Medical technologies and financial sustainability – do we know what we need to know? A systems‘ view

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NO!

But how do we get there?
Background

Medical technology industry relevant in terms of employment and turnover but not very visible in policy and academia

-> plausible industry claim of innovativeness (and therefore “value” to society)

-> but scarcity of European data on medical and economic value of medical technologies

-> might lead to application of financing, evaluation and regulatory instruments derived from pharmaceuticals
Different policy objectives …

- **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)**

Way of medical devices into and through the health care system
Addressing gaps and challenges – Research on Medical Technology

• Aims and objectives
  – Conduct high level research on the economic and health implications of medical technologies, in particular, medical devices
  – Bridge the gap between medical technology industry, academia and health policy
  – Provide decision-makers with robust evidence on the social & economic value of medical technology
  – Contribute to the debate on access, availability, diffusion and optimal use of medical technologies in Europe
Addressing gaps and challenges – The research agenda

• Bringing health technologies onto academic (-> publications) and policy agendas

• Understanding market access, coverage, financing, utilisation and actual/ potential benefit of selected technologies

• Comparing regulatory policies across countries and technologies in respect to current (and future) economic, health and social policy objectives and overall „economic value“

• Identifying „good“ and „bad“ regulatory policies in order to help shaping future policy
Conceptualizing „economic value“

- Mortality ↓
- Morbidity ↓
- Function/ qol ↑

Medical value/ benefit to patient

- Non-medical device costs of service (short-term) ↓
- Future health care costs ↓

+ others  

Current HTA perspective

Productive population ↑

Economic value ↑
Research questions

- Mortality ↓
- Morbidity ↓
- Function/ qol ↑

How to measure this for medical devices (vs. drugs)?

Does this link hold for non-active (elderly/ disabled) persons?

Medical value/ benefit to patient

- Non-medical device costs of service (short-term) ↓
- Future health care costs ↓

+ others

Productive population ↑

Economic value ↑

Current HTA perspective

How to add up the two sources? How to express it (€, GDP)?
# Medical technologies classification – causing more confusion than clarity?

<table>
<thead>
<tr>
<th>No.</th>
<th>Category</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Active implantable technology</td>
<td></td>
</tr>
<tr>
<td>02</td>
<td>Anaesthetic and respiratory technologies</td>
<td></td>
</tr>
<tr>
<td>03</td>
<td>Dental technologies</td>
<td></td>
</tr>
<tr>
<td>04</td>
<td>Electromechanical medical technologies</td>
<td>X-ray, CT scanner</td>
</tr>
<tr>
<td>05</td>
<td>Hospital hardware</td>
<td></td>
</tr>
<tr>
<td>06</td>
<td>In-vitro diagnostic technology</td>
<td></td>
</tr>
<tr>
<td>07</td>
<td>Nonactive implantable technologies</td>
<td></td>
</tr>
<tr>
<td>08</td>
<td>Ophthalmic and optical technologies</td>
<td>Eye glasses, contact lenses; ophthalmoscope</td>
</tr>
<tr>
<td>09</td>
<td>Reusable instruments</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Single-use technology</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Technical aids for disabled people</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Diagnostic and therapeutic radiation techn.</td>
<td></td>
</tr>
</tbody>
</table>
A structure of medical device technologies based on financing and usage in health care system

**Category 0 “Supporting technologies to Category I to III”**
Reusable instruments, single use technology etc.: syringes, X-ray films, …. Technology = part of Cat. I to III, not reimbursed separately

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

**Category II “artificial body parts”**
medical devices which stay at or in the patient (e.g. knee endoprostheses, stents): only one component of a broader “service package” to implant or adapt the (hardware) product” to the individual patient

**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)

**Example technologies**
- incontinence pads
- wheelchair
- pregnancy test
- knee (endo-)prosthesis
- Implanable Cardio-Defibrillator
- coronary stents
- operating room equipment
- imaging devices: X-ray, CT, MRI

**In-between category I-II:**
“medical aids with large service component”
(e.g. exo-prostheses)

**For discussion:**
separation in actual “assisting” technologies (e.g. endoscope, ehealth solutions) and high technology (e.g. scanner, OR equipment)
Relationships between patients, payers, providers, manufacturers and distributors of medical devices

- Patient
- Service Provider
- Goods Distributor
- Third party payer
- Manufacturer
- Regulator

Reimbursement for goods and/or services

Cost sharing

Premium/contribution/taxes
Note: the numbers I, II, IIIa and IIIb refer to the technology categories in previous figure
But the world of medical devices is more complex …

Licensing decision

Coverage decision

Reimbursement decision
## Licensing decision in the EU

<table>
<thead>
<tr>
<th>Licensing regulation</th>
<th>EU regulation (medical devices directives), transposed into national law</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual licensing decision on a certain medical device</td>
<td>Notified bodies in 27 member states (but decision is also valid in all other 26 countries) – decision depends on safety concerns, functionality, product quality</td>
</tr>
</tbody>
</table>

- **Not effectiveness/medical benefit to patient**

  - Coverage decision
  - Reimbursement decision
Coverage decision in the EU

- Licensing decision

  Coverage (public benefit basket)
  - EU member states, usually at national level, either through government or through self-governing bodies

- Reimbursement decision
Decisions on coverage of medical devices – usage of Health Technology Assessment (HTA)

- **Category I** “medical aids”
  - standard products which are prescribed and given to an individual patient
  - device = benefit in Category I

- **Category II** “artificial body parts”
  - technical equipment supporting professionals in diagnostics and/or treatment
  - only one component of a broader “service package” to implant or adapt the “(hardware) product” to the individual patient

- **Category III** “assistance for professionals”
  - technical equipment for professionals in indication/service/product combination
  - only one component of a broader “service package” to implant or adapt the “(hardware) product” to the individual patient
  - refinancing via use (diagnostics/treatment)

**Currently role for HTA, typically for indication/service/product combination**
- Little HTA

**Limitations to particular patients, products or service providers possible**
Currently ...

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)
... and soon
a changing regulatory environment?

... but evaluation is more complex than for pharmaceuticals and cannot be copied!
But are evaluations of medical technologies for HTA possible?

- Short product cycles -> evaluation takes too long and impedes access
- Small patient groups -> randomisation/control group not possible (untrue!)
- Placebo often not possible -> good use of data under routine conditions necessary!

**SOLUTION:** include in benefit basket if at least as good as old one; if priced higher, reimburse it only for a limited time and in exchange for proper evaluation
Evaluation of routine care is possible: PTCA only vs. No PTCA

• To give an idea what EHTI results will look like
• Risk-adjustement (propensity score) needs to be improved
• Further variables have to be integrated in the regression
• with stable model comparison to stents (bare metal & DES)
Reimbursement decision in the EU

Licensing decision

Coverage decision

Reimbursement rates
National or sub-national, either through government or through self-governing bodies
Reimbursement of medical device technologies

**Medical Technologies**

1. **Category I**
   - "Medical aids"
   - Standard products which are prescribed and given to an individual patient.
   - Product constitutes "benefit", i.e., reimbursement for product, possibly limited by reference price (RP).
   - RP necessitates a proper differentiation of products.

2. **Category II**
   - "Artificial body parts"
   - Medical devices which stay at or in the patient (e.g., knee endoprostheses, stents).
   - "Benefit" = service, reimbursement includes product and/or is complemented by additional payment if expensive or innovative.
   - DRGs (case fees)/additional payments necessitate proper differentiation of patients and products.

3. **Category III**
   - "Assistance for professionals"
   - Technical equipment for professionals.
   - "Benefits" = different services with reimbursement usually unrelated to price of technology.

- DRGs (case fees)/additional payments
- RPM necessitates a proper differentiation of products.
- Endoscope (for e.g., gastroscopy)
- [Operating room equipment]
- [Imaging devices: X-ray, CT, MRI]
## Number of DRGs/HRGs for particular devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Germany</th>
<th>Italy</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implantable Cardio-Defibrillator</td>
<td>9</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Knee replacement</td>
<td>13</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Negative pressure/vacuum therapy</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Conclusions

• Medical technologies play an important part of health care
• … but variable terminology and regulatory framework leads to misunderstandings and
• both under- and overestimation of benefit
  -> coherent framework necessary
  -> proper evaluation necessary, but methodology cannot be copied
  -> important role for health and cost data gathered under routine conditions