Health Technology Assessment: What are the key challenges to assess medical devices?

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From «Does it work?» to «Is it worth?»

- Over the past decades, the quality of clinical evidence has become the primary criterion for accepting and funding technologies (i.e. capacity to benefit from the technology)
- Increasing concerns around healthcare costs escalation has brought the attention of policy-makers to combine clinical effectiveness to economic efficiency (i.e. capacity to benefit from the technology per Euro spent)
Health Technology Assessment

• HTA is a multi-disciplinary process studying the medical, economic, social and ethical implications of diffusion and use of health technology aimed at informing policy-decisions to efficiently allocate scarce resources

• Economic Efficiency and Clinical Effectiveness dominate HTA activities and economic evaluation studies, namely Cost-Effectiveness Analysis, normally make the most of HTAs
A large number of organisations undertake or commission HTAs across the world and many of them increasingly link HTA to a particular decision about reimbursement, coverage, access and use of technologies.
Countries using HTA as an explicit assessment tool

Australia
Belgium
Brazil
Canada
Croatia
Denmark
Finland
France
Germany
Hungary
Korea
Italy
Mexico
Netherlands
Ireland
New Zealand
Norway
Portugal
Poland
Slovakia
Sweden
Taiwan
UK
USA
HTA: is it an accomplished task?

• Although largely diffused, several challenges remain unsolved when assessment of MDs is at stake:
  – Source and quality of clinical evidence
  – Learning curve in the use of devices
  – Uncertainty about final outcomes
  – Time of assessment
  – Organisational implications
Source and quality of clinical evidence (1)

- Meta analysis
- RCT
- Cohort studies
- Case series
- Animal research
- In-vitro research

Increasing validity
Are experimental studies always the golden standard for MDs?

- Unethical (when evidence is clear)
- Not possible (e.g. surgical procedures)
- Difficult (e.g. patients refuse randomisation)
- What do we compare?
  - Clinical effectiveness of new program vs. current practice? Or inexperience with the new program vs. experience of the current practice?
  - Learning curve poses the question of uncertainty about final outcomes and timing of assessment
Timing of assessment

• Buxton’s Law*: “It is always too early [for rigorous evaluation] until, unfortunately, it’s suddenly too late”

Organisational implications

- Many technologies are likely to have relevant organisational implications once introduced in clinical practices (e.g. new skills to be developed, new way of delivering same services, modifications of inter-professional relations, logistics,..)
- In a recent literature review, only one article out of 210 addressed the organisational aspect of HTA*

What can be done?

• Develop international standards for the level of evidence required for each risk category of device* (e.g. IRFMD)

Methods for Health Technology Assessment of Medical Devices: a European Perspective

The focuses of the MedtecHTA is on improving the existing methodological framework within the paradigm of Health Technology Assessment (HTA) for the assessment of medical devices, and to develop this framework into a tool that provides structured, evidence-based input into health policies. The project aims at filling the gap on the current research debate on the challenges to the available methodological framework for HTA when applied to medical devices.

The MedtecHTA project is expected to make a substantial contribution for a wide range of key stakeholders (policy makers, scientific community, HTA agencies, healthcare providers, medical device industry and patients) to make informed decisions concerning the cost-effectiveness and appropriate use of and patients’ access to medical devices.
MedtecHTA Work Packages

WP1. Cross-country analysis of HTA practices for medical devices
WP2. Geographic variation in access to medical devices
WP3. Comparative effectiveness of medical devices
WP4. Economic evaluation and HTA
WP5. Uncertainty and value of information analysis for medical devices
WP6. Organizational impact of medical devices: development of survey and empirical analysis
WP7. Recommendations on HTA methods for medical devices
What can be done?

- Develop international standards for the level of evidence required for each risk category of device* (e.g. IRFMD)
- Consider evidence generation as a continuous process, spanning the pre-launch and post-launch phases (e.g. EXCITE)
The first harmonized, pre-market evaluation programme in the world for medical devices

By combining studies and generating evidence to satisfy regulatory and HTA processes simultaneously, EXCITE is making these processes less expensive and shorter

The program offers:
- field evaluation and clinical trials to satisfy regulatory/licensing criteria (safety and efficacy) and assessment of clinical utility within the health care system;
- systematic review of competing technologies;
- economic analysis to determine whether the technology is cost effective and a budget impact for the health care system.
What can be done?

- Develop international standards for the level of evidence required for each risk category of device* (e.g. IRFMD)
- Consider evidence generation as a continuous process, spanning the pre-launch and post-launch phases (e.g. EXCITE)
- Develop Coverage with Evidence Development (CED) schemes (e.g. Centers for Medicare and Medicaid Services, USA, OHTAC, Canada)
Coverage with Evidence Development

- CED is used in situations where there is insufficient evidence to make a definitive reimbursement decision.
- Normally, temporary funding is provided while more evidence on effectiveness (and cost-effectiveness) is gathered, with the intention of confirming, or removing, funding at a later date.
- This approach is particularly well-suited to devices, as often evidence of effectiveness is sparse at the time of market entry for devices and also the learning curve means that final device performance will only be known after use in regular practice.
Predictions for the Future

- Tougher pre-market controls, especially for high-risk devices
- More extensive post-marketing surveillance, including mandated registries
- Medical devices will be required to demonstrate evidence of cost-effectiveness in an increasing number of jurisdictions, including emerging markets
- There will be increased collaboration between regulatory agencies and payers on evidence requirements, in some cases on an international level
- The balance of evidence generation will be post-launch, as opposed to pre-launch for drugs (e.g. through ‘coverage with evidence development’)
- The implementation of cost-effectiveness findings will be primarily through the agreement of hospital/out-patient care reimbursement rates and physician fee schedules
- Budget Impact Analysis would be further required
Thank You

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