Assessment Of Medical Devices In Low-Income Settings

Dr Leandro Pecchia
University of Warwick
IFMBE HTA Division Chairman
• This field analysis was part of a research project (PI Dr Pecchia) funded by:
  • *The University of Warwick thought:*
    • EPSRC Impact Acceleration Account
    • Warwick Global Research Priority on Technology and Science for Health
    • Warwick Impact Found 2016/2017
  • *The IFMBE HTAD (project N9 ‘HTA-related capacity building’, budget 2015/2018)*

• *The content of this study represents the views of the authors and is its sole responsibility.*
**HTA of Medical Devices**

**Medical devices vs Drugs**

<table>
<thead>
<tr>
<th>Devices</th>
<th>VS</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principal action</strong></td>
<td></td>
<td>Pharmaco./Immunologic/Metabolic Chemical based</td>
</tr>
<tr>
<td>Other than principally drugs</td>
<td></td>
<td>Long life cycle Unchanging compound</td>
</tr>
<tr>
<td>Mechanical/Electromagnetic/Materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Product life cycle</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short life cycle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constantly evolving components/parts</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical evaluation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficult to blind (no placebo)</td>
<td></td>
<td>Easy to blind</td>
</tr>
<tr>
<td>Multiple end users</td>
<td></td>
<td>Usually one end users</td>
</tr>
<tr>
<td>Long learning curve</td>
<td></td>
<td>Short learning curve</td>
</tr>
<tr>
<td>Strongly dependent by settings/users</td>
<td></td>
<td>Less dependent by settings/users</td>
</tr>
<tr>
<td>Complex to standardize for RCT</td>
<td></td>
<td>Easy to standardize for RCT</td>
</tr>
<tr>
<td><strong>Use issues</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>User-dependent efficacy</td>
<td></td>
<td>Efficacy is less user-dependent</td>
</tr>
<tr>
<td>Often require intensive training</td>
<td></td>
<td>Usually do not require training</td>
</tr>
<tr>
<td>Complication decrease with use</td>
<td></td>
<td>Complication increase with use</td>
</tr>
<tr>
<td><strong>Diversity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mainly small companies/few large co.</td>
<td></td>
<td>Mainly large multinationals</td>
</tr>
<tr>
<td>Diagnostic or therapeutic</td>
<td></td>
<td>Therapeutic</td>
</tr>
<tr>
<td><strong>Costs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varying overheads/slow return</td>
<td></td>
<td>High overheads with quicker return</td>
</tr>
<tr>
<td>Higher distribution costs</td>
<td></td>
<td>Lower distribution costs</td>
</tr>
<tr>
<td>Higher maintenance/installation costs</td>
<td></td>
<td>No maintenance/installation</td>
</tr>
</tbody>
</table>

...for MD, HTA should assess:
- the whole process
- the context
- the users
- ... and many more dimensions. (...MCDA?)
HTA of Medical Devices
Do we need different approach?

MEDICAL DEVICE

People
Staff
Public
Patients

STRUCTURAL
TECHNOLOGICAL
ORGANIZATION

MINIMUM REQUIREMENTS
INTERNATIONAL STANDARD
Medical Devices
...& minimum requirements.

Organizational requirements:
• Required competences (e.g., medical, clinical, administrative, technical). Devices developed for the European market assume that minimum requirements are met.
• Since device efficacy and safety depend from users & operational environment, are HTA/BME results still reliable when those requirements are not met?

E.g.:
• What happens when a surgery is not performed by a specialized clinician?
• What if the pre- (e.g., diagnosis) and post-surgery (e.g., follow-up) path are not available?
• What if there are no anesthesiologists in the LMIC?
• Nurse in intensive care units?

Challenges:
• Developers should take this into account and make devices resilient to (lay)users, especially where specialized healthcare professionals are not available.
• Scientists should capture/model the dependence of their assessment from environmental conditions.
• Decision-makers should analyze at what extend the absence or non-standardization of organizational requirements may deteriorate devices’ efficacy and safety.
Structural requirements:

- In Europe, minimum requirements regarding healthcare settings (e.g. medical setting layouts, level of sterilization, electrical safety, state of the art implants) are clearly defined according to the level of care intensity (e.g. ambulatory, surgery theater, etc.).
- In order to maintain those standards over time, medical settings require periodic and COMPETENT maintenance.
- Given the strong dependencies of devices from the operational environments, not meeting those minimum requirements could invalidate HTA/EMB results.

E.g.:

- For instance, equipotential nodes, isolation transformers and ground-fault circuit interrupters are mandatory in Europe for medical settings in which the patient is exposed to high risk of micro-shock. The absence of one or more of those three components significantly compromises Device safety.
- What happens if a Medical Device intended to be used in a group 2 medical setting is operationalized in absence of those standard?
- What if a Radiology is not properly isolated?
- What if a well-designed medical setting is altered without properly considering consequences?

Challenges:

- Developers should take this into account and make MD resilient to environmental conditions.
- Scientists should capture/model the dependence of their assessment from medical settings.
- Decision-makers should analyze at what extend the absence or non-standardization of medical settings may deteriorate costs (e.g., device burned by current instability), efficacy (e.g., dialysis when water is not properly treated) and safety (e.g., micro-shock)
Some electric measures in LMIC Hospitals:

...Voltage on the neutral...

...Voltage on the ground...
Medical Devices
minimum requirements in LMIC

... more voltages on the ground...
Medical Devices
minimum requirements in LMIC

... ‘poorly shielded’ X-Ray settings...
Medical Devices
minimum requirements in LMIC

...Voltage over 24 hours in Europe...

...Voltage over 24 hours in LMIC Hospital ward (axes have the same scale)...

3rd WHO Global Forum on Medical Device
Leandro Pecchia. l.pecchia@warwick.ac.uk
Minimum requirements in LMIC

...Voltage over 24 hours in Europe (histogram)...

...Voltage over 24 hours in LMIC Hospital ward (histogram, same scale)...

Medical Devices
minimum requirements in LMIC

...Voltage over time in surgical theatre...

Recurrent patterns before black-outs
Conclusions

• **Medical devices** are strongly dependent from operational conditions:
  • Organizational
  • Structural
  • Technological
• Because of this dependence, results obtained in one study (e.g., RCT, HTA) are not easily translated into a different setting

• Heterogeneity of operational conditions in LMIC makes really difficult to translate European HTA results into real contests

• In Europe, we started introducing standards and minimum requirements before EBM and HTA were introduced:
  • are those standard evidence based?
  • should those basic concept be reconsidered?

• **Focusing on medical devices, ignoring their operational conditions, equate to care the symptoms without treating the disease.**
• Strong campaigns should be focused on increasing the standards of medical settings in LMICs (e.g., education, introduce minimum requirements, encourage/support more studies in LMICs...)

• In the meantime:
  • designers should make medical devices more resilient to operational conditions (e.g., group II devices instead of group I)
  • donors should recondition medical devices, making them more resilient to operational conditions (e.g., group II devices instead of group I)

...but, there is hope...
The department has released 5 promotions with a total of 106 (27 women / 79 men) Biomedical Technicians.

- The 1st promotion of 19 (5 women / 14 men) biomedical technicians in 2012
- The 2nd promotion of 22 (8 women / 14 men) biomedical technicians in 2013
- The 3rd promotion of 26 (6 women / 20 men) biomedical technicians in 2014
- The 4th promotion of 17 (2 women / 15 men) biomedical technicians in 2015
- The 5th promotion of 22 (6 women / 18 men) biomedical technicians in 2016.
Our challenges for the health system in Benin.

Many ambitions.
At present, Benin, with 12 administrative divisions, is organized in 34 sanitary zones.
Département de Génie Biomédical
Department of Biomedical Engineering

Our challenges for the health system in Benin.

➢ Produce 3 biomedical technicians for each sanitary zone.

- So on average $3 \times 77 = 231$ biomedical technicians.

➢ Open the Master's degree program to train biomedical engineers who can develop strategies:

- Of Clinical Engineering in Hospitals in Benin

- Assessment of Medical Technology
We are currently working on a project with APEFE for the development of our Department of Biomedical Engineering of EPAC / BENIN.

Conduct a statistical study on the occupancy rate of technicians already trained in biomedical and hospital maintenance at EPAC.
Tank you for your attention!

**Applied Biomedical Signal Processing and Intelligent eHealth (ABSPIE) Lab University of Warwick**

**PhD Students**

- **Rossana Castaldo**
  - Signal processing/Machine learning
  - (2014)

- **Luiss Montesinos**
  - Balance/falls
  - (2015)

- **Tim Siu Wang**
  - Behavioural modelling
  - (2016)

- **Michaela Porumb**
  - Signal processing/data analytics
  - (2017)

- **Carlo Federico**
  - eHTA
  - (2017)

**2016 Associate/Visiting Researchers/Academics**

- **Dr Paolo Melillo**
  - Second University of Naples

- **Dr Giovanna Sannino**
  - Italian CNR

- **Mariangela Caserta**
  - Federico II

- **Claudio Guerra**
  - Univ. of Parma

- **Davide Piaggio**
  - Politecnico Torino

- **Hummel**
  - Phylips

- **Tarricone**
  - Bocconi

- **Polisena**
  - CADHT

- **Clark**
  - NICE

- **Ciani**
  - Bocconi

- **Fico**
  - Madrid

- **Velazquets**
  - WHO

- **Böhler**
  - European Commission

---

*Leandro Pecchia*  
{l.pecchia@warwick.ac.uk
Tank you for your attention!

Particular acknowledgments go to the charity that organized the logistic for this field study, and its infatigable President, Prof Enrico Di Salvo, and the local friends that work hard daily doing their best.

http://www.sorridiafrica.org/