Health Technology Assessment of Medical Devices in Low and Middle Income countries: 
challenges and opportunities

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The resolution on Health Intervention and Technology Assessment in Support of Universal Health Coverage (WHA67.23, 2014) called on the World Health Organization (WHO) to develop global guidance on methods and processes for Health Technology Assessment (HTA). HTA is described WHO Executive Board EB134/30 as:

‘…..is the systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences. The approach is used to inform policy and decision-making in health care, especially on how best to allocate limited funds to health interventions and technologies. The assessment is conducted by interdisciplinary groups using explicit analytical frameworks, drawing on clinical, epidemiological, health economic and other information and methodologies. It may be applied to interventions, such as including a new medicine into a reimbursement scheme, rolling-out broad public health programmes (such as immunization or screening for cancer), priority setting in health care, identifying health interventions that produce the greatest health gain and offer value for money, setting prices for medicines and other technologies based on their cost–effectiveness, and formulating clinical guidelines.’
HTA: definition

• **HTA is ‘a multi-disciplinary field of policy analysis studying the medical, economic, social and ethical implications of the development, diffusion and use of health technologies**

• **HTA is a two-stage iterative process**
  
  • First, a scientific *assessment* of the evidence (clinical, economic) for a health technology is undertaken.

  • Then, based on this assessment, an *appraisal* of the evidence (together with consideration of political, social, ethical factors) is made, and a policy decision made, e.g., whether to fund or not to fund the therapy in question (Taylor et al. 2009).
Overview of the HTA Process

1. Identifying topics for assessment/ specifying the decision problem

2. Systematic review of the clinical evidence
3. Economic evaluation
4. Assessing social, legal and ethical implications

5. Formulating recommendations and implementation of policies
6. Monitoring impact
HTA: the topic of assessment

Source: Technologies for global health, Lancet 2012
Identifying Topics for Study

• Specify criteria for selection of topics
  - disease burden
  - existence of treatment alternatives
  - clinical impact
  - economic or budgetary impact
  - level of controversy
  - existence of evidence
  - variation in practice
  - timeliness of the assessment
  - ethical, legal or social implications
  - general level of interest
Systematic Review of the Clinical Evidence

- Objective is usually to obtain unbiased estimates of relative treatment effect and other key parameters for the HTA
- Bias in estimates can occur because of selective publication, or methodological deficiencies
- Evidence needs to be both of sufficient quality and relevant to the decision problem

- Important issues to consider:
  - Choice of comparator («standard practice»)
  - Check for publication bias
  - Assess the quality of studies (trials, observational studies)
  - Timing of assessment (especially for medical device)
Economic Evaluation

- Full economic evaluation analysis identifies, measures, and evaluates cost and consequences (health outcomes) of alternative health technologies
- The relative clinical effectiveness (or broader benefits) of the interventions are compared with their costs
- These constitute assessments of ‘cost-effectiveness’ or ‘value for money’

- Mostly used techniques: cost-effectiveness analysis
Cost-effectiveness analysis

- Costs A
  - Outcomes A
  - ICER
- Costs B
  - Outcomes B
- Choice
Assessing Social and Ethical Implications

- **Social effects:**
  - Changes in equity or access to care produced by implementation of a technology

- **Ethical aspects:**
  - Exploration of all possible effects of technology on values. It is possible that the adoption of some technologies could require changes in legislation
Organizational impact

- Organizational issues may address changes in:
  - Utilization of service
  - Treatment location
  - Human resources (training/qualification requirements)
  - Job satisfaction
  - Care pathways/patient flow
  - Logistics
Should HTA be different for medical devices vs. drugs?

- **Drugs** are essentially molecules (active ingredients) that interact with biochemical pathways in the human body.
- **Devices** make use of a great diversity of actions and reactions (e.g., radiation, heat, mechanical, electrical).
- **Devices** may be used for both diagnostic and therapeutic purposes.

There is no doubt that drugs and medical devices differ in nature.
Should HTA be different for medical devices vs. drugs?

1. **Many devices are **diagnostic**
   - Mutuality between the value of the diagnosis and the value of the treatment
   - Multiple applications: similar to multiple indication for drugs but devices are indivisible (e.g. CAT)
Should HTA be different for medical devices vs. drugs?

2. Randomized Controlled Trials are more difficult in devices:

- For drugs, the results from trials provide a reasonable basis for conducting an economic evaluation
- Blinding difficult/unethical
- Devices frequently undergo product modifications, some of which may impact on efficacy
- Learning curve (e.g. surgical devices) → evaluation of the new procedure: what is it about, really?
  - Clinical effectiveness of new program vs. current practice? Or inexperience with the new program vs. experience of the current practice?
Should HTA be different for medical devices vs. drugs?

3. **The efficacy of a device** depends not only on the device itself, but how it is used while drugs are “embodied technologies” → use is a complementary part of the technology
   - user performance is a potential confounder in the analysis of observational data on the efficacy of devices → Multicentric design is preferable

$1 + 2 + 3 = $ study designs for identifying efficacy are more challenging in devices
Should HTA be different for medical devices vs. drugs?

4. Implementation of a new therapy involving a device can have wider economic implications compared to drugs
   - Training
   - Organizational setting matters (ability to switch patients across alternative or complementary treatments)
   - Evaluation results may highly depend on context (then “importing” clinical results and cost data from studies conducted in other setting could be questionable)
   - In drugs this is much less important

5. Prices are less stable:
   - In devices prices are much more likely to change over time because of the market entry of new products, or because of the ways in which procurement takes place in many health-care systems.
   - On the other hand, in many countries, once the price of a drug is negotiated, it is more likely to stay at or near that level until the patent expires.
Production and synthesis of evidence

- Conclusions of HTA report = answers to research questions
- Conclusions include the following points:
  - Summarize quality/origin of the evidence;
  - Summarize evidence on all aspects assessed;
  - Give size of effect (benefit/adverse);
  - Highlight differences among groups of patients (if found);
  - Highlight variations of effect with varying characteristics of technology (if found);
  - Discuss applicability of evidence for national/local context and
  - Point out fields where further research is needed

- Assessment is followed by appraisal
HTA in decision making: appraisal

*WHO global survey on HTA (2015)*:

- Formal HTA procedures are used predominantly by high income, and upper-middle income countries for assessment of medicines and medical devices.

- For those that are not using HTA, the most common barriers at the country level included *lack of qualified human resources*, and a *lack of clear process embedding HTA in the decision making*.

- With more choices in terms of medical product coming to the market, combined with uncertainty of their health impact countries are calling for greater transparency and use of evidence in decision making.

- Hence countries that have hitherto not used HTA now wish to do so.

- In conclusion it was suggested by the WHO global survey that *HTA usage, is increasingly relevant in resource limited settings*, that WHO has a role to play both in HIC as well as in LMIC in this area and that there is a specific need for capacity building.
HTA in LMICs: challenges

**Key points:**
- lack of, and need for, local or localized data in HTA assessments
- the need for capacity to use existing data for generating information for decision making

**Recommendations from the WHO Survey:**
- Countries need to **identify sources of local data** in relation to costs, utilization and expenditures for the purpose of undertaking assessments and monitoring.
- There must be capacity to manage the data and analyze it, as well as to synthesize, interpret, and incorporate it into decision-making. Establishing a unit within a MOH to carry out this work should have a **high priority**.
- Countries should be able to use whatever **local data they already have**, or use estimates from neighboring countries with similar epidemiological and health system profiles, as a start.
Globalization of « HTA » : EunetHTA- Joint Action

- Led the national HTA agencies but also by the European Commission and the ministries of Health, includes 60 partners and 24 EU Member States, 2 EEA (Norway, Iceland), Switzerland and a wide variety of international collaborators (e.g. OECD, WHO, HTAi,...) as well as American, Israeli, Australian and Canadian collaborators.

- The aim is to create a network that would help and support decision-makers (HTA agencies and ministries of health) at national level

- EUnetHTA supports collaboration between European HTA organizations that brings added value at the European, national and regional level through

  - facilitating efficient use of resources available for HTA
  - creating a sustainable system of HTA knowledge sharing
  - promoting good practice in HTA methods and processes.
MedTecHTA

- European Commission 7th Framework Programme, Small or Medium-Scale Focused Research Project Call identifier: FP7-HEALTH-2012-INNOVATION-1
- Overall Value of the Project: 2.5 mln€
- EC contribution: 2,055,134.00€
- Duration: 36 months
- Period: 01/01/2013 – 31/12/2015
Medtechta: results and recommendations (1/4)

- Improving the process for HTA of medical devices
- Developing methods for HTA of medical devices
- Optimizing the diffusion of medical devices

*Tarricone et al. Key Recommendations from the MedtecHTA Project. *Forthcoming*
1. Align regulatory and HTA processes for devices with respect to data requirements
2. Harmonize the HTA evaluative framework for devices across international HTA agencies
3. Conditional coverage and evidence development decisions should be assessed
4. Consider the likely prospects of research and who should pay for it
Developing methods for HTA of medical devices

1. Consider MD-related interventions as ‘complex interventions’ and refine existing methods
2. Consider the challenges arising from user experience, future price changes, patient eligibility, user dependence, study design, and rapid evolution of the technology
3. Consider study designs, in addition to RCTs, in CER of MDs
4. Establish disease-based or device-based registries of high quality
5. Consider an iterative process to the evaluation as additional evidence and learning emerges over time
Optimizing the diffusion of medical devices

1. Leverage routinely collected data to investigate the adoption and diffusion of MDs
2. Endorse the use of a common coding system
3. Include factors driving the adoption of MD systematically in HTA reports
4. Focus on developing the understanding of physicians’ personal goals and motivation and KOL’s role in the adoption of MDs
5. Monitor manufacturers’ actions
Conclusive remarks

• Central challenge for those conducting and using HTA in many LMICs is the scarcity, quality and accessibility of data

• Additional challenges stem from other health-system constraints, including substantial human resource shortages, financing arrangements which result in substantial out-of-pocket expenditure, and fragmented and sometimes weak governance.

• Complex and informal funding processes compound the challenges for researchers seeking to increase the use of HTA in priority setting LMICs.

• Increasing opportunities to leverage on international collaborations

• Despite the challenges, HTA is an important aid to public health decision-making, even more importantly in contexts with very limited resources