How Medical Devices Are Reimbursed in Europe

Rational decision making in reimbursement decisions to provide optimal care at acceptable cost?

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Synergus AB
European Reimbursement: A Snapshot of Some Healthcare Systems

UK
- 152 Primary Care Trusts
- 105 Foundation Trusts
- 10 Strategic Health Authorities (England)
- HRG (DRG) Prospective payment system

Spain
- 17 autonomous regions
- High decision making power at hospital level (global budget)

France
- Public & Private – centralized decision making
- DRG (T2A) system prospective payment system
- Device specific reimbursement

Belgium
- 1 centralized system
- Device specific reimbursement

Denmark
- 5 Counties
- High decision making at hospital level (global budget)

Germany
- 16 counties – 134 public & 43 private sickness funds
- High decision making power at hospital level
- G-DRG prospective payment system

Italy
- 21 local health authorities
- High decision power at regional level
- DRG prospective payment system

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Agenda

- The reimbursement question
- Country-examples
  - Germany
  - France
• The reimbursement question?
  – Innovation
    • Does the new technology address a relevant question in the healthcare?
    • How do we know if it works?
    • What can we afford?
    • How should we introduce this?
    • How to monitor that it provides expected outcomes

  – Existing technologies
    • How to incentivize productivity improvements in the healthcare delivery
Pricing decisions

• In most countries in Europe:
  – Payer pays for clinical intervention including all required products.
  – Pricing of products is determined by negotiation between hospital and medical device company
  – Payment for intervention is based on historical resource utilization including material and labour.
  – No cross borderer comparison

• Two exceptions:
  – Belgium and France have product specific reimbursement with national pricing decision for some technologies (implants/medical aids)
DRG – A system to distribute healthcare funds

Demands on healthcare are increasing (e.g. with age)

Amount is "fixed"

Good distribution from a healthcare/payer perspective:
- is fair for small and big hospitals
- does support efficiency gains => less costs for produced healthcare
- has the ability to introduce innovations
Balancing the interest of the two parties!? 

German Hospital Association 

Association of Statutory and Private Health Insurances 

INEK 

A well designed DRG-system’s role in a Healthcare System
DRGs list which treatments (including medical devices) that can be provided to patients.

DRGs are meant to cover all costs that arise from a certain medical procedure – apart from investment costs (capital equipment). Those costs are instead financed by the regions (states/länder).

Medical device prices are negotiated between the hospital and the respective medical device manufacturer.

In addition to DRGs there is the option to apply for innovation funding, called NUB.

For certain specific procedures and treatment there may be established supplementary payment called Zusatzentgelt (ZE).
DRG tariffs are not intended to cover the cost of each individual procedure but should suffice on average.

- On average, DRGs are intended to provide sufficient reimbursement.
- Some procedures have a higher cost than the tariff, while some have a lower cost.
- For some procedures the hospitals make a profit and for some procedures they make a loss – but on average they should be sufficiently reimbursed.

Note: Conceptual illustration

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Key-factors for a well developed DRG-system

• Appropriate number of DRG’s to enable fair payment:
  – Too few DRG’s: unfair payment to some hospitals
  – Too many: Missing the intent with a case-mix system => per case payment..

  *Test: Simulate the payment for hospitals to ensure fair payment based on historical resource/cost data.*

• Dynamic system that evolves with change in clinical practice
  – Innovation payment to enable introduction of new technologies
  – Regular collection and analysis of high-quality resource and cost data
  – Updating of grouping of procedures to ensure appropriate reflection of current cost.
  – Reflecting cost reductions in purchasing or operational efficiency.

• Leadership of the utilization of the system.
G-DRG Saturation Curve

- G-DRG
- ZE
- # NUB Status 1
- # NUB to ZE
- # NUB to DRG

Year

#
Different ways to apply solution
DRG vs. Global Budget

- Detailed coding-system
- Less detailed coding-system
- 'Global budget'
Comparing DRG - dynamics

<table>
<thead>
<tr>
<th>Country</th>
<th>Updating cycle</th>
<th># of DRG’s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Irregular</td>
<td>982</td>
</tr>
<tr>
<td>England</td>
<td>Annual</td>
<td>1216</td>
</tr>
<tr>
<td>France</td>
<td>Annual</td>
<td>2297</td>
</tr>
<tr>
<td>Germany</td>
<td>Annual</td>
<td>1387</td>
</tr>
<tr>
<td>Italy</td>
<td>??</td>
<td>679</td>
</tr>
<tr>
<td>Poland</td>
<td>Irregular</td>
<td>518</td>
</tr>
<tr>
<td>Sweden</td>
<td>Annual</td>
<td>773</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Annual</td>
<td>1052</td>
</tr>
</tbody>
</table>
Casestudy
Open Heart valve replacement = Transapapical Heart valve replacement

Procedure cost: 18 000 €

Procedure cost: 32 000 €
## Cost Data for Open Aortic Heart Valve Replacement

### Table: Costs breakdown

<table>
<thead>
<tr>
<th>Costs</th>
<th>Sub cost</th>
<th>F03F (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel cost</td>
<td>Physicians¹</td>
<td>2826</td>
</tr>
<tr>
<td></td>
<td>Nursing</td>
<td>2532</td>
</tr>
<tr>
<td></td>
<td>Technician</td>
<td>2001</td>
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<tr>
<td></td>
<td>Total²</td>
<td>7359</td>
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<tr>
<td>Material cost</td>
<td>Device/Implant³</td>
<td>5367</td>
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<tr>
<td></td>
<td>Drugs</td>
<td>994</td>
</tr>
<tr>
<td></td>
<td>Total²</td>
<td>6361</td>
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<tr>
<td>Other costs</td>
<td>Medical Infrastructure</td>
<td>1211</td>
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<tr>
<td></td>
<td>Non-Medical Infrastructure</td>
<td>2759</td>
</tr>
<tr>
<td></td>
<td>Total²</td>
<td>3970</td>
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<td>Total reference cost, 2008</td>
<td></td>
<td>17690</td>
</tr>
<tr>
<td>Reimbursement, 2010</td>
<td></td>
<td>19828</td>
</tr>
</tbody>
</table>

### Scenario

**Different heart valve (percutaneous)**
Substantially more expensive

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Ref: G-DRG browser from InEK, version 2008/2010, UKM webgrouper 2010
Scenario 1

- Current Cost Curve
- New product

€18,900

€14,000 (Additional product price)

€32,900

Justifies DRG Split

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Two key-aspects of changing a DRG

1. Changes driven by historical data
   - OPS-change (DIMDI)
   - Has cost data been reported
     - Yes
     - DRG-change (InEK)
     - Even distribution
       - Additional funding ZE
       - Negotiation Sickness fund
       - Healthcare provider
     - Uneven distribution
       - Regrouping of DRG
       - Negotiation Sickness fund
       - Healthcare provider
   - No

2. Innovation funding
   - Covered sufficiently by G-DRG
     - Yes
     - Innovation Funding
     - InEK Evaluation (NUB)
     - Reimbursement
   - No
     - DRG with fixed cost-weight
     - Reimbursement (1 year)
What is a DRG-problem leading to change?

1. Changes driven by historical data

1. Procedural difference
2. Price difference
What triggers change in a DRG-system?

• Is there data to observe a problem?
  – Procedure codes exist
    • The codes have meaningful procedural differences, not different technical solutions.
  – Sufficient volume data reported to:
    • This is in order to establish if there is a problem. A few outliers is not a problem.
    • Provide consistent data to establish the correct cost.
Ways of change in DRG-system

• Scenario 1: Slow adoption:
  – DRG tariff updated based on historical cost data
    (UP and DOWN)

• Scenario 2: Faster adoption
  (requires reported data to demonstrate the problem)
  – New DRG
  – Regrouping of procedure to other DRG with appropriate Tariff
Reimbursement systems will adapt to real cost
Two Scenarios

1. Changes driven by historical data

1. **Scenario 1:**
   Gradual adaptation of reimbursement tariffs. “Automatic”

2. **Scenario 2:**
   Adaptation of reimbursement tariff based on change in reimbursement system
### Scenario 1:
Standard Pathway to change the weight / tariff of

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Year 6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Existing procedure (18 900 €)</strong></td>
<td>95%</td>
<td>90%</td>
<td>80%</td>
<td>60%</td>
<td>...</td>
<td>....</td>
</tr>
<tr>
<td><strong>New procedure (32 900 €)</strong></td>
<td>5%</td>
<td>10%</td>
<td>20%</td>
<td>40%</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td><strong>Reimbursement</strong></td>
<td>18 900</td>
<td>18 900</td>
<td>19 600</td>
<td>20 300</td>
<td>21 700</td>
<td>24 500</td>
</tr>
</tbody>
</table>

- Two year delay to reflect difference in case-mix
- Disincentive to use new technology
Scenario 2: New DRG or regrouping based on reported data.

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Existing procedure</td>
<td>99%</td>
<td>98%</td>
</tr>
<tr>
<td>(18 900 €)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New procedure</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>(32 900 €)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reimbursement</td>
<td>18 900</td>
<td>18 900</td>
</tr>
</tbody>
</table>

- Without the ability to get innovation funding, the financial disincentive will be too substantial to generate sufficient volume to demonstrate the problem leading to change.
Catch 22 in changing DRG-system

• To create change in a DRG-system requires reported procedures with new higher cost.
• Hospitals are not likely to adapt new therapies with high volume before sufficient payment is in place

• Two solutions:
  – Temporary funding programs to bridge introduction, like NUB in Germany.
  – Discretionary funding within the hospital budget.
Example of innovation funding

Innovation payment on top of the DRG provides add-on payment to cover for new procedures and enable volume uptake which leads to the permanent change.
Adaptation of G-DRG System

If procedure codes, DRGs and ZEs will be granted, they will be usable from the 1st January on (therefore the gradient colouring).

2. Innovation funding
DRG-systems

Well used, a good system to incentive effectiveness improvements in healthcare.
Device Funding & Reimbursement Mainly Organized at a National Level with a Focus on Clinical Effectiveness

The T2A (La Tarification à l’Activité) is the French activity-based hospital financing system which is similar to other DRG (Diagnosis-Related Group) systems.

Criteria for eligibility for LPPR inclusion:

- **Statistical criteria** (degree of heterogeneity within the cost distribution that would result from the integration of the product within the GHM).
- **Medical criteria** (strong innovation supported by clinical evidence).
- **Economic criteria** (high-cost devices supported by cost-effectiveness (CE); new rule: CE-study should be done in order to aim towards ASA [expected benefit improvement or added clinical value] 1, 2 or 3).

New Fast Track procedure:

- Grant reimbursement for whole package (medical device + procedure + medical fees).
- Limited period and in a restricted area (set by Health Ministry).
- Applicable since March 1st of 2010.

CCAM, Classification Commune des Actes Médicaux (procedure code classification); GHM, Groupe homogène de malades (DRG); GHS, Groupe Homogène de Séjour (DRG tariff); UNCAM, Union nationale des caisses d'assurance maladie; CNEDiMTS, Commission Nationale d'Évaluation des Dispositifs Médicaux et des Technologies de Santé; SEAP… SED… LPPR, Liste de Produits et Prestations Remboursables; PHRC, Programme hospitalier de recherche Clinique; STIC, Soutien aux techniques innovantes et coûteuses.

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Going through LPPR to Gain Reimbursement Implies both a Clinical and Budget Impact Evaluation

1. Notification about launch of medical device on French market
2. Declaration of the LPPR codes intended to be used (after inclusion in ANSM list)

Can be given by any European Notified Body
Required for the monitoring of MD market
Simultaneous submission to HAS and CEPS Only for "brand name" pathway
Any similar device on LPPR

“Brand name” pathway
“Generic description” pathway

Any similar device already exists on the LPPR

Economic dossier
Evaluation of the expected public health benefit (takes ~90 days)

Economic dossier
Based on the advisory opinion of CNEDIMTS (takes ~90 days)
Based both on the evaluation by the CNEDIMTS and by the CEPS

Decision by the Ministry of health

Manufacturer

Evaluation by CEPS

Evaluation by the CNEDIMTS/SED

SA sufficient
SA not sufficient
STOP

Application ANSM

Publication in the JORF then Registration on LPPR

Submission to CEPS

Submission to HAS

Average period in 2009 between Submission and Publication in the JORF* ~398 days (vs. 180 days in theory)

Clinical and technical dossier

* CEPS activity report 2009
Sources: CEPS, ANSM, HAS

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Content for LPPR application dossier (1/2)

1. Clinical and technical dossier

✓ Administrative data
✓ History of development, marketing, and reimbursement of the product
✓ Associated procedure codes, if applicable
✓ Proof of the **Actual Benefit (SA)**, claimed by the applicant (description of the product benefit and of the current strategy, impact on the public health, risks and adverse effects); can result in
  - SA
  - No SA

<table>
<thead>
<tr>
<th>Level of scientific evidence for published data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
</tr>
<tr>
<td>Randomised controlled trials of high power (low alpha and beta risks) / Meta-analyses</td>
</tr>
<tr>
<td>Level 2</td>
</tr>
<tr>
<td>Randomised controlled trials of low power (high alpha and beta risks)</td>
</tr>
<tr>
<td>Level 3</td>
</tr>
<tr>
<td>Non randomised prospective comparative studies or Cohort or prospective studies</td>
</tr>
<tr>
<td>Level 4</td>
</tr>
<tr>
<td>Comparative studies with historical series or studies containing bias</td>
</tr>
<tr>
<td>Level 5</td>
</tr>
<tr>
<td>Case series or retrospective studies</td>
</tr>
</tbody>
</table>

✓ Demonstration of the Improvement in **Added Clinical Value (ASA)** claimed by the applicant
  - Proposed comparator
  - Description of endpoints used to assess ASA
  - Level of ASA with justifications
  - Demonstrations of ASA
✓ Target population
✓ Recommendation on conditions of prescription and use

<table>
<thead>
<tr>
<th>Level of Added Clinical Value (ASA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Major improvement</td>
</tr>
<tr>
<td>II. Substantial improvement</td>
</tr>
<tr>
<td>III. Moderate improvement</td>
</tr>
<tr>
<td>IV. Minor improvement</td>
</tr>
<tr>
<td>V. No improvement</td>
</tr>
</tbody>
</table>

1 **SA**: service attendu (expected actual benefit)
2 **ASA**: amélioration du service rendu (expected benefit improvement or added clinical value)
Conclusion

• Coverage with Evidence development
  – Controlled introduction of innovation

• Evolvement of clinical guidelines to reflect best practice

• HTA
  – Later stage evaluation of new methodologies

• Payment for interventions including device
  – Transparent updating based on historical resource utilization
  – Incentivizing efficiency improvements
Thank You!