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

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The Question

The German NUB System – why talk about it?

NUB: „Neue Untersuchungs- und Behandlungsmethode“ = new diagnostic and treatment method

Is it an Inspiration for other countries?

What else can be done to improve innovation funding for medical devices?

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We have to go back in time...

Before the NUB System was introduced, a G-DRG system was created in Germany in 2003 based on the Australian AR-DRG system.

However innovations had a hard time. Why?

At least four years gap between **CE marking** of a new method and **first reimbursement.**

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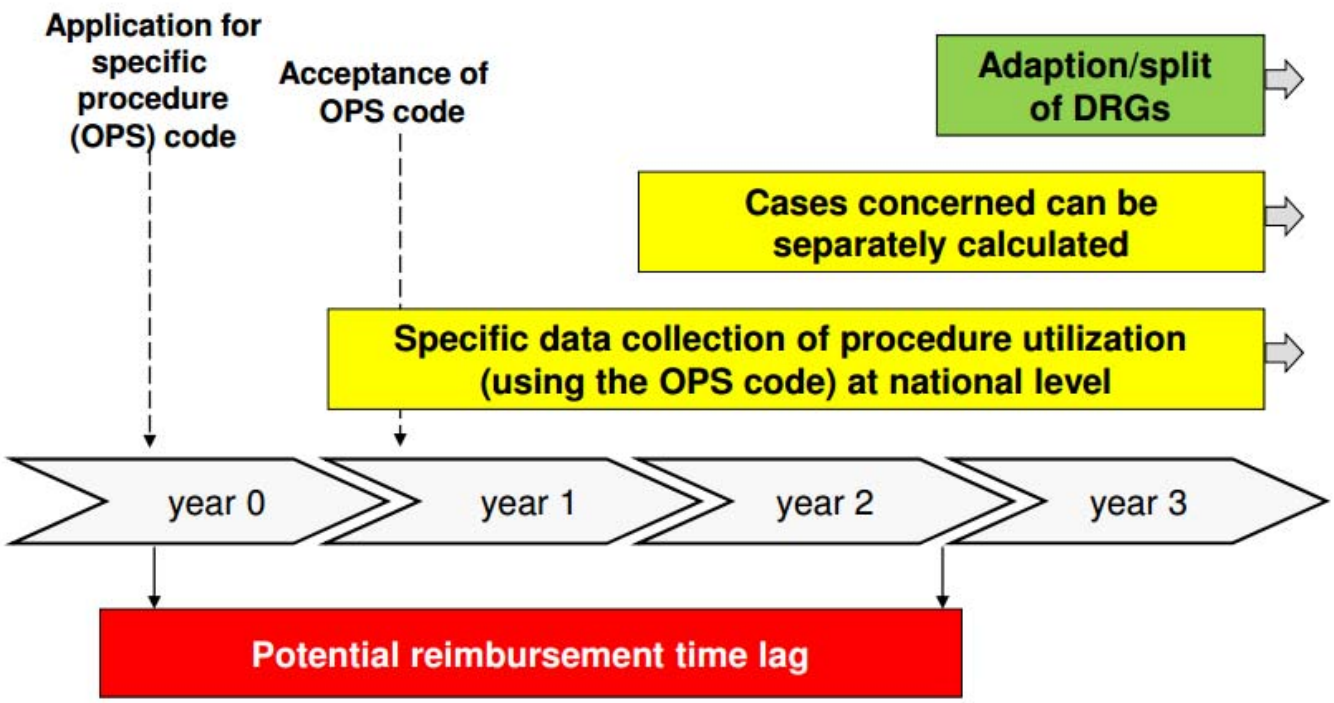
DRG systems have a critical time lag for innovations



Source: based on Roeder 2004

1. Application needed for a specific procedure code (must be supported by medical society)
2. Collection of cost data based on procedure code for a complete year
3. Calculation of new reimbursement based on cost data
4. New DRGs being published by DRG-institute (InEK)

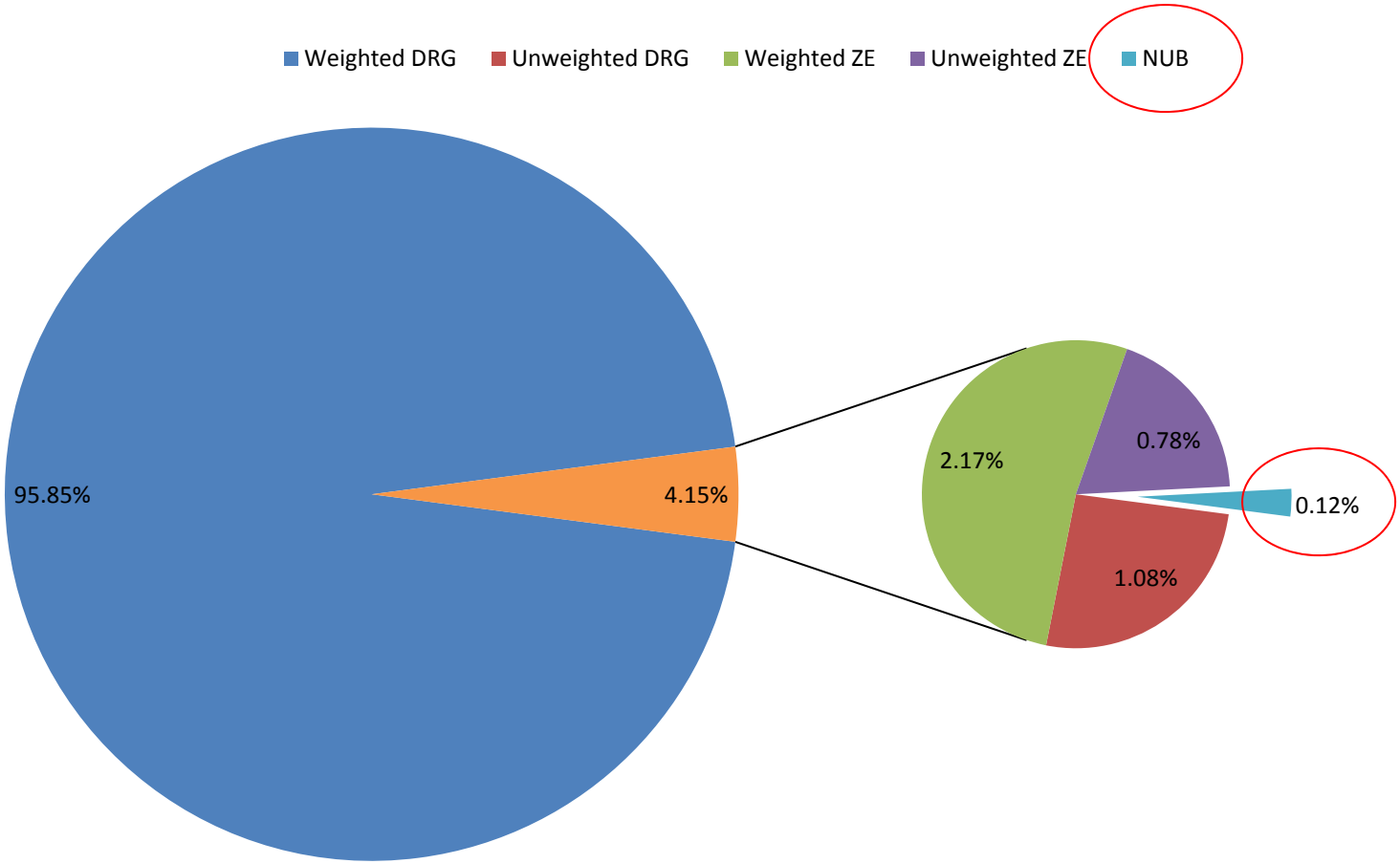
What did the NUB System aim for?

- To close the gap between CE marking and possible reimbursement
- Allow each hospital in collaboration with industry to apply individually
- Payment must be negotiated between each single clinic and the payers
- Contract only applicable and usable for one year (re-application neded for two more years)

NUB General Conditions

- **Technologies eligible for NUB:**
  - New CE-marked Innovative diagnostic or therapeutic method(not longer than 3 years used in Germany)
  - Costly (> 500 ,- EUR)
- **Supplementary payment for technologies that are not included yet into the German DRG-reimbursement**

But: NUB-Reality Check – overall spending



Why it is not working?

- The institute (InEk) responsible for NUB collection and rating is a black box
- Even if a NUB was granted and it can be negotiated, **the Payers decided not to negotiate the new treatment methods**
- **There is no extra budget to handle innovations**
- There is no agreement prior to the process that this method is worth exploring. **Payers are included too late into the discussions.**

New scheme combines NUB with conditional coverage

New Law: Medtech Benefit Assessment

Berlin. With its Law on Stabilization and Structural Reform of the Statutory Health Insurance (VSG), the Federal Government intends to strengthen the "benefit assessment of new methods involving medical devices of a high risk category." The bill proposed in mid October 2014 by the Health Ministry implements the guidelines set out in the coalition agreement. The statute stipulates that the Joint Federal Committee (JFC) will assess new methods in "systematic, obligatory and scheduled proceedings." The methods referred to involve medical devices of the highest risk categories II b and III, and methods for which a hospital seeks an agreement on the reimbursement for new examination and treatment methods (NUB). The regulation will have no effects on existing technologies or gradual ("step-by-step") innovations.

- **Faster introduction of innovations into health care system**
- **Hospitals can apply for a study in order to test an innovative diagnostic/therapeutic method**

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What do you expect from something called innovation funding?

- It sounds good
- It allows Market and Patient Access
- It is for new technologies / procedures

- **There is a budget**

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What about a conditional coverage schemes?

- A new CE marked device can be introduced quickly into a market
- The procedure and the device are reimbursed in a conditional way
- **The conditions are transparent**
- There is an agreement on the expected outcome
- The outcome of the procedure is being monitored
- A final funding decision will be taken after a defined period of time and after the outcome is acceptable to the Stakeholders involved
- The Risk: In case the outcome is bad the therapy will not be reimbursed and therefore not be used by physicians.

Bringing all relevant Stakeholders around the table at the beginning is key to success.

Questions around Conditional Coverage

- What is the true motivation of a new Reimbursement Scheme?
- What is the budget and how many years will the scheme last?
- Who is responsible? (Government, Role of Physicians, Role of HTA Agencies, Role of Payers)?
- How can each Stakeholder be optimally involved in developing the scheme?
- Who can Stakeholders approach if the scheme turns out to be unfair or not working?

Are Coverage with Evidence Development Schemes predictable for industry?

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Belgium – options for a new policy

- **Run a Multi-stakeholder Innovation Program which brings together**
  - **Payers**
  - **Innovaters and Medical Devices Companies**
  - **Hospitals**
  - **Physicians**
  - **HTA Agencies**
  - **...**
- **Create a transparent and fair Conditional Coverage System that grants early Patient Access with a bridge to routine Reimbursement**
- **Consider a MedTech Innovation Fund**

Thank you!

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