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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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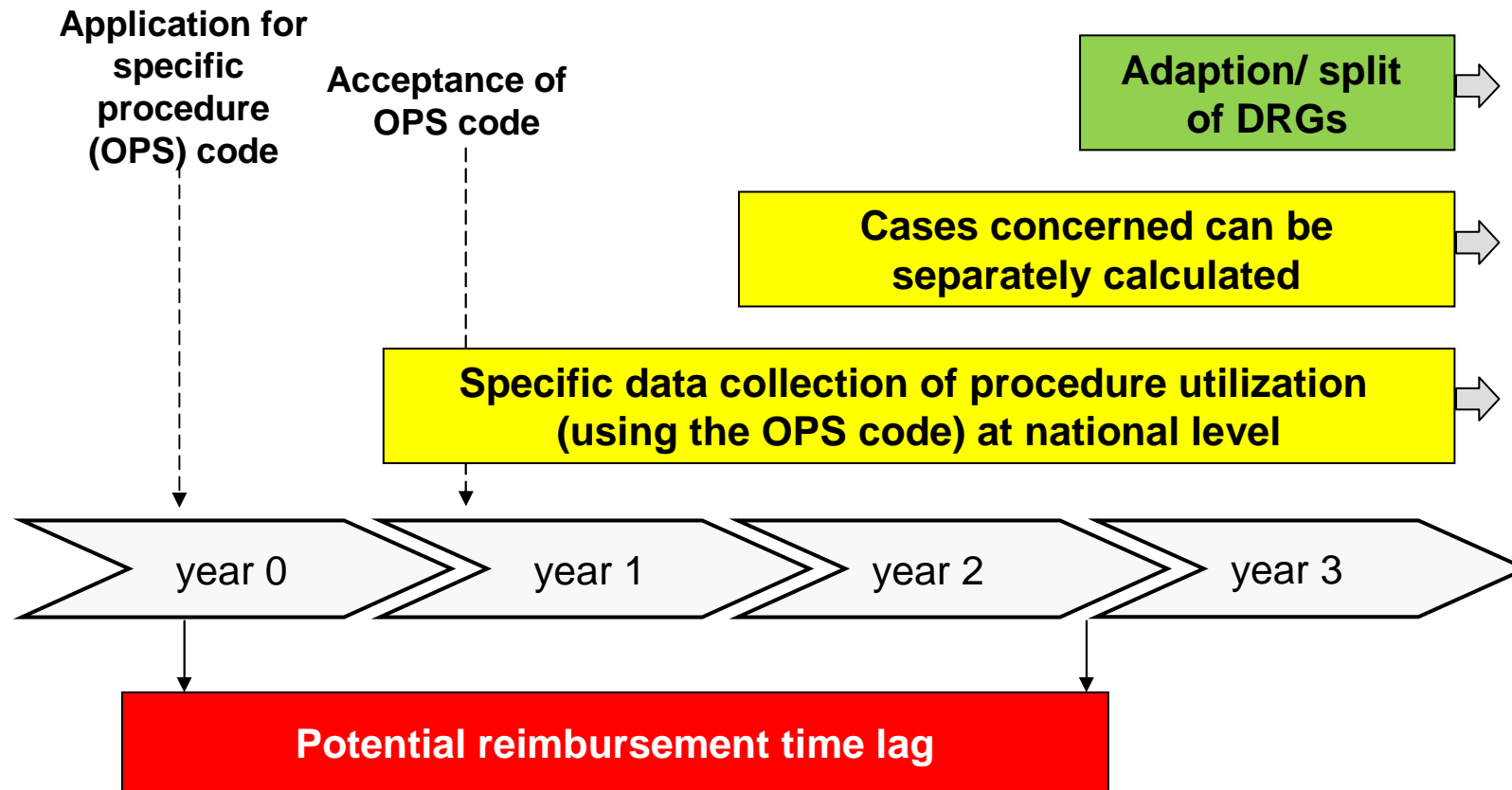
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European Health Technology Institute for Socio-Economic Research

Background

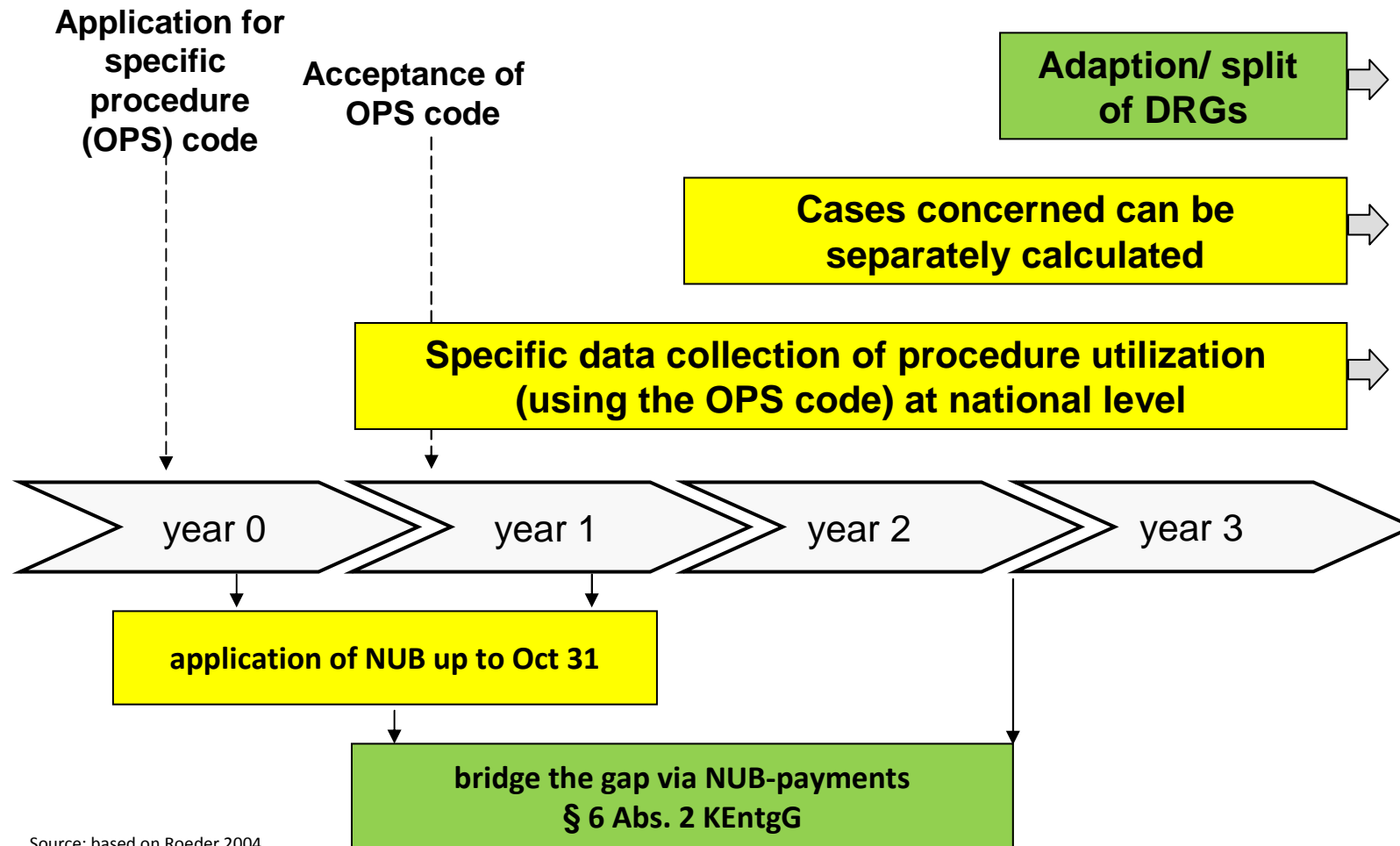
- Innovations may be associated with dramatic improvements in life expectancy and/or quality of life
 - Reimbursement systems might influence
 - the utilization through providers
 - the future revenues of manufacturers
 - the incentives to develop new devices
 - In Germany, a large share of innovative medical devices are introduced first in the inpatient sector
 - In general, 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 into the catalogue of case fees (G-DRG)**

Problem: Relative Time-Lag of the G-DRG System



Source: based on Roeder 2004

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



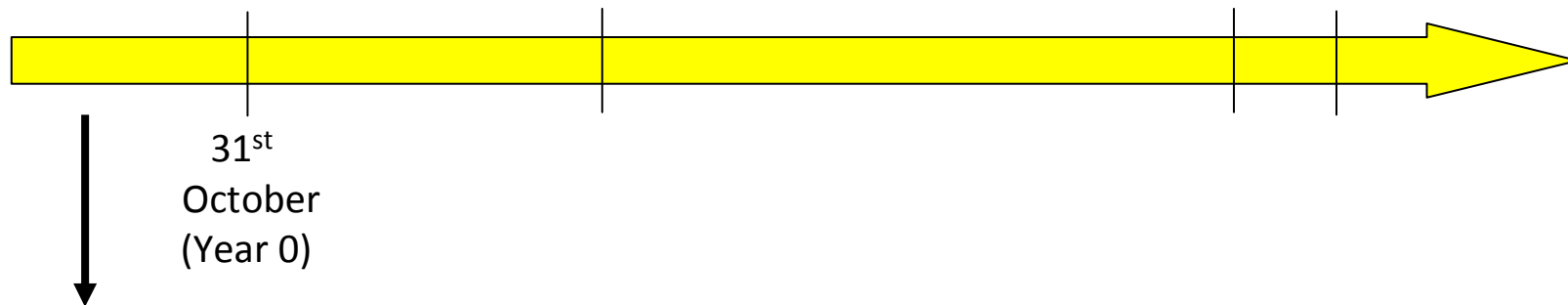
Source: based on Roeder 2004

Research Objectives

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

The NUB Process

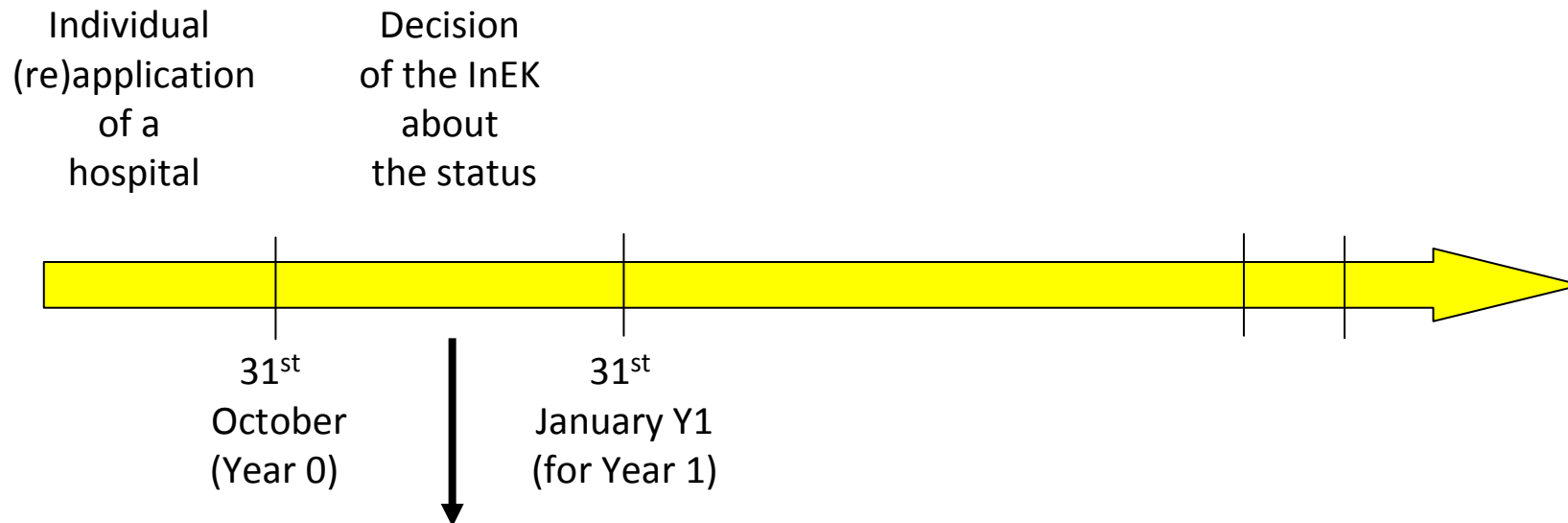
Individual
(re)application
of a
hospital



Application for the 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

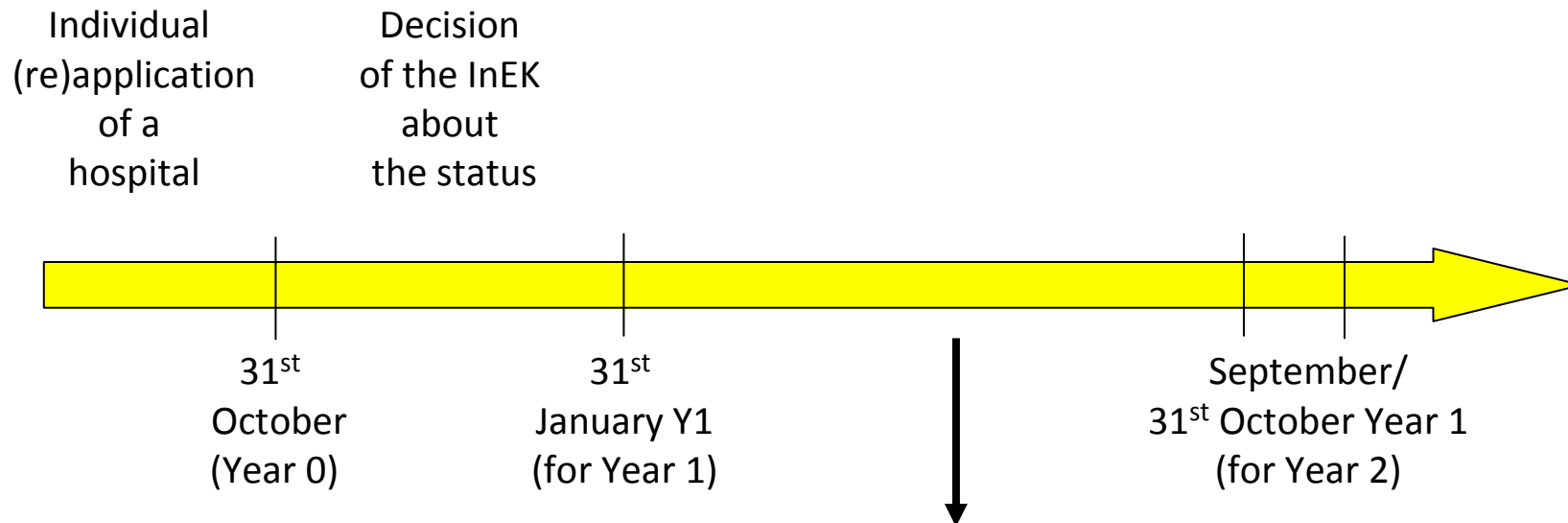
The NUB Process



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 prescription of the method

The NUB Process



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

		Add-on payment/ additional fee		Specific case fee	
		Local negotiations	Uniform payments		
		NUB regulation	Integrated in regular case fee catalogue		
OPS-Code existent	High number of treated patients and low cost variation			<div style="border: 1px solid black; padding: 5px; text-align: center;"> Supplementary fee (valuated) </div>	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Specific DRG </div>
	Low number of treated patients or too great cost variance	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Accepted NUB (with OPS) </div>	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Supplementary fee (unvaluated) </div>		
OPS-Code not existent	Low number of treated patients or too great cost variance	<div style="border: 1px solid black; padding: 5px; text-align: center;"> Accepted NUB (without OPS) </div>			

Number of Technologies Accepted for the First Time

Year	Total Number of New 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 years	21	11	10
2009	26	10	16

Source: Own calculation based on data of InEK

Evidence on Integration from the NUBs into the regular system

➤ Several ways 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) Integration 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

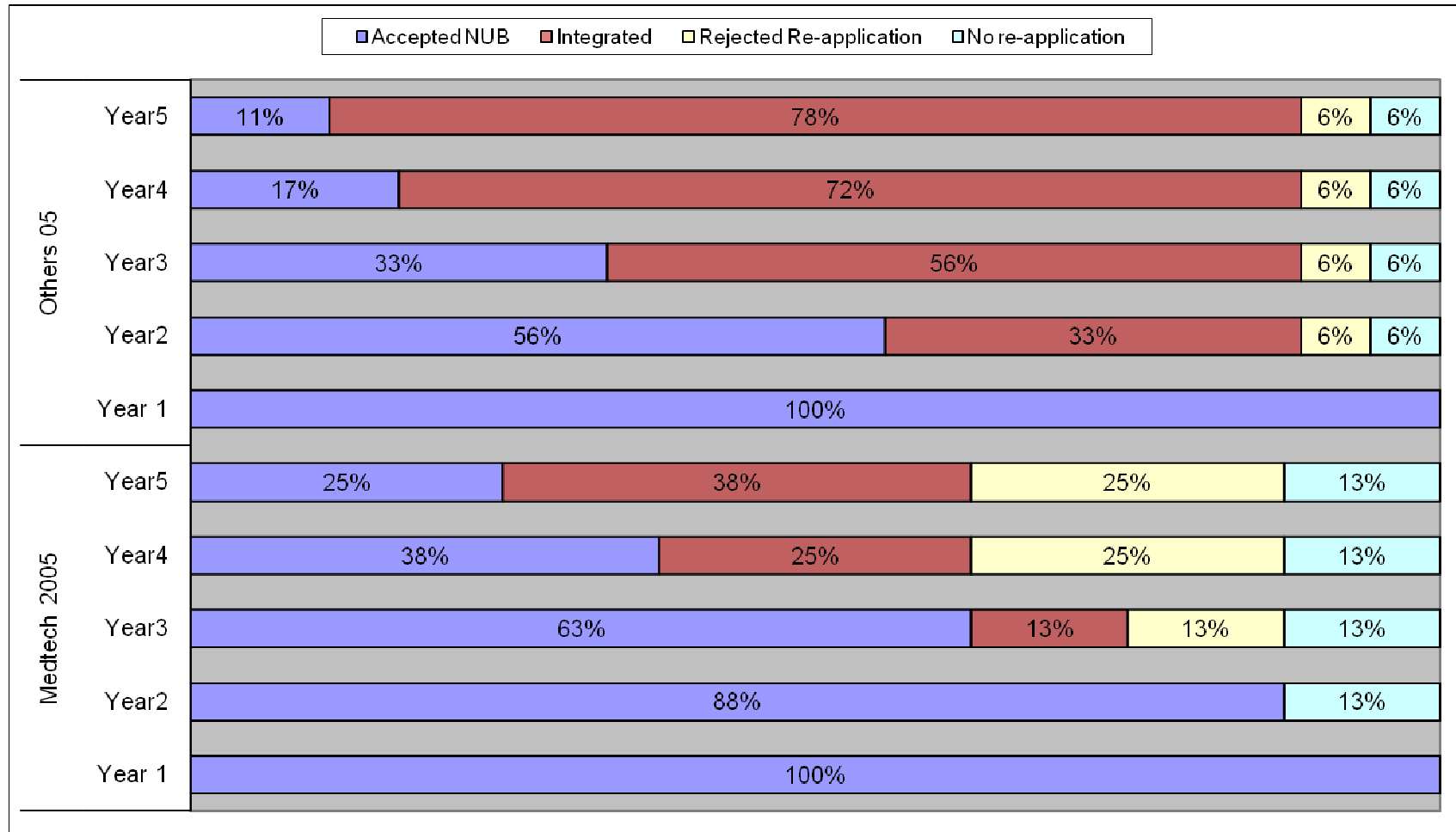
- no existence of a financing gap between the existing tariffs and the costs for the new technology → tariffs are already meant to cover the costs for the technology sufficiently
- insufficient information transmitted by the hospital during the application process

(4) No re-application by a hospital anymore

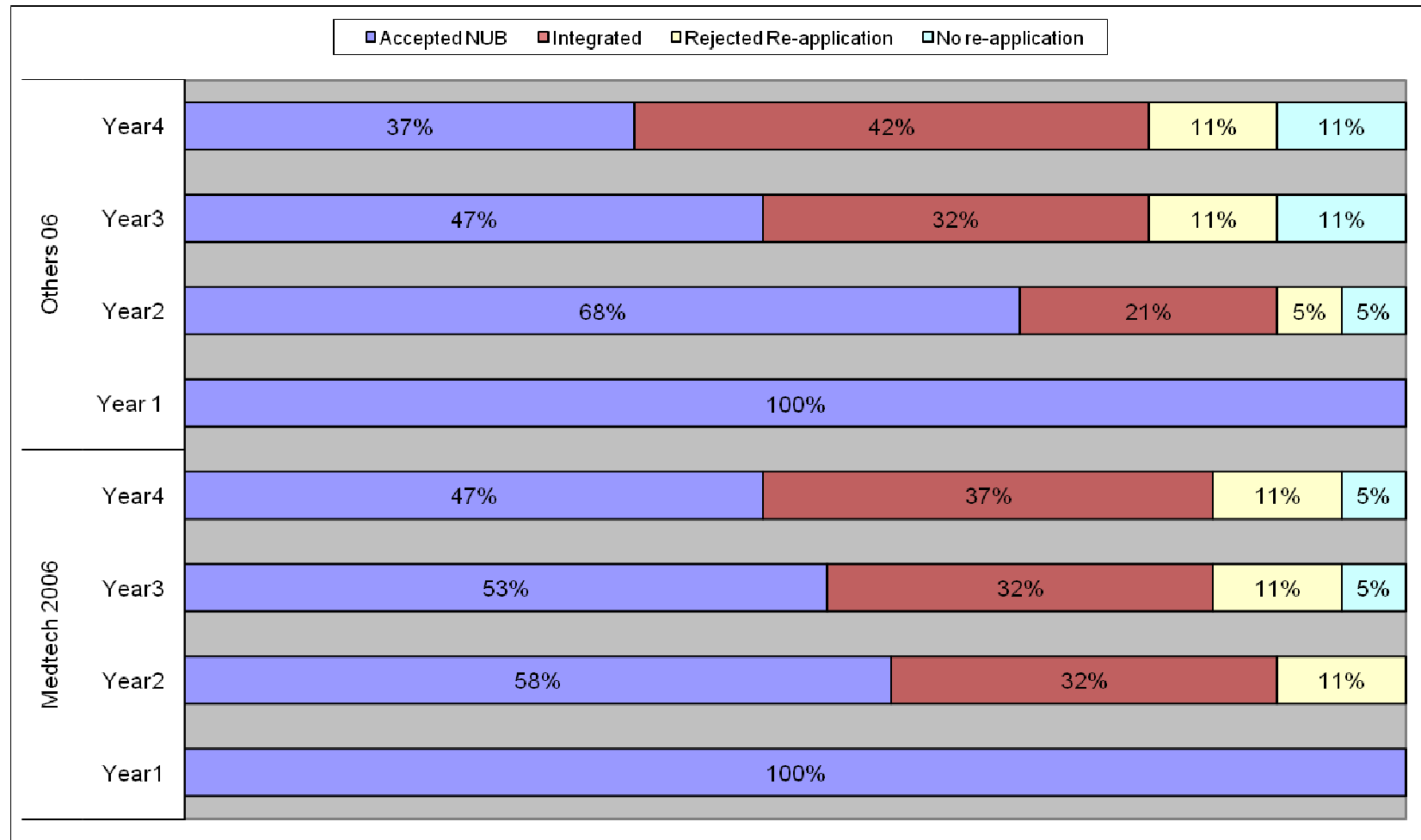
- the use of the technology may not be desired by the hospital anymore
- financial reasons : The hospital does not expect any cost-differences between the regular reimbursement tariff and the costs arising from the procedure.

→ Stratification for medical devices and other technologies

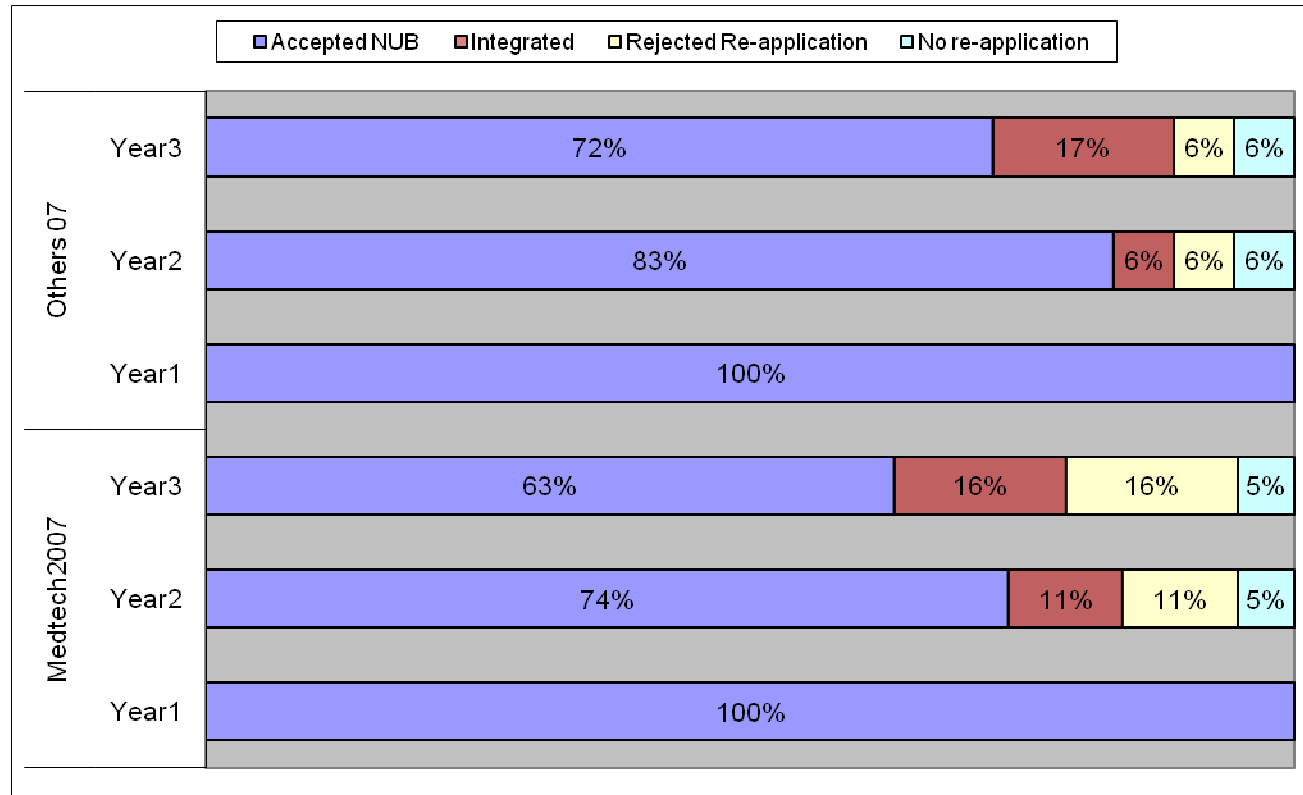
Integration of NUBs Accepted in 2005 (= Year 1)



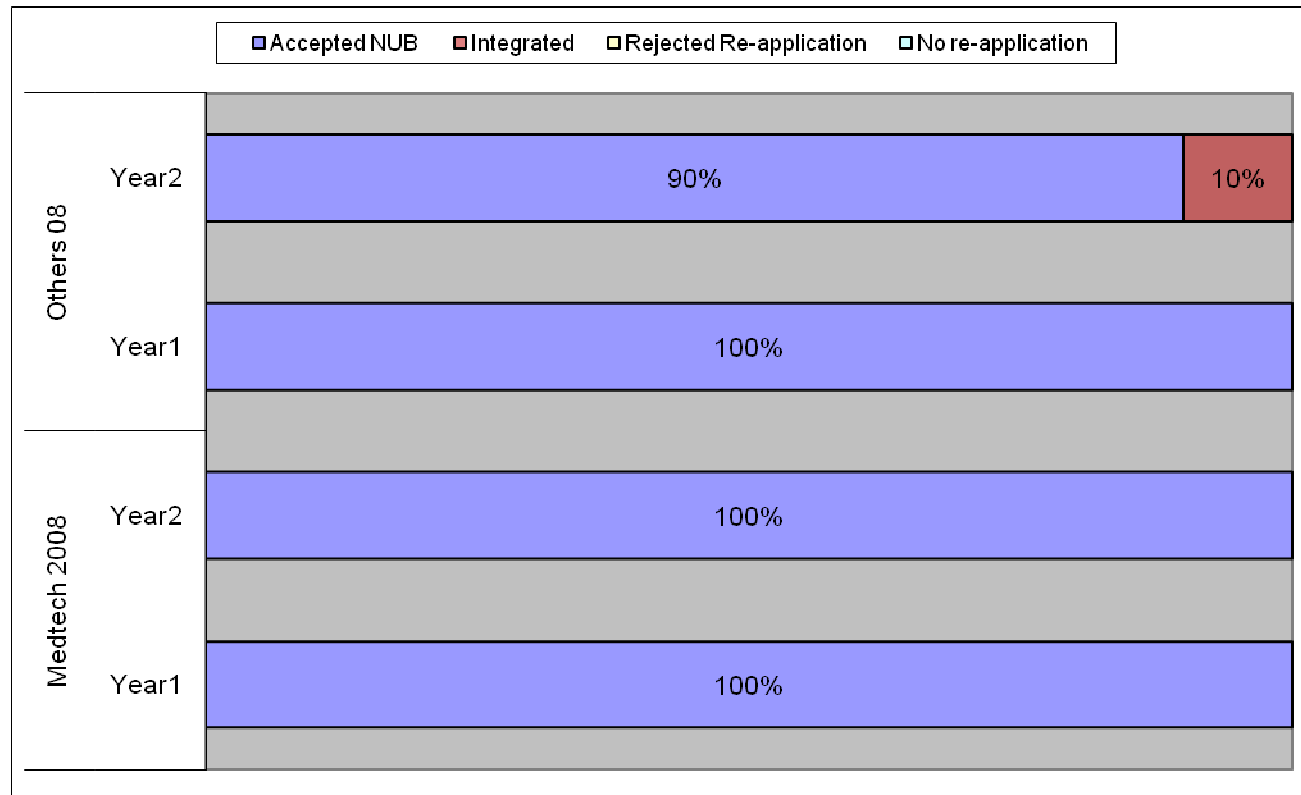
Integration of NUBs Accepted in 2006 (= Year 1)



Integration of NUBs Accepted in 2007 (= Year 1)



Integration of NUBs Accepted in 2008 (= Year 1)



Conclusion and Policy Implications (1)

- Effective innovative medical devices should be a 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
 - system' capability to become a more efficient at risk
- The German NUB system implies a relative expeditious access to innovative medical devices:
- an intermediate step for integrating innovative products into the regular G-DRG system
 - Less than 1/4 of medical devices and 1/3 of other products are integrated within two years after first acceptance as NUB
 - therefore the system (rightly!) provides no guarantee for the integration into the SHI's benefit basket

Conclusion and Policy Implications (2)

→ Today's policy:

- (non-) integration is mainly driven by utilization numbers and need for extra-funding
- medical devices do not have to show their effectiveness in the treatment of patients → possible problem from a 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