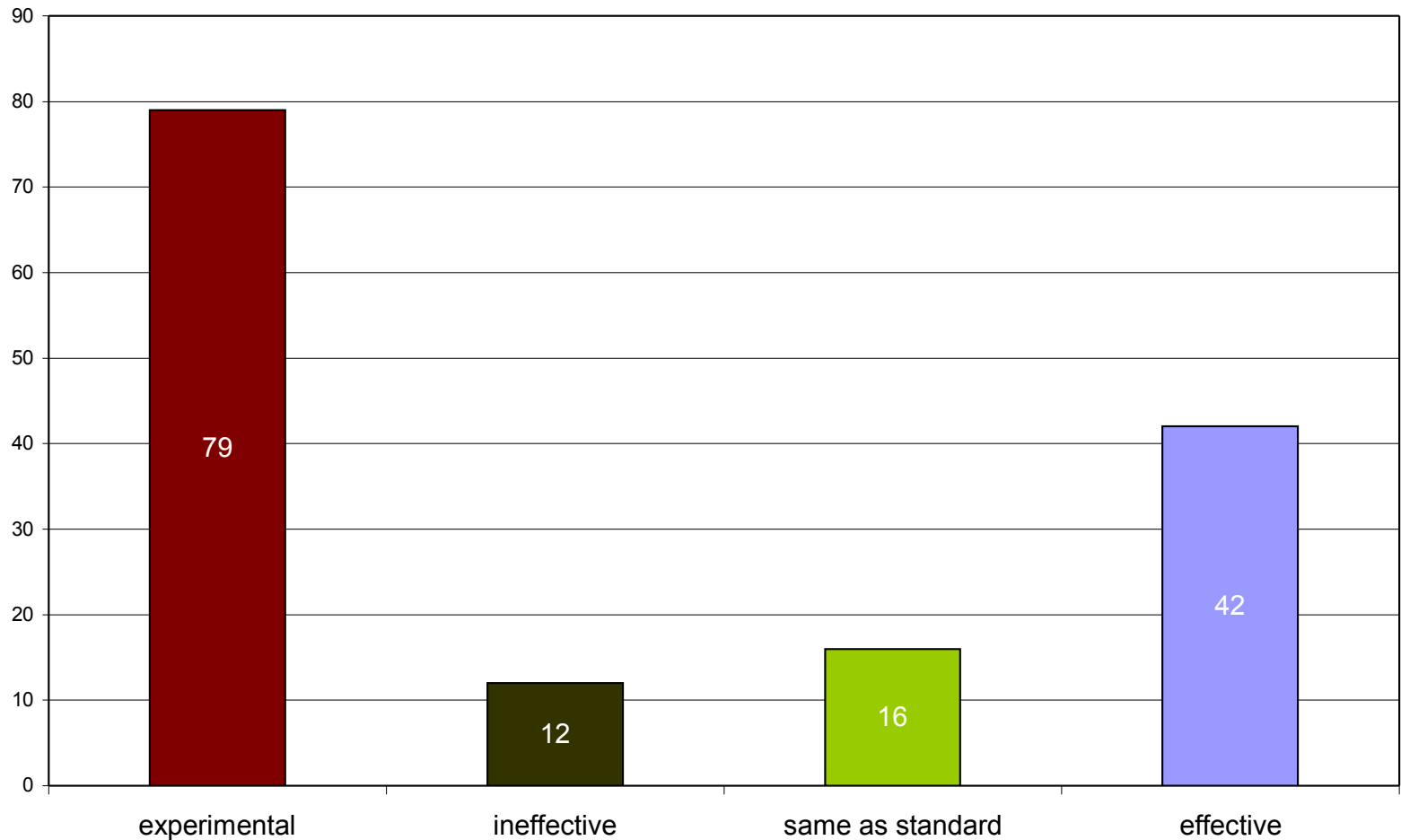
# Monthly evaluations



# Conclusion from EBM report



# Conclusion from EBM report



# Analysis

- Evaluation of references and scientific material sent as support to the application
  - Clinical trials
  - Clinical guidelines
  - Advertisement
  - Unpublished study
  - Expert opinion
  - No references sent

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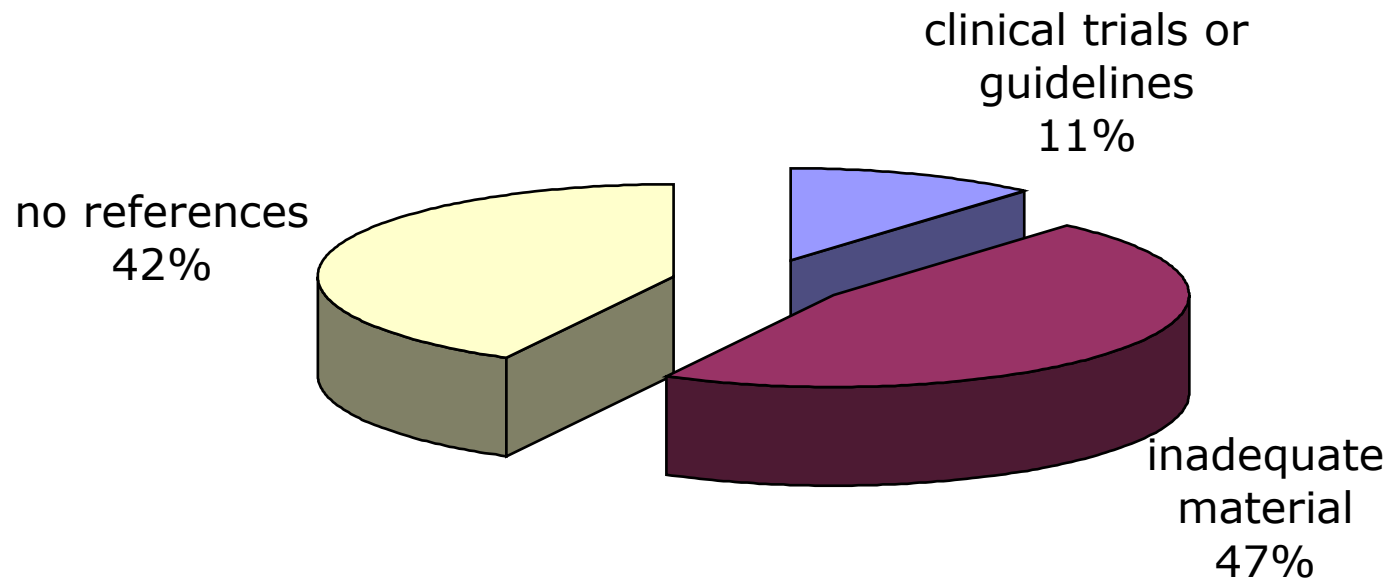
**Adequate material**

# Analysis

- Evaluation of references and scientific material sent as support to the application
  - Clinical trials
  - Clinical guidelines
  - Advertisement
  - Unpublished study
  - Expert opinion
  - No references sent

**Inadequate material**

# Quality of references sent – total





# Quality analysis

- Applications based on low-quality bibliography or no references
  - 132 applications (89%)
- EBM team research:
  - high quality trial (RCT or SR) for 92 items
  - 35 (27%): considered effective
  - 57 (43%): ineffective or experimental
  - 40 (30%): no studies found (experimental)

# Quality analysis

- Applications based on adequate literature
  - 17 applications (1 based on a Cochrane Review)
- Final conclusion
  - 7 considered effective
  - 7 experimental
  - 2 same efficacy as standard
  - 1 ineffective
    - The only one based on a Cochrane review

# Economic analysis

- 8 new procedures with recommendation against coverage
  - Estimated use of standard
  - Estimated substitution by new (as opposed to truly better) drugs and medical devices

# Economic analysis

Universe of 500.000 patients (estimative)

New peocedure	Estimated use (in a month)	Cost of standard (in a month)	Cost of new (in a month)	Annual potential savings
Levosimendan	250	6.092,50	711.010,00	8.459.010,00
Metalyse	17	5.920,26	57.260,50	616.082,93
portocath	24	9.909,31	17.560,14	91.810,00
stent com rapamicina	37	99.000,00	480.333,33	4.576.000,00
Parecoxib	11660	53.869,78	361.110,20	3.686.885,07
cateter Spiral	130	0,00	1.300.000,00	15.600.000,00
Sling transobturatório	47	82.513,67	163.013,67	966.000,00
Sling suprapúbico	47	82.513,67	163.013,67	966.000,00
			<b>Total</b>	<b>34.961.788,00</b>

**US\$ 15.9 million**

# Conclusions

- Recommendation of EBM training to all physicians
  - 90% of physicians don't justify their clinical decisions appropriately
  - Most physicians don't understand results coming from clinical trials.
  - Most physicians use pharmaceutical advertisement material to support their clinical decisions

# Conclusions

- An EBM program adds reliability and efficiency in standardizations inside a health plan administration
  - Gives the best evidence for physicians and patients
  - Avoid experimental treatments
  - Optimize resources allocations
  - Brings more safety to the physicians and to health plan administrator
  - Makes audit process easier

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