W5: VALUE ASSESSMENT FOR MEDICAL DEVICES: LATIN AMERICAN PERSPECTIVE.

The Health Insurer perspective.

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CEMIC

Background.

- CEMIC (Centro de Educación Médica e Investigaciones Clínicas "Norberto Quirno")
  - *Is a non-profit organization dedicated to health care, research, and teaching.*
  - *It hold a health insurance with 25.000 affiliates, two teaching hospitals, and a University.*

The opinions expressed in this presentation are the author's own and do not reflect the view of the CEMIC.

Background.

- Argentina (WB data-2015)
  - *Total population: 43,417,765*
  - *Health expenditure: 4,8% of the GDP (total GDP 584.711 Billion US$)*.*
  - *Health system in organized in three subsystems:*
    - Public (mostly used by the uninsured population -38%-)
    - Social Security (formal workers, retired and their families -50%-)
    - Private insurances (people who can afford the payment -12%-).

*Recent unpublished estimations are between 8 and 9%

Background.

- Superintendence of Health Services (SSS) regulates Private Insurances and Social Security organizations.
  - *Since 2002, PMO (Compulsory benefit program) is the basic health benefit package that sets the mandatory minimum coverage. It states:*
    - 100% coverage for some devices listed by generic name: stents, pacemakers, etc.
    - 100% coverage for given procedures that involve the use of a medical device.
    - 100% coverage for internal and permanent prostheses.
    - 50% coverage for external orthotics and prosthetics.

For all above, the mandatory covered or reimbursed amount will be equal to the lowest price in market, imported alternatives are allowed when there is no national alternative.

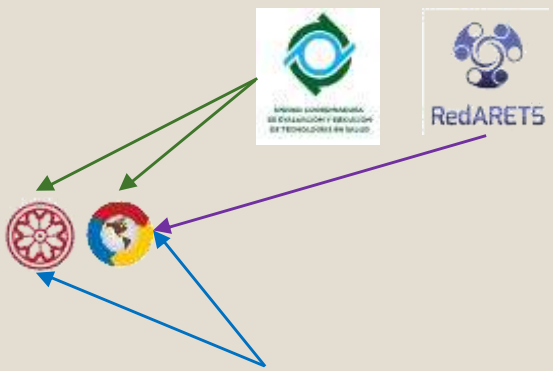
MoH statements about HTA in Argentina.

- Is considered an effective analytical tool that estimates the value and relative contribution in the improvement of health of the application of a technology.
- Provide rational, transparent and evidence-based information to support to the decision making process.
- Evaluation and updating process of PMO should be based on systematized and detailed analyzes of evidence to ensure the proven effectiveness of any diagnostic or therapeutic product or procedure to be financed by the National Health Insurance System.
- Specifically, that process should be based on evidence-based medicine and include cost-effectiveness and cost-benefit analysis, in order to assess the evidence that supports the incorporation and/or exclusion of technologies.

In July 2016, the MoH brought a Bill to the Congress proposing the setting-up of a National HTA Agency (AGNET).

http://www.sssalud.gov.ar/archivos/web/documentos/5262_2914.pdf
http://www.senado.gov.ar/parlamentario/comisiones/verExp/82.16/PE/PL

HTA in Argentina.



Public HTA networks

Academic non-governmental organizations

Everyday decision making process.

- The Law states minimum requirements:
  - *we must reimburse or cover 100% of prosthesis and some procedures including the use of a medical device (I.E. radiofrequency ablation for arrhythmias).*

How do we decide between the different options offered by the market?

Everyday decision making process.

- As health insurers, health providers and research institution we must maintain the balance between different goals:
  - *Provide high quality and equitable healthcare.*
  - *Manage resources in the most efficient possible way.*
  - *Allow innovation and development of new scientific evidence.*
  - *Maintain and enhance professional practice.*
  - *Maintain and increase the insured population satisfaction.*

We take into account: the law, the health problem, the patient context, the state of the art, our goals and the available evidence.

When life is easy.

- There is only one option for the treatment of a given condition supported by evidence and/or eligibility criteria for the use of a high-cost technology is stated in SUR
- Clinical practice guidelines support one option/device.
- The available evidence demonstrate the clinical effectiveness of a given device:
  - *High quality studies compared devices head to head reporting efficacy, safety and clinical effectiveness.*
  - *Indirect comparison's or observational studies report efficacy, safety and clinical effectiveness.*

But things usually aren't easy…

- There is a lack of evidence.
- Evidence development is slower than the production and replacement of medical devices.
- Different physicians' prefer different devices, and that choice is not always evidence based.
- Companies replace devices with newer versions ruling out the option of using the “old” one.

In absence of evidence, what we do?

- We set a limit to reimburse according to law and we leave the choice of the device in hands of the physician and the patient. Patient pay the difference out of pocket.
  - *It doesn't work for:*
    - Very expensive devices
    - When there is only one option in the market

Actions to improve our decision making process.

- Agreement with the physicians to define which patients will benefit the most of the use of new and expensive devices.
- Risk-sharing agreements.
- Real world evidence development.

Muito obrigado
Thank you
Gracias

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