The German NUB Regulation – A Gateway for Introducing Innovative Medical Devices into the German Inpatient Reimbursement System?

Cornelia Henschke
Michael Bäumler
Sabrina Weid
Reinhard Busse

Dept. of Health Care Management, Berlin University of Technology (WHO Collaborating Centre for Health Systems Research and Management) & European Health Technology Institute for Socio-Economic Research
Background

• Innovations may be associated with dramatic improvements in life expectancy and/or quality of life

• Reimbursement systems might influence
  ➢ utilization through providers
  ➢ future revenues of manufacturers
  ➢ incentives to develop new devices

• In Germany, a large share of innovative medical devices are first introduced in the inpatient sector

• In G-DRG system, costs for medical devices are included in the regular case fee catalogue (specific case fees/supplementary fees)


→ Importance of an adequate and quick inclusion of effective innovations in the case fee catalogue
Problem: Relative Time-Lag of the G-DRG System

Application for specific procedure (OPS) code

Acceptance of OPS code

Adaption/split of DRGs

Cases concerned can be separately calculated

Specific data collection of procedure utilization (using the OPS code) at national level

Potential reimbursement time lag

Year 0 → Year 1 → Year 2 → Year 3

Source: based on Roeder 2004
NUB (New Diagnostic and Treatment Methods) – The Political Instrument to Bridge the Time Lag

Application for specific procedure (OPS) code

Acceptance of OPS code

Adaption/split of DRGs

Cases concerned can be separately calculated

Specific data collection of procedure utilization (using the OPS code) at national level

Application of NUB by Oct 31

Bridge the gap via NUB-payments § 6 Abs. 2 KEntgG

Source: based on Roeder 2004
Research Objectives

• Does the NUB procedure work, i.e. does it bridge the gap to full integration into the G-DRG system?
• Description and analysis of the integration process for innovative medical devices into the G-DRG system, with special focus on the NUB-system
• Starting with a prototypical ideal way of integration for innovative medical devices
• Compare the prototypical way of integration with the available evidence on actual integration
The NUB Process

Individual (re)application of a hospital

31st October (Year 0)

Application for acceptance:
- A description of the new diagnostic and treatment method, specifying its innovative aspects
- A description of patients who will be treated
- Any additional labour and material costs and
- The reason why the new diagnostic or treatment method is not appropriately integrated into the current G-DRG system
The NUB Process

Individual (re)application of a hospital

Decision of the InEK about status

31st October (Year 0)

31st January Y1 (for Year 1)

Status of submitted NUBs
1. Procedures that fulfil the criteria of the NUB arrangement (accepted NUBs)
2. Procedures that do not fulfil the criteria of the NUB arrangements (refused NUBs)
3. Application that could not be processed until 01/30
4. Applications with missing information/insufficient description of the method
The NUB Process

Individual (re)application of a hospital

Decision of the InEK about status

31st October (Year 0)
31st January Y1 (for Year 1)

September/31st October Year 1 (for Year 2)

If Status 1:
InEK considers inclusion for the next version of the catalogue and publishes the next DRG version;
if not included: re-application as NUB possible
Three Hurdles for Integration of New Technologies

1. Acceptance of the application by the InEK

2. Agreement with the sickness funds about an additional payment/an innovation case fee including the uncertainty of negotiations with sickness fund

3. Integration of the procedure into the regular case fee catalogue to lower transaction costs for negotiations and uncertainty for the hospitals
   - Supplementary fee (unvaluated)
   - Supplementary fee (valuated)
   - Specific DRG
# Different Degrees of Integration

<table>
<thead>
<tr>
<th>Add-on payment/additional fee</th>
<th>Specific case fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local negotiations</td>
<td>Uniform payments</td>
</tr>
<tr>
<td>NUB regulation</td>
<td>Integrated in regular case fee catalogue</td>
</tr>
</tbody>
</table>

## OPS-Code exists

- **High number of treated patients and low cost variation**
  - Accepted NUB (with OPS)
  - Supplementary fee (valuated)
  - Specific DRG

## OPS-Code does not exist

- **Low number of treated patients or too great cost variance**
  - Accepted NUB (without OPS)
  - Supplementary fee (un-valuated)
  - Accepted NUB (without OPS)
## Number of Technologies Accepted for the First Time

<table>
<thead>
<tr>
<th>Year</th>
<th>Total Number of Newly Accepted Technologies</th>
<th>Medical Devices</th>
<th>Others (metabolic function)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>Follow-up over 4 years</td>
<td>26</td>
<td>8</td>
</tr>
<tr>
<td>2006</td>
<td>Follow-up over 3 years</td>
<td>38</td>
<td>19</td>
</tr>
<tr>
<td>2007</td>
<td>Follow-up over 2 years</td>
<td>37</td>
<td>19</td>
</tr>
<tr>
<td>2008</td>
<td>Follow-up over 1 year</td>
<td>21</td>
<td>11</td>
</tr>
<tr>
<td>2009</td>
<td></td>
<td>26</td>
<td>10</td>
</tr>
</tbody>
</table>

Source: Own calculation based on data of InEK
Evidence on Integration from the NUBs into the regular system

Several paths a technology can take within the system after successful application at the InEK:

(1) Once again accepted as an NUB
   • hospitals discover a significant gap between reimbursement and costs
   • confirmation of the InEK

(2) Explicitly integrated into the regular system
   • the best case from the hospitals’ point of view
   • the hospital receives a specific DRG reimbursement, a well-defined supplementary fee or may at least negotiate supplementary fees according to the regular DRG catalogue

(3) The rejection of a re-application
   • there is no financing gap between the existing tariffs and the costs for the new technology \( \rightarrow \) tariffs are already meant to cover the costs for the technology sufficiently (implicitly integrated)
   • insufficient information supplied by the hospital during the application process

(4) No re-application by a hospital
   • the use of the technology may no longer be desired by the hospital
   • financial reasons: the hospital does not expect any cost differences between the regular reimbursement tariff and the costs arising from the procedure (implicitly integrated)

\( \rightarrow \) Stratification for medical devices and other technologies
# Integration of NUBs Accepted in 2005 (= Year 1)

<table>
<thead>
<tr>
<th>Year</th>
<th>Accepted NUB</th>
<th>Integrated</th>
<th>Rejected re-application</th>
<th>No re-application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year5</td>
<td>11%</td>
<td>78%</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Year4</td>
<td>17%</td>
<td>72%</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Year3</td>
<td>33%</td>
<td>56%</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Year2</td>
<td>56%</td>
<td>33%</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Year1</td>
<td>100% (18)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year5</td>
<td>25%</td>
<td>38%</td>
<td>25%</td>
<td>13%</td>
</tr>
<tr>
<td>Year4</td>
<td>38%</td>
<td>25%</td>
<td>25%</td>
<td>13%</td>
</tr>
<tr>
<td>Year3</td>
<td>63%</td>
<td>13%</td>
<td>13%</td>
<td>13%</td>
</tr>
<tr>
<td>Year2</td>
<td>88%</td>
<td></td>
<td></td>
<td>13%</td>
</tr>
<tr>
<td>Year1</td>
<td>100% (8)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Others 05**

**Medtech 2005**
### Integration of NUBs Accepted in 2006 (= Year 1)

<table>
<thead>
<tr>
<th>Year</th>
<th>Accepted NUB</th>
<th>Integrated</th>
<th>Rejected re-application</th>
<th>No re-application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>100% (19)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td>68%</td>
<td>21%</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Year 3</td>
<td>47%</td>
<td>32%</td>
<td>11%</td>
<td>11%</td>
</tr>
<tr>
<td>Year 4</td>
<td>37%</td>
<td>37%</td>
<td>11%</td>
<td>5%</td>
</tr>
</tbody>
</table>

**Others 06**

<table>
<thead>
<tr>
<th>Year</th>
<th>Accepted NUB</th>
<th>Integrated</th>
<th>Rejected re-application</th>
<th>No re-application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>100% (19)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td>68%</td>
<td>21%</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Year 3</td>
<td>47%</td>
<td>32%</td>
<td>11%</td>
<td>11%</td>
</tr>
<tr>
<td>Year 4</td>
<td>37%</td>
<td>37%</td>
<td>11%</td>
<td>5%</td>
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</tbody>
</table>

**Medtech 2006**

<table>
<thead>
<tr>
<th>Year</th>
<th>Accepted NUB</th>
<th>Integrated</th>
<th>Rejected re-application</th>
<th>No re-application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>100% (19)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td>58%</td>
<td>32%</td>
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<tr>
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<td>32%</td>
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<td>5%</td>
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<tr>
<td>Year 4</td>
<td>47%</td>
<td>37%</td>
<td>11%</td>
<td>5%</td>
</tr>
</tbody>
</table>
### Integration of NUBs Accepted in 2007 (= Year 1)

<table>
<thead>
<tr>
<th>Medtech 2007</th>
<th>Year3</th>
<th>63%</th>
<th>16%</th>
<th>16%</th>
<th>5%</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Year2</td>
<td>74%</td>
<td>11%</td>
<td>11%</td>
<td>5%</td>
</tr>
<tr>
<td></td>
<td>Year1</td>
<td>100% (19)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Others 07</th>
<th>Year3</th>
<th>72%</th>
<th>17%</th>
<th>6%</th>
<th>6%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Year2</td>
<td>83%</td>
<td>6%</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td></td>
<td>Year1</td>
<td>100% (18)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Legend:
- Accepted NUB
- Integrated
- Rejected re-application
- No re-application
Integration of NUBs Accepted in 2008 (= Year 1)

<table>
<thead>
<tr>
<th>Year</th>
<th>Accepted NUB</th>
<th>Integrated</th>
<th>Rejected re-application</th>
<th>No re-application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>100% (10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td>100%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others 08</td>
<td>90%</td>
<td></td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Medtech 08</td>
<td>100% (11)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Conclusion and Policy Implications (1)

- Effective innovative medical devices should be part of the benefit basket
- Without the eligibility for reimbursement:
  - no access of many insured patients to innovative devices
  - little incentives for manufacturers to develop new products
  - the capability of a more efficient health care system is at risk

→ The German NUB system enables relatively expeditious access to innovative medical devices:
- an intermediate step for integrating innovative products into the regular G-DRG system
- About 1/4 of medical devices and 1/3 of other products are explicitly integrated within two years after first acceptance as NUB
- therefore the system (rightly!) provides no guarantee for the integration into the SHI benefit basket
Today’s policy:
• (non-)integration is driven mainly by utilization numbers and need for extra funding
• medical devices do not have to show their effectiveness in the treatment of patients → possible problem resulting from too fast integration

Future policy should also consider effectiveness (as in ambulatory care sector) and possibly cost-effectiveness:
• acceptance as NUB may be tied with requirement to evaluate (may also increase willingness of sickness funds to pay for NUBs)
• evidence of higher effectiveness might improve the speed of integration
Thanks to the audience!

• Presentation and further information available at:

  www.mig.tu-berlin.de

• Further information on the European Health Technology Institute on Socio-Economic Research is available at:

  www.ehti.info