“Observatory” (= my) take on Medical Technology

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What do we expect from Medical Devices?

Past (say, until now) ...

- Economic policy: innovation, jobs, ...
- Public health policy: safety
- Social policy: access
- Health care policy: affordability and (financial) sustainability

- research & development
- market authorization
- reimbursement (inclusion in benefit basket)
- market (with price/ expenditure controls)
… but soon
a changing regulatory environment?

- safety, effectiveness, patient benefit
- cost-effectiveness
- access
- affordability and (financial) sustainability

- innovation, jobs, ...
- extended rules for market authorization
- “fourth hurdle” (inclusion in benefit basket)
- market (with price/ expenditure controls)

… but evaluation is more complex than for pharmaceuticals and cannot be copied
Real and pretended differences to pharmaceuticals I

• **Short product cycles** (step-wise innovations) → evaluation takes too long and impedes access (but do we want access to devices of unproven benefit?)

• **Small patient groups** → randomisation/ control group not possible (untrue, think of orphan drugs!)

• **Placebo often not possible** → good use of data under routine conditions necessary, through *(i) Coverage for Evidence Development (new technologies) and (ii) registers* (disease-, not product-oriented for control group)

• **No evaluations done to be used in HTA (or no evaluations because HTA is not a requirement)!? !! !?**
Real and pretended differences to pharmaceuticals II

• Possible **wider economic effects** (due to necessary organizational changes etc.) → need to be taken into account

• Some medical devices can be **diagnostic** (true → separate methods needed)

• Greater effect of **operator learning curve** (true → assessment time important)

Figure 1 Hypothetical learning curves for medical device versus drug. Adapted from Ramsay et al. (2001) [7].
Further challenges ...

for evaluating Medical Devices from the view point of European HTA institutions (n=16; e.g. NICE, IQWiG, KCE)

### Table 2

Challenges specific to MD assessment from a structural, procedural, methodological and regulatory perspective.

<table>
<thead>
<tr>
<th>Major themes and themes</th>
<th>Summary of theme</th>
<th>Quote</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) Challenges from a structural perspective</td>
<td>Lack of information about which MDs are entering or are currently on the market. No central register/database for MDs with CE mark.</td>
<td>‘[It is] legally forbidden to get data from notification/certification body.’</td>
<td>Many</td>
</tr>
<tr>
<td>Transparency</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>National legal framework</td>
<td>No flexibility in the process of evaluation due to predefined criteria by national legal framework.</td>
<td>‘We have regulatory criteria for reimbursement. This criteria are mandatory—we have to assess medical devices with this regulatory criteria.’</td>
<td>Some</td>
</tr>
<tr>
<td>Capacity</td>
<td>Lack of resources (e.g. staff) for conducting HTA.</td>
<td>‘I hope we get new stuff for the HTA department [...]’</td>
<td>Some</td>
</tr>
<tr>
<td>(ii) Challenges from a procedural perspective</td>
<td>Lack of standardised submission process of data: (ad-hoc) requests to manufacturers. Difficulties in the identification process of the most relevant literature due to rapid pace of innovations (i.e. incremental vs breakthrough innovations).</td>
<td>‘[...] sometimes devices go through a very short life cycle before they undergo an improvement and we sort of have to start the assessment all over again for the updated versions of devices, how do you handle assessments of that, when there is a minor technological change [...]’</td>
<td>Most</td>
</tr>
<tr>
<td>Information retrieval</td>
<td></td>
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</tr>
<tr>
<td>Coordination of assessment</td>
<td>Stakeholder input at different points during the assessment to expand limited information.</td>
<td>‘[...] we tend to create ad-hoc groups, depending on the technology [...] sometimes we can resolve an issue ourselves and sometimes this can lead to a working group where we involve the different parties [...]’</td>
<td>Many</td>
</tr>
<tr>
<td>Prioritisation</td>
<td>Difficulties regarding topic selection due to the broad spectrum of MDs.</td>
<td>‘[...] we do not really know what things might be dangerous and should be evaluated better than others.’</td>
<td>Some</td>
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Source: Fuchs et al., 2017
Further challenges ...

for evaluating Medical Devices from the view point of European HTA institutions (n=16; e.g. NICE, IQWiG, KCE) II

| (iii) Challenges from a methodological perspective | Evidence base | Weak evidence level  
Lack of publicly available information (e.g. CE mark documents, fewer studies conducted/published)  
Weak reporting quality of available studies (e.g. no reporting of learning curves) | 'For me it's the evidence threshold. There are quite often lower levels of evidence, and that gives us challenges in terms of its credibility, but also the assessment of it in terms of the methods of the assessment.' | Most  
| Broader perspective of the assessment | Evaluation of complex interventions (e.g. treatment and companion diagnostic)  
Increased necessity of considering elements beyond effectiveness and safety (e.g. ethical aspects)  
Diagnostic (incl. prognostic and screening) and therapeutic MDs require different types of information | 'Medical devices are also commonly connected with procedures, so you should also include this organizational issue, staff issue, this learning curve not applied to pharmaceuticals. So I can say that the assessment of medical devices is much broader than the assessment of pharmaceuticals.' | Many  
| Methodological tools | Lack of specific quality assessment tools for available evidence (e.g. GRADE for prognostic studies)  
No existing support tool for framing research questions  
No existing tools for evaluation of learning curves  
No gold-standard of PICO aspects (e.g. comparator) | 'And I haven't actually seen good methodological descriptions that are very sharp on the learning curve. But we try to be sharp in that but I think it's one of our main issues in the assessment.' | Some  
| Transferability | Difficulties to transfer results across product modification and settings | 'There are lots of things that we often think about, both in terms of the ways that medical devices change and develop over time and how we can know whether the evidence is generalisable […]--is it still relevant for the version that you’re still looking at. That's something we often wonder about.' | Some

Low requirements for licencing

| (iv) Challenges from a regulatory perspective | Weak EU Regulation regarding licensing of MDs | Proof of effectiveness not required for licensing  
Decentralized licensing process | 'I think for us the major aspect to change is to strengthen the level of proof of the CE mark. It's a weakness in the process. Some medical devices are accessing the market without any clinical data' | Many

Source: Fuchs et al., 2017
How can we classify medical devices...

A structure of medical device technologies based on coverage, reimbursement and usage in health care system

**Category I**

"medical aids"

- products which are prescribed and given to an individual patient

**Example technologies**
- incontinence pad
- wheel chair
- pregnancy test

**Category II**

"artificial body parts"

- medical devices which stay at or in the patient (e.g. knee endoprotheses, stents): only one component of a broader “service package” to implant or adapt the “(hardware) product” to the individual patient

- knee (endo-) prosthesis
- Implantable Cardio-Defibrillator
- coronary stent

**Category III**

"assistance for professionals"

- technical equipment supporting professionals in diagnostics and/or treatment with two-stage financing:
  - IIIa: investment
  - IIIb: refinancing via use (diagnostics/treatment)

- endoscope (for e.g. gastroscopy)
- operating room equipment
- imaging devices: X-ray, CT, MRI
... taking health financing (not risk) into account?

A structure of medical device technologies based on coverage, reimbursement and usage in health care system

**Category I**
“medical aids”
products which are prescribed and given to an individual patient

**Device constitutes technology for coverage decision**

**Example technologies**
- incontinence pad
- wheel chair
- pregnancy test

**Category II**
“artificial body parts”
medical devices which stay at or in the patient (e.g. knee endoprostheses, stents):

Device is (important) component of a procedure (hip implant → hip implantation)

**Device constitutes technology for coverage decision**

**Example technologies**
- knee (endo-)prosthesis
- Implantable Cardio-Defibrillator
- coronary stent

**Category III**
“assistance for professionals”
technical equipment supporting professionals in diagnostics and/or treatment with two-stage financing:

Device can be used for different procedures, e.g. brain CT scan for headache ...

**Example technologies**
- endoscope (for e.g. gastroscopy)
- operating room equipment
- imaging devices: X-ray, CT, MRI
The process in France (after licencing)

- **Medical device Process**
  - HTA: Assessment of clinical and societal value by HAS specialized committees
  - CNEDiMTS (Assessment Committee for Medical Devices and procedures)
    - Submission of a file by the company

- **Medical procedure Process**
  - Submission of a file by scientific societies

- **Pricing**
  - CEPS (Economic Committee for Health Products & Services)
    - Fixes prices after negotiations with company
  - CHAP (Committee of grading of Medical Procedure):
    - Located within the UNCAM
    - Fixes reimbursement tariffs and rates for medical procedures after negotiation with Health professional unions

- **Coverage decision**
  - Ministry of Health: Establishes lists of reimbursable medical devices (LPPR)
  - UNCAM (National Health Insurance funds): Establishes lists of reimbursable medical procedures
Helping policy-makers and HTA doers to prioritize and select methodology – our taxonomy

| Classification criteria of EU-Directives according to risk aspects: | Classification according to the relevance of product & service and reimbursement characteristics (includes OECD Classification of Health Care Functions) + HTA logic |
|---|---|---|---|---|---|
|  | Diagnostic Technologies | Therapeutic Technologies |
|  | Assistive technology devices (directly used by patients) A1 | Artificial body parts (implanted by medical procedure) B1 | Medical devices for the assistance of medical professional C1 | Assistive technology devices (directly used by patients) A2 | Artificial body parts (implanted by medical procedure) B2 | Medical devices for the assistance of medical professional C2 |
| I | Thermometer | Stethoscope | Walking frame | Spatula |
| IIa | Pulse oximeter | Ultrasound | Hearing aids | Dental crown | Tracheal tube |
| IIb | | X-ray | Insulin pen; Corrective lenses | Dental implant; Bone prosthesis | Laser RT- Unit |
| III | Neuro-endoscope | Condoms with spermicide | Cardiac stents; Artificial joints | Angioplasty balloon catheter |
| IV | ICD: heart monitor unit | | ICD: defibrillator unit |
| V | Glucose strip; pregnancy test | ABO/Rh (D) blood analyser |

Source: Henschke et al., 2015

Medical devices with a diagnostic and a therapeutic function possibly need to be evaluated twice
Testing the taxonomy looking at 1237 HTA reports with 1396 devices from 33 agencies, 2004-2015

Source: Fuchs et al., 2018
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<td>B2</td>
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<td>C2</td>
</tr>
<tr>
<td>Example</td>
<td>No.</td>
<td>Example</td>
</tr>
<tr>
<td>Ophtalmoscope</td>
<td>11</td>
<td>Wrist splint; Insoles</td>
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<td>MRI; Ultrasound</td>
<td>115</td>
<td>Grommets; Dentures</td>
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Source: Fuchs et al., 2018
Available HTA guidance for medical devices

Figure 2. Overview of identified and analyzed methodological documents.
Note. MDs = medical devices; DACEHTA = Danish Centre for Health Technology Assessment; HAS = Haute Autorité de Santé; LBI = Ludwig Boltzmann Institute for Health Technology Assessment; NICE = National Institute for Health and Care Excellence; ZiN = Zorginstituut Nederland; *Nine out of 45 general methodological documents could not be extracted due to language barrier and thus are not considered in the analysis.

Source: Fuchs et al., 2016
References


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• Tarricone R, Torbica A, Drummond M. Challenges in the assessment of medical devices: the MedtecHTA project. Health Economics 2017;26(S1):5–12
