Decision-making: the link between reference pricing and procurement

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Relationships between patients, payers, providers, manufacturers and distributors of medical devices

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

**Reimbursement for goods and/or services**

- premium/contribution/taxes
- **Cost sharing**
- **Purchasing/procurement of goods**
• First observation: complicated relationships, varying among medical technologies (and countries)

• Second observation: complicated/confusing terminology – What is procurement? What is price? What is reference price? Does it refer to reimbursement or procurement?
Structure of medical device technologies

- **Category I**
  - "medical aids"
  - standard 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 endoprosthesis, stents): only one component of a "service package" to get the "product" to the 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)

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

Choose technologies:
- incontinence pads
- knee (endo-)prostheses
- ICD
- coronary stents
- endoscope (for e.g. gastroscopy)
- [operating room equipment]
- [imaging devices: X-ray, CT, MRI]

Note: underlined technologies are part of the first part of the project
Relationships between patients, payers, providers, manufacturers and distributors of medical devices

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 …

1. Licensing decision
2. Coverage decision
3. 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>

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
How is the benefit basket structured? What is the taxonomy? How explicit is it?

Figure 1. Spanish Health Basket

- Spanish Health Basket (RD 1030/06)
  - Public health (Annex I)
  - Primary care Services (Annex II)
  - Specialized care Services (Annex III)
  - Emergency care Services (Annex IV)
  - Pharmaceutical services (Annex V)
  - Orthopaedic services (Annex VI)
  - Dietary Products (Annex VII)
  - Patient transportation (Annex VIII)
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Legally binding</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y (only technology appraisals)</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Decision-makers</td>
<td>Parliament</td>
<td>Parliament</td>
<td>Secretary of State; SHAs; Monitor</td>
<td>DH; external reference groups</td>
<td>DH; Appraisal Committee; National Collaborating Centres; Advisory Committee; stakeholders</td>
<td>DH</td>
<td>Secretary of State for Health; PPD</td>
<td>DH: professional bodies and associations</td>
<td></td>
</tr>
<tr>
<td>Original purpose</td>
<td>Establishes duties and powers for broad categories of care</td>
<td>Clarify or amend primary legislation</td>
<td>Direct action of NHS bodies</td>
<td>Improve quality and decrease variation of services</td>
<td>Improve quality and decrease variation of services</td>
<td>Reimbursement</td>
<td>Reimbursement</td>
<td>Reimbursement</td>
<td>Reimbursement</td>
</tr>
<tr>
<td>Positive or negative definition of benefits</td>
<td>P</td>
<td>P/N</td>
<td>P</td>
<td>P</td>
<td>P/N</td>
<td>P</td>
<td>P</td>
<td>P</td>
<td>P</td>
</tr>
<tr>
<td>Degree of Explicitness*</td>
<td>1</td>
<td>1-3</td>
<td>2</td>
<td>2 or 3</td>
<td>2 or 3</td>
<td>1-3</td>
<td>2 or 3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Updating</td>
<td>Irregular</td>
<td>Irregular</td>
<td>No</td>
<td>Unclear</td>
<td>Every 4 to 6 years</td>
<td>Infrequent</td>
<td>Still evolving</td>
<td>Monthly</td>
<td>Annually</td>
</tr>
<tr>
<td>Criteria for Defining Benefits</td>
<td>Political judgment: ‘necessary to meet all reasonable requirements’</td>
<td>Need, costs, cost-effectiveness, budget, safety</td>
<td>Need, effectiveness, budget</td>
<td>Need and effectiveness</td>
<td>Costs, effectiveness, and cost-effectiveness</td>
<td>Need and budget</td>
<td>Costs and budget</td>
<td>Costs, cost-effectiveness, budget, safety, quality, and appropriateness</td>
<td>Need and budget</td>
</tr>
</tbody>
</table>

*1—all necessary, 2—areas of care, 3—items
Decisions on coverage of medical devices

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

**Category II**
“artificial body parts”
medically necessary products 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:
- implants
- endoscope (for e.g. gastroscopy)
- [operating room equipment]
- [imaging devices: X-ray, CT, MRI]

**Large emphasis on HTA, typically for indication/service/product combination**

Service (not product) is focus of HTA

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

**Category I**
"medical aids"
- Product constitutes "benefit", i.e. reimbursement for product, possibly limited by reference price (RP)
- RP necessitates a proper differentiation of products

**Category II**
"artificial body parts"
- "Benefit" = service, reimbursement includes product and/or is complemented by additional payment if expensive (UK, F, partly I) or innovative (D)
- DRG/ additional payments necessitate proper differentiation

**Category III**
"assistance for professionals"
- "Benefits" = different services with reimbursement usually unrelated to price of technology
- • endoscope (for e.g. gastroscopy)
- • [operating room equipment]
- • [imaging devices: X-ray, CT, MRI]
Reimbursement of medical aids in Germany

- Sickness funds shall implement public tenders for standardized products

- Sickness funds shall conclude contracts for further products

- Sickness funds shall conclude individual contracts for products with high service intensity (e.g. exoprostheses)

- For certain categories of products, RPs exist. If contracts based on tenders are concluded for these categories, these RPs serve as maximum prices.
Relationships between patients, payers, providers, manufacturers and distributors of medical devices
• There are reference prices (RPs) for 6 out of 33 categories of medical aids

• RPs serve as a reimbursement limit

• Products are grouped in homogeneous classes; for each group, reference prices are set (based on current market)
# Reference prices for Incontinence Pads in Germany

<table>
<thead>
<tr>
<th>Number of position</th>
<th>Term</th>
<th>Reference price [€] [each]</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.25.01</td>
<td>absorptive incontinence pad</td>
<td></td>
</tr>
<tr>
<td>15.25.01.0</td>
<td>Anatomical formed incontinence pad, normal absorptive capacity, size 1</td>
<td>0.29</td>
</tr>
<tr>
<td>15.25.01.1</td>
<td>dito., size 2</td>
<td>0.35</td>
</tr>
<tr>
<td>15.25.01.2</td>
<td>dito., size 3</td>
<td>0.43</td>
</tr>
<tr>
<td>15.25.01.3</td>
<td>rectangular formed incontinence pad, size 1</td>
<td>0.19</td>
</tr>
<tr>
<td>15.25.01.4</td>
<td>rectangular formed incontinence pad, size 2</td>
<td>0.23</td>
</tr>
<tr>
<td>15.25.01.5</td>
<td>incontinence pad for urinary incontinence</td>
<td>0.21</td>
</tr>
<tr>
<td>15.25.03</td>
<td>absorptive incontinence pants</td>
<td></td>
</tr>
<tr>
<td>15.25.03.0</td>
<td>incontinence pants, size 1</td>
<td>0.49</td>
</tr>
<tr>
<td>15.25.03.1</td>
<td>incontinence pants, size 2</td>
<td>0.51</td>
</tr>
<tr>
<td>15.25.03.2</td>
<td>incontinence pants, size 3</td>
<td>0.69</td>
</tr>
</tbody>
</table>

(Version: Bundesanzeiger No. 170, 11.09.2007)
### Table 25 Urinary incontinence pads in Spain – reimbursable products

<table>
<thead>
<tr>
<th>TYPE OF PAD</th>
<th>ABSORPTION RATE (cc)</th>
<th>MAXIMUM PRICE PER UNIT (Pesetas)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DAY</strong> for medium incontinence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectangular</td>
<td>600 – 900</td>
<td>65</td>
</tr>
<tr>
<td>Anatonic Shaped</td>
<td>600 – 900</td>
<td>78</td>
</tr>
<tr>
<td><strong>NIGHT</strong> for medium nightly or heavy daily incontinence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectangular</td>
<td>900 – 1200</td>
<td>92</td>
</tr>
<tr>
<td>Anatonic Shaped</td>
<td>900 – 1200</td>
<td>110</td>
</tr>
<tr>
<td><strong>SUPER NIGHT</strong> for heavy night incontinence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectangular</td>
<td>More than 1200</td>
<td>109</td>
</tr>
<tr>
<td>Anatonic Shaped</td>
<td>More than 1200</td>
<td>132</td>
</tr>
</tbody>
</table>

Source: (INSALUD 1988)
Reference prices for medical aids in Germany

- There are reference prices (RPs) for 6 out of 33 categories of medical aids
- RPs serve as a reimbursement limit
- Products are grouped in homogeneous classes; for each group, reference prices are set (based on current market)
- Manufacturers have a voice in this process
- Patients have to make co-payments
- Patients are free to choose any product with a price higher than the RP if they are willing to pay the difference between the actual selling price and the RP
Medical Aids: Expenditures from public sources under the German RP regime

- Incontinence pads
- All non-reference-price categories
- Hearing aids
- Ostomy products
- Arch support
- Compression therapy

Expenditures relative to 100%:
- 2003: 100%
- 2004: 105%
- 2005: 110%
- 2006: 115%

## Number of DRGs/HRGs for particular devices

<table>
<thead>
<tr>
<th></th>
<th>Germany</th>
<th>Italy</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICDs</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>Neg. pressure/vacuum therapy</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
Innovative devices: knee endoprostheses and coronary stents in Germany

National uniform standards

A1 Emergency care
(§ 1 Abs. 2, 4 KHG, § 4 Abs. 5 S. 2 KHEntgG)

A2 Accompanying persons
(§ 17b Abs. 1 S. 4 KHG)

A3 Quality assurance surcharges & deductions
(§ 7 S. 1 Nr. 7 KHEntgG)

B1 Surcharges for day-outlier with a longer length of stay
(§ 1 Abs. 2 FPV 2006)

B2 National uniform valuated DRG cost-weights (n=914)
(Case Fees Catalogue 2006)

B3 Deductions for day-outlier with a shorter length of stay and early patient transfer
(§ 1 Abs. 3 and § 3 FPV 2006)

D1 Not national uniform valuated DRG cost-weights (n=40)
(Appendix 3 FPV 2006 I.V.m. § 6 Abs. 1 S. 1 Nr. 2 KHEntgG)

D2 Not national uniform valuated supplementary fees (n=42)
(Appendix 4 und 6 FPV 2006)

D3 Day cases of curative care
(§ 6 Abs. 1 S. 1 Nr. 2 KHEntgG)

D4 Additional fees for highly specialised services which are not reimbursed appropriately
(§ 6 Abs. 2a KHEntgG)

D5 Foreign patients
(§ 4 Abs. 10 KHEntgG)

D6 Contracts for integrated care

E1 Surcharges for innovative diagnostic & treatment procedures
(§ 6 Abs. 2 KHEntgG)

E2 Surcharges for specialised centres e.g. heart centre
(§ 5 Abs. 3 KHEntgG)

E3 Apprenticeship surcharge
(§ 17a KHG)

E4 Service guarantee surcharge
(§ 5 Abs. 2 KHEntgG)

E5 Foreign patients
(§ 4 Abs. 10 KHEntgG)

E6 Contracts for integrated care

Revenue budget
Other revenues with compensation
(§ 6 Abs. 3 KHEntgG)

“NUB-Procedures”
Includes 2 types of stents – hospital-specific prices

Innovative diagnostic & treatment procedures
(§ 6 Abs. 2 KHEntgG)

Innovative diagnostic & treatment procedures
(§ 6 Abs. 2 KHEntgG)

Figure: Reimbursement Components of Inpatient Care in Germany (Schreyögg J, Tiemann O, Busse R (2006) Cost accounting to determine prices: How well do prices reflect costs in the German DRG-system? Health Care Manage Sci 9:269-279. With own adaptations and extensions)

Effects on diffusion of innovation?
-> work-in-progress of TUB team
Relationships between patients, payers, providers, manufacturers and distributors of medical devices

- **Third party payer**
  - **Reimbursement** for goods and/or services
  - premium/contribution/taxes

- **Patient**
  - **Cost sharing**

- **Service Provider**

- **Goods Distributor**

- **Public tenders**
  - **RP**es
    - **Purchasing/procurement of goods**
    - **Manufacturer**
Purchasing/procurement criteria for medical device technologies

Category I
“medical aids”

Category II
“artificial body parts”

Category III
“assistance for professionals”

HTA dimensions: effectiveness, cost-effectiveness …

Price

Perceived degree of innovation and quality

Chosen technologies
- incontinence pads
- knee (endo-)prostheses
- ICD
- coronary stents
- endoscope (for e.g. gastroscopy)
- [operating room equipment]
- [imaging devices: X-ray, CT, MRI]

Note: underlined technologies are part of the first part of the project
Procurement by individual service providers: France

**Figure 2: Procurement processes in France**

- **Public Procurement**
  - **Public Hospitals**
    - Most hospitals purchase directly from manufacturers.
    - Sales organizations within the public sector mainly assist smaller entities.
    - UGAP
    - CAHPP

- **Private Procurement**
  - **Private Hospitals/Pharmacies**
    - Sales organizations coordinate purchase for the private sector: mainly basic products.
    - CAHPP/CACIC
    - General de Santa
  - **General Practitioners & Specialists**
    - Office-based physicians purchase medical devices directly from manufacturers to distributors.
Figure 4: Procurement process in England

- **Public Procurement**
  - NHS Trusts & PCTs
  - NHS PASA
  - Procurement organizations initiate public bidding and close contracts.

- **Private Procurement**
  - Private Clinics/Hospitals/Pharmacies
  - Independent Hospital Procurement Teams

- **Medical Device Manufacturers**

  Direct sales to hospitals and GPs are not common.

  Sales organizations distribute medical device products to both public and private hospitals, GPs, and pharmacies.
Figure 5: Procurement mapping of VAC therapy
Individual purchasing the rule (but with hospital groups gaining power): France, Germany

From national to coordinated group purchasing: UK

Mixture of individual and regional purchasing with national regulation (RPs! – but different type): Italy
In conclusion …

- knowing about the limitations of this analysis
- we need to develop/ use common framework to understand what we are talking about when using the same terms
- collect data on effects on patient outcomes, diffusion of innovation, costs …
- have a dia- or rather trialogue (academics/industry/politicians)