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

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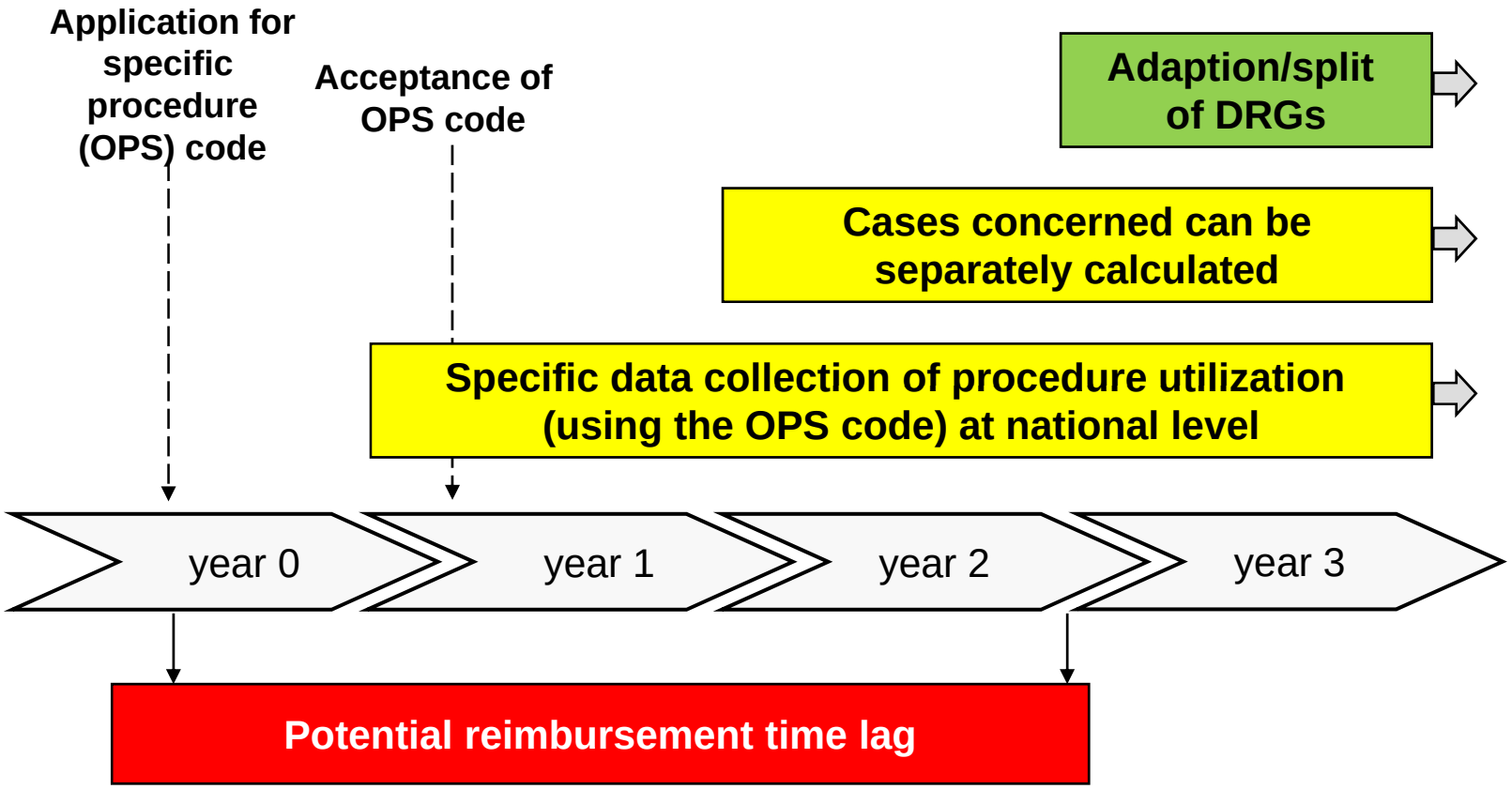
Background

- 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



Source: based on Roeder 2004

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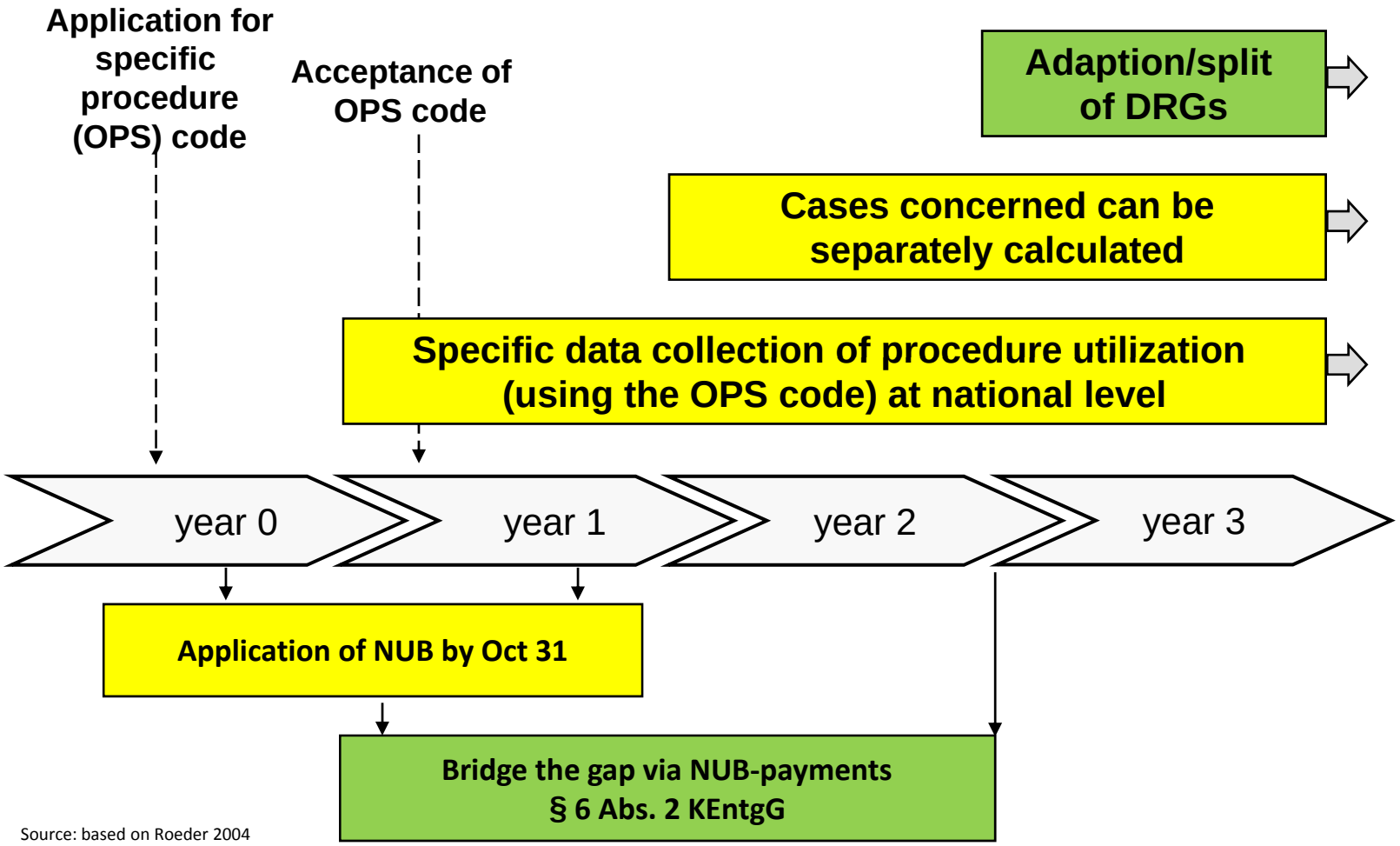
NUB (New Diagnostic and Treatment Methods) – The Political Instrument to Bridge the Time Lag



Source: based on Roeder 2004

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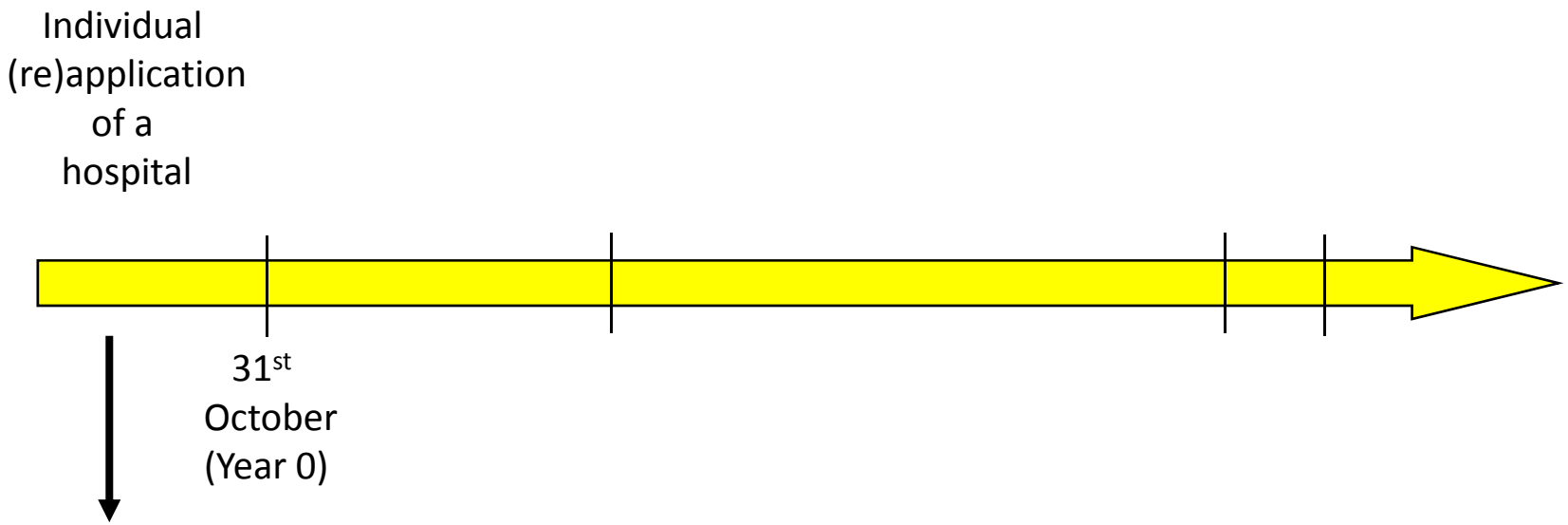
Research Objectives

- 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

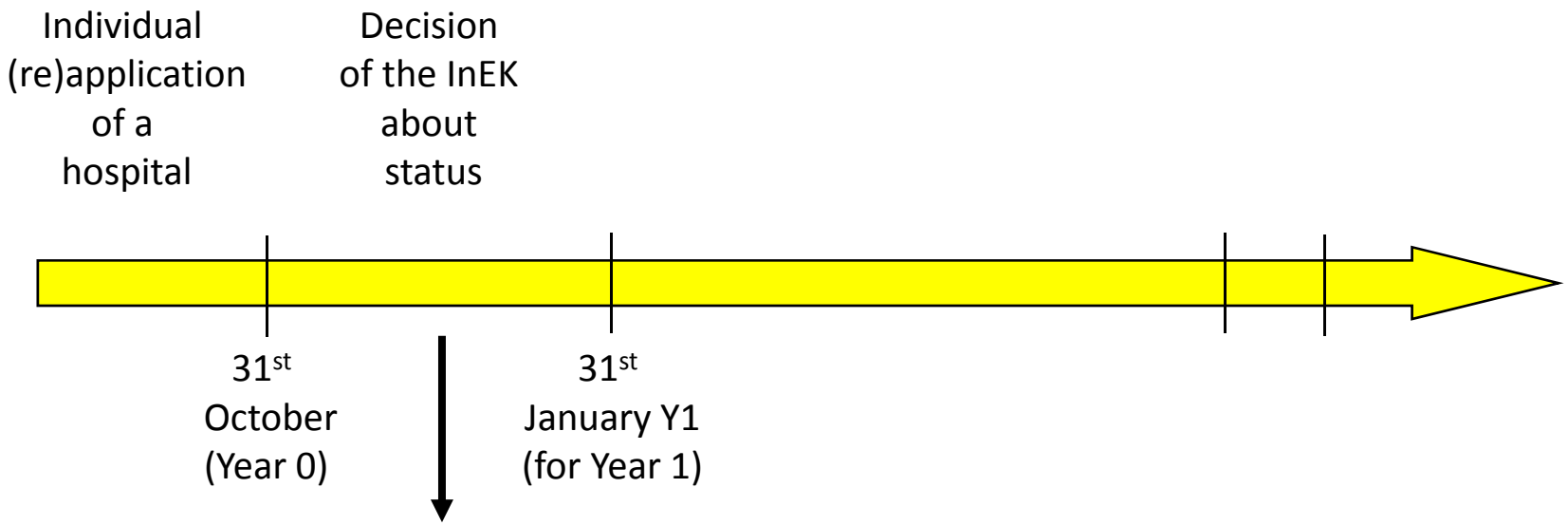
The NUB Process



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

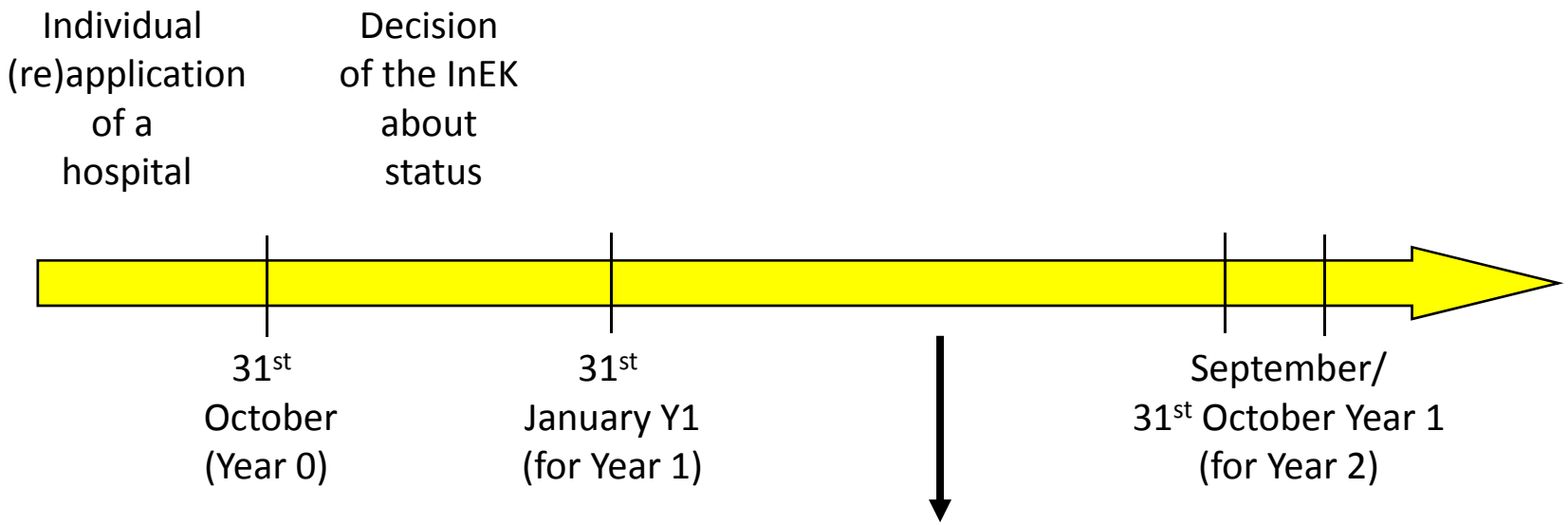
The NUB Process



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



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

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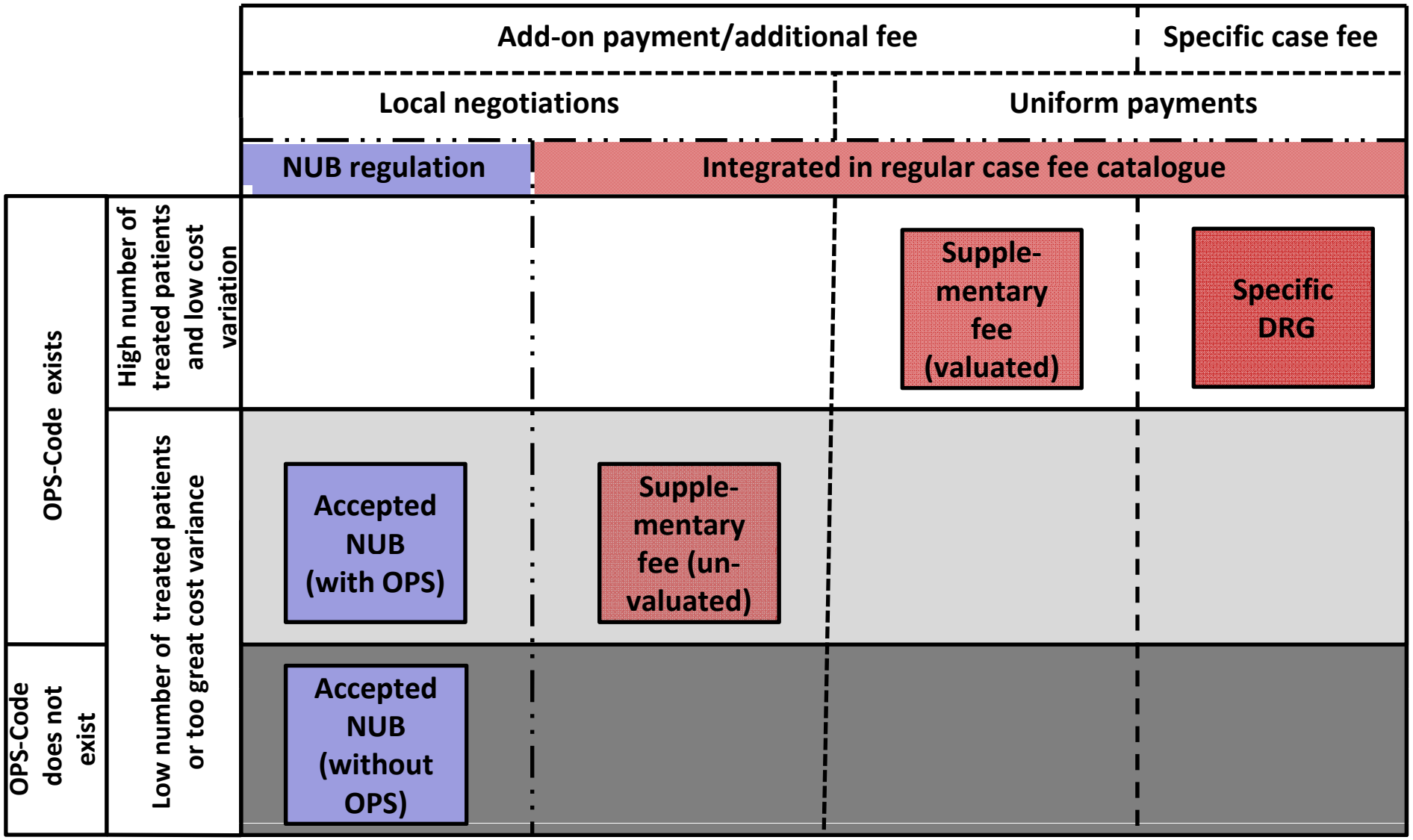
Different Degrees of Integration



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Number of Technologies Accepted for the First Time

Year	Total Number of Newly Accepted Technologies	Medical Devices	Others (metabolic function)
2005 Follow-up over 4 years	26	8	18
2006 Follow-up over 3 years	38	19	19
2007 Follow-up over 2 years	37	19	18
2008 Follow-up over 1 year	21	11	10
2009	*26*	*10*	*16*

Source: Own calculation based on data of InEK

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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

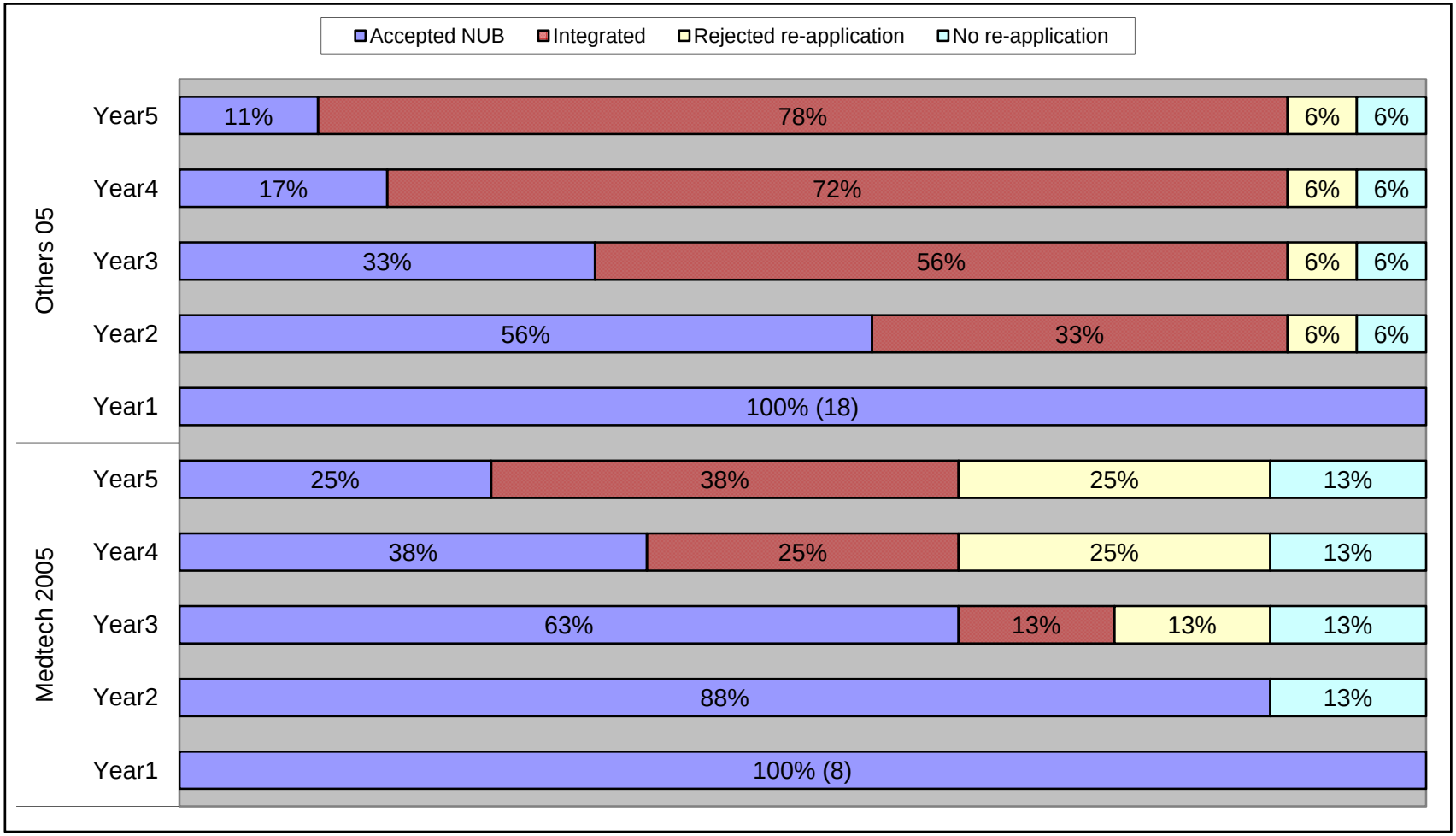
(2) Explicitly integrated into the regular system
- the best case from the hospitals' point of view
- the hospital receives a specific DRG reimbursement, a well-defined supplementary fee or may at least negotiate supplementary fees according to the regular DRG catalogue

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

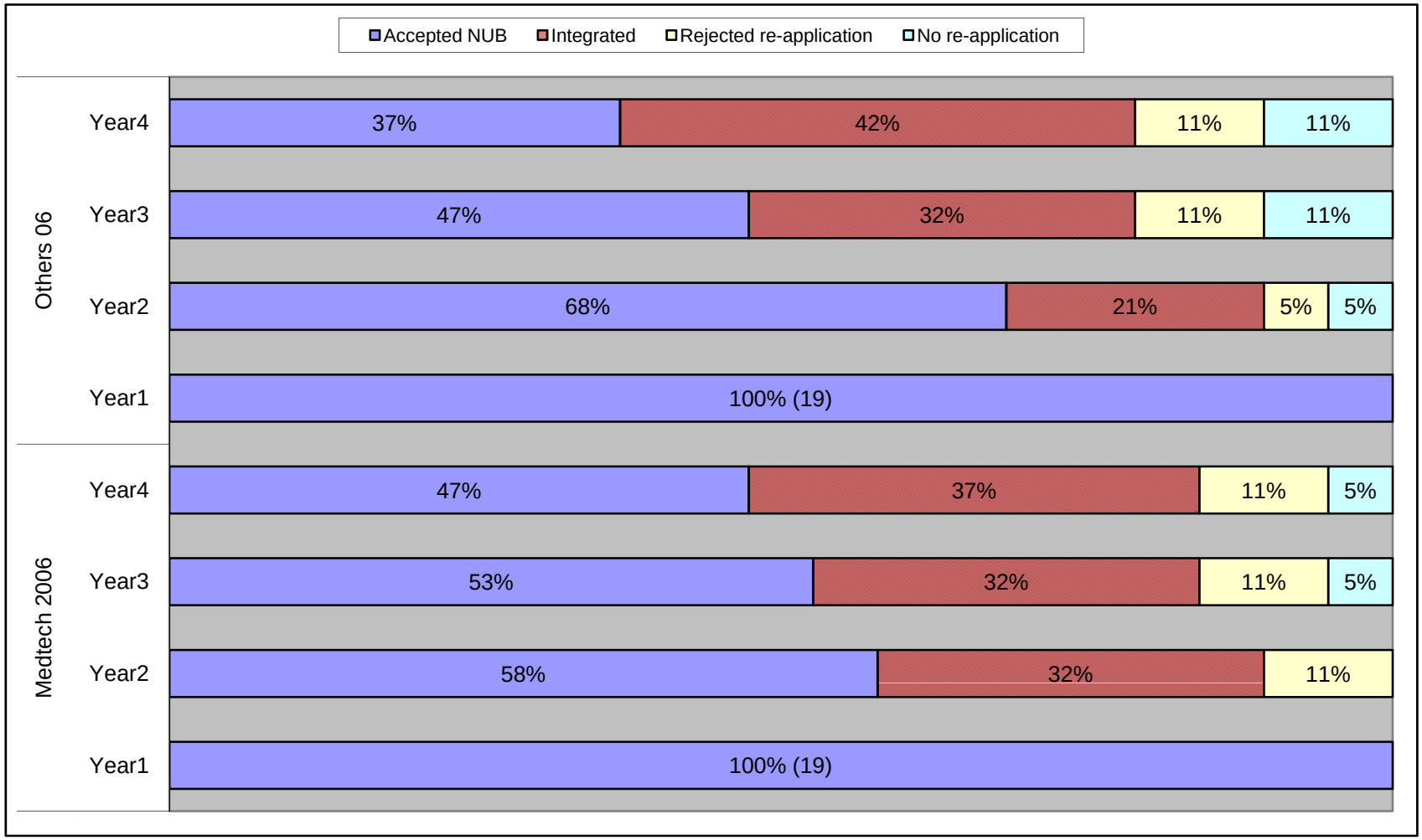
(4) No re-application by a hospital
- the use of the technology may no longer be desired by the hospital
- financial reasons: the hospital does not expect any cost differences between the regular reimbursement tariff and the costs arising from the procedure (implicitly integrated)

→ Stratification for medical devices and other technologies

Integration of NUBs Accepted in 2005 (= Year 1)



Integration of NUBs Accepted in 2006 (= Year 1)



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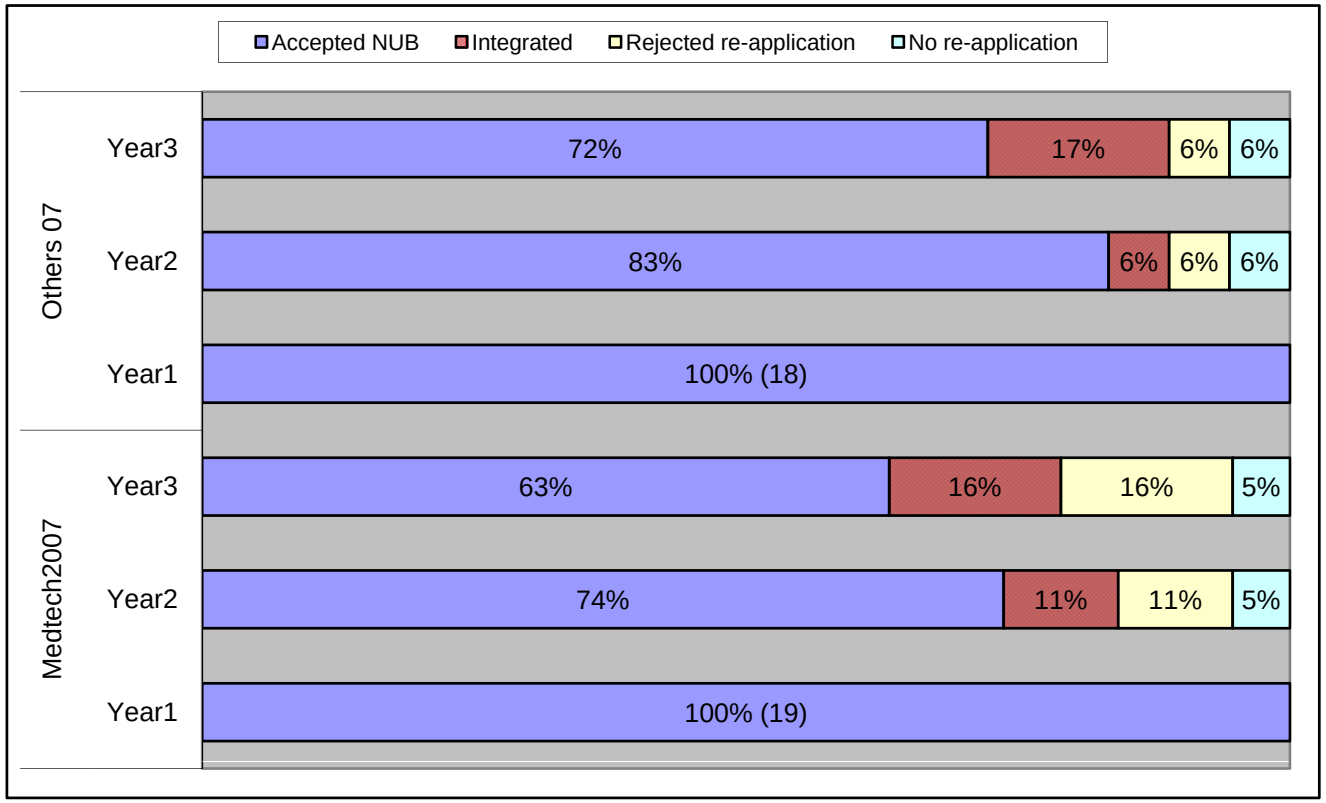
Integration of NUBs Accepted in 2007 (= Year 1)



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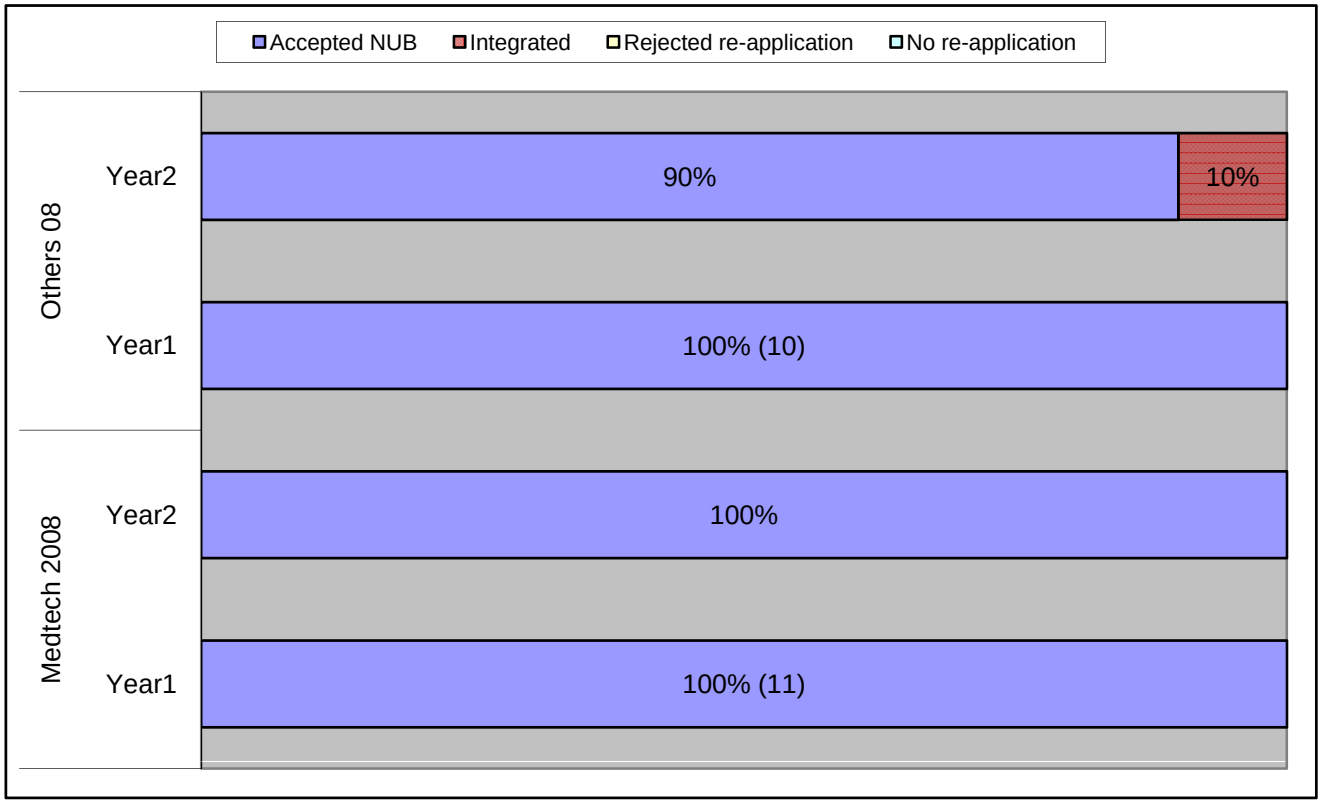
Integration of NUBs Accepted in 2008 (= Year 1)



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

Conclusion and Policy Implications (2)

→ 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

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