Health Technology Assessment For Medical Devices

Pascale Brasseur
June 23rd 2015
Agenda

- A few facts about Medical Devices
- HTA of Medical Devices
- Market Access Jigsaw
- Initiatives at European level
Every year

10,000 patent applications to EPO

3,500 technologies approved in EU
500 Class III
DIVERSITY OF MEDICAL DEVICES

high risk

$100 billion market

low risk

Class I

Class IIb

Class III

95% SMEs

25’000 companies in EU
MEDICAL DEVICES THROUGHOUT LIFE
Expenditure on MedTech

It is estimated that only around 7.5% of total European healthcare expenditure is attributed to MedTech.

The spending on medical technology varies significantly across European countries, ranging from around 5% to 10% of the total healthcare expenditure.
Breakdown of total healthcare expenditure in Europe

Source: WHO, Eurostat, EFPIA, EDMA, Eucomed calculations.
HTA
Health Technology Assessment
Economic Evaluation for Devices and Drugs—Same or Different?

Michael Drummond, PhD,1 Adrian Griffin, MSc,2 Rosanna Taricone, MSc, PhD3
1Centre for Health Economics, University of York, York, England, UK; 2LifeScan EMEA, High Wycombe, England, UK; 3Ecomed, Belgium,
Department for Institutional Analysis and Public Management, Bocconi University, Milan, Italy

Assessing the Clinical and Cost-Effectiveness of Medical Devices and Drugs: Are They That Different?

Rod S. Taylor, MSc, PhD,1 Cynthia P. Iglesias, MSc, PhD2,3
1Department of Primary Care, Peninsula Medical School, Universities of Exeter & Plymouth, Plymouth, England, UK; 2Department of Health
Sciences, University of York, York, England, UK; 3Centre for Health Economics, University of York, York, UK
Specificities for HTAs on Medical Devices

Research Brief II

Improving HTA in Medical Technology: Six Goals for Constructive Engagement

Medical technology companies need to help health technology assessment processes become better at identifying real value. Research by EHTI is looking at how they might do this.

http://www.ehti.info
Specificities for HTAs on Medical Devices

• Problems in conducting clinical studies
• Learning curve
• Generization - Class effect
• Accounting for the wider organizational impacts
Learning curve

Assessing the impact of volume of interventions

Le volume des interventions chirurgicales et son impact sur le résultat : étude de faisabilité basée sur des données belges

Source: KCE report 113 – 2009
Assessing the impact of volume of interventions

BACKGROUND
The association between hospital volume and the death rate for patients who are hospitalized for acute myocardial infarction, heart failure, or pneumonia remains unclear. It is also not known whether a volume threshold for such an association exists.

METHODS
We conducted cross-sectional analyses of data from Medicare administrative claims for all fee-for-service beneficiaries who were hospitalized between 2004 and 2006 in acute care hospitals in the United States for acute myocardial infarction, heart failure, or pneumonia. Using hierarchical logistic-regression models for each condition, we estimated the change in the odds of death within 30 days associated with an increase of 100 patients in the annual hospital volume. Analyses were adjusted for patients’ risk factors and hospital characteristics. Bootstrapping procedures were used to estimate 95% confidence intervals to identify the condition-specific volume thresholds above which an increased volume was not associated with reduced mortality.

RESULTS
There were 734,972 hospitalizations for acute myocardial infarction in 4128 hospitals, 1,324,287 for heart failure in 4679 hospitals, and 1,418,252 for pneumonia in 4073 hospitals. An increased hospital volume was associated with reduced 30-day mortality for all conditions (p<0.001 for all comparisons). For each condition, the association between volume and outcome was attenuated as the hospital’s volume increased. For acute myocardial infarction, once the annual volume reached 610 patients (95% confidence interval [CI], 539 to 670), an increase in the hospital volume by 100 patients was no longer significantly associated with reduced odds of death. The volume threshold was 500 patients (95% CI, 433 to 566) for heart failure and 210 patients (95% CI, 142 to 284) for pneumonia.

CONCLUSIONS
Admission to higher-volume hospitals was associated with a reduction in mortality for acute myocardial infarction, heart failure, and pneumonia, although there was a volume threshold above which an increased condition-specific hospital volume was no longer significantly associated with reduced mortality.

Source: Ross et al, Hospital Volume and 30-day Mortality for 3 Common Medical Conditions, NEJM; March 25, 2010, 362; 12, 1110-1118
Example of evaluation report (France)

<table>
<thead>
<tr>
<th>Eléments conditionnant le SA :</th>
<th>Aucune exigence supplémentaire par rapport aux spécifications techniques proposées par le fabricant</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Spécifications techniques :</td>
<td>Composition du plateau technique Les pré-requis indispensables à l’implantation de valves pulmonaires par voie veineuse transcathétérienne ont été définis comme suit :</td>
</tr>
<tr>
<td>- Modalités de prescription et d’utilisation :</td>
<td>- le centre médico-chirurgical doit regrouper sur le même site et dans le même bâtiment, les plateaux techniques de cardiologie interventionnelle congénitale et de chirurgie cardiaque congénitale dans le cas où une conversion en urgence est nécessaire ;</td>
</tr>
<tr>
<td></td>
<td>- l’acte doit être réalisé dans une salle de cathétérisme conforme à un bloc opératoire en termes d’asepsie avec une salle de réveil à proximité ;</td>
</tr>
<tr>
<td></td>
<td>- la nécessité d’une définition optimale d’images radiographiques pour la réalisation des procédures de cathétérisme et de contrôle radiologique ;</td>
</tr>
<tr>
<td></td>
<td>- la possibilité de réaliser dans le centre une circulation extra-corporelle. D’autre part, l’accès à un capteur biplan est recommandé.</td>
</tr>
<tr>
<td></td>
<td>Composition de l’équipe pluridisciplinaire Pendant l’intervention, en salle de cathétérisme doivent être présents deux cardiologues interventionnels ayant l’expérience des cardiopathies congénitales et un anesthésiste réanimateur habitué à la chirurgie à cœur ouvert et à la prise en charge des patients ayant des cardiopathies congénitales. Dans le centre, doit également être présent un chirurgien cardiaque ayant l’expérience du traitement des cardiopathies congénitales.</td>
</tr>
<tr>
<td></td>
<td>Formation et expérience requises Pour prétendre à l’implantation d’une valve pulmonaire par voie veineuse transcathétérienne, les praticiens doivent :</td>
</tr>
<tr>
<td></td>
<td>- avoir une formation de cathétérisme cardiaque interventionnel congénital ;</td>
</tr>
<tr>
<td></td>
<td>- avoir acquis, dans le cadre d’une formation initiale spécifique aux dispositifs implantés dans le centre, la connaissance nécessaire à cette activité et la maintenir ;</td>
</tr>
<tr>
<td></td>
<td>- avoir une formation pratique à la technique effectuée par compagnonnage.</td>
</tr>
<tr>
<td></td>
<td>Nombre de centres pouvant réaliser l’implantation et volume requis Pour une répartition géographique optimale, entre 7 à 10 centres en France peuvent prétendre à l’implantation des valves pulmonaires par voie veineuse transcathétérienne. Chaque centre implanteur ne doit pas réaliser moins de cinq procédures par an.</td>
</tr>
</tbody>
</table>

Source: CNEDIMTS assessment report – Percutaneous pulmonic valve
Summary and table with main recommendations

The inclusion of non-randomised studies (NRS) in HTA may be useful in specific circumstances, but leads to several challenges in terms of internal validity assessment. The aim of this guideline was to recommend tools or checklists that are suitable for assessing risk of bias (RoB) in NRS evidence.

RoB tools were identified from previous systematic reviews and own systematic literature searches. Key criteria, such as coverage of relevant bias domains, were used to evaluate the tools. In addition, tools were required to be free of items on reporting quality and external validity (or applicability). Literature findings concerning reliability and ease-of-use were used as additional criteria.

A total of 11 tools were identified and assessed in detail. Two tools emerged as the currently best instruments for assessing RoB in NRS: ACROBAT-NRSI (A Cochrane Risk of Bias Assessment Tool) and RoBANS (Risk of Bias Assessment Tool for Nonrandomised Studies). As both tools have been developed only very recently, data on reliability are sparse, but it is clear that adequate training is required before assessing NRS evidence. Because ACROBAT-NRSI offers endpoint-specific assessments, requires a summary rating and comes with detailed instructions and documentation guides, this tool is recommended as primary RoB tool for assessment of NRS.
Market Access Jigsaw
The Market Access Jigsaw

- Regulatory: Always

- HTA: Sometimes

- Reimbursement: More often by procedure
  - In-patient / Out-patient / Community Care
  - Implantable / non-implantable
  - Class / single brands

- Procurement:
Where HTA Informs the Route to Market

- Regulatory Approval
- Reimbursement
- HTA

Regional Contract
- HTA
- National Contract
- HTA

Central procurement
Hospital procurement
Coverage (DRG)
Innovation Payments
Local procurement
Regional procurement

HTA
HTA for Medical Devices across EU

- **Formal HTA process**
  - Clear link to reimbursement
  - Impact on diffusion

- **Formal HTA process**
  - No clear link to reimbursement
  - Impact on diffusion

- **Some kind of a HTA process**
  - No clear link to reimbursement
  - No impact on diffusion

- **Very sporadic or no HTA**

- **No information**
A few numbers

• About **365 HTA reports** involving medical technologies in 2014
• 12 countries
• 80% of these HTA reports were published in **4 Countries** (France, Spain, UK, and Sweden)
• **50%** of these HTA reports were published in **France**
Different types of HTA

- National level
- (Regional level)
- Local (hospital level)
Hospital-based HTA

Provide decision-makers with contextualised assistance on how to make sound investment decisions on innovations, thus ensuring that good-value innovative health technologies reach clinical practice.

- Tailoring HTA to specific hospital circumstances (comparators, how care is organised in the hospital, BIA,…)
- Keeping a sharper focus on technologies that are of specific interest for the hospital
- Timely adjustment to hospital context
- In collaboration with “decision makers” (end users)
Five most important domains in decision-making by type of manager.

<table>
<thead>
<tr>
<th>Domains of the AdHopHTA survey</th>
<th>Clinical manager</th>
<th>Hospital manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1: Health problem</td>
<td>74%</td>
<td>51%</td>
</tr>
<tr>
<td>D2: Technology characteristics</td>
<td>16%</td>
<td>19%</td>
</tr>
<tr>
<td>D3: Safety</td>
<td>82%</td>
<td>77%</td>
</tr>
<tr>
<td>D4.1: Clinical outcome effect size</td>
<td>84%</td>
<td>74%</td>
</tr>
<tr>
<td>D4.2: Quality of evidence</td>
<td>74%</td>
<td>72%</td>
</tr>
<tr>
<td>D5.1: Economic - societal point of view</td>
<td>24%</td>
<td>23%</td>
</tr>
<tr>
<td>D5.2: Economic - hospital point of view</td>
<td>42%</td>
<td>61%</td>
</tr>
<tr>
<td>D6: Ethical</td>
<td>24%</td>
<td>19%</td>
</tr>
<tr>
<td>D7: Organizational aspects</td>
<td>11%</td>
<td>30%</td>
</tr>
<tr>
<td>D8: Social</td>
<td>11%</td>
<td>5%</td>
</tr>
<tr>
<td>D9: Legal</td>
<td>26%</td>
<td>21%</td>
</tr>
<tr>
<td>D10.1: Strategic</td>
<td>26%</td>
<td>35%</td>
</tr>
<tr>
<td>D10.2: Political</td>
<td>0%</td>
<td>7%</td>
</tr>
</tbody>
</table>
## Hospital-based HTA and EUnetHTA domains

<table>
<thead>
<tr>
<th>Domain</th>
<th>EUnetHTA</th>
<th>HB-HTA Core model</th>
<th>AdHopHTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1: Health problem and current use</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D2: Description and technical characteristics</td>
<td>✔ relevant</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
</tr>
<tr>
<td>D3: Clinical effectiveness</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D4: Safety aspects</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D5: Costs and economic evaluation</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D5.1 Societal point of view</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D5.2 Hospital point of view</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D6: Ethical aspects</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D7: Organizational aspects</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D8: Social aspects</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D9: Legal aspects</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D10: Political and strategic aspects</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D10.1 Political aspects</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
<tr>
<td>D10.2 Strategic aspects</td>
<td>✔ relevant</td>
<td>✔ ✔ ✔ most important</td>
<td>✔ relevant</td>
</tr>
</tbody>
</table>
HTAs performed on Medical Devices

- More or less assessments?
- Different evaluation pathways?
- Different methodologies?
- Different requirements in terms of evidence?
HTA-related initiatives at EU level

1. Permanent HTA network (October 2013)
2. EUnetHTA JA2 (January 1, 2013 - September 30, 2015)
3. AdHopHTA (October 2012 – September 2015): Hospital HTA

* LYG and outcome weighted survival metrics, DALYs / QALYs
Key principles for the conduct of HTAs:

- scientific rigour
- timeliness
- inclusiveness
- transparency
- review
- support for implementation

- specificities of medical devices
  (commensurate evidence – learning curve)
A few websites

- http://www.eucomed.org
- http://www.eunethta.eu
- http://www.adhophta.eu
- http://www.advance-hta.eu
- http://www.integrate-hta.eu
- http://www.medtechta.eu/wps/wcm/connect/site/medtechta/home
Thank you !