OBJECTIVES

- Within the German hospital landscape (in-patient), NuBs (Neue Untersuchungs- und Behandlungsmethoden) represent a key method to achieve reimbursement for new, cost-intensive drugs, medical products or procedures. Long-term reimbursement requires uptake into the German DRG (G-DRG) system.
- The NuB pathway allows market access, but requires significant effort for the applicants. TuBs are paid on top of hospital budget and hence represent additional funding for hospitals. There are four different TuB-status (1-4) and hospitals can only start SHI negotiations for reimbursement once innovations have been given NuB status 1 (in exceptional cases also 4).
- The objective of this research was to analyse the proportion of drugs (vs. methods, medical products) receiving NuB status 1-4 and to give an overview, which indications are in focus.

METHODS

- The NuB application is recognizing the need for a mechanism allowing innovation within the G-DRG system. The application process is monitored by the InEK (Institute for the Hospital Remuneration System), which coordinates and determines the "G-DRG on-top" funding process for innovative products and new market entries in general respectively.
- During the NuB process hospitals can file applications for products / procedures that have recently (5 year time span) been introduced in the German market. Each hospital applies separately for NuBs (electronic application to the InEK) and the "on-top" payment, if approved, will only be available to those hospitals that applied, limited to twelve months and would have to file yearly.
- NuB status is critical for future reimbursement of new costly products, since it is the precursor of the subsequent additional payment ZE ("Zusatzentgelt") which grants long-term entry into the G-DRG coding landscape.
- The InEK monitors approved applications and should the new products / procedures be adequately used, correctly coded by the 300 panel clinics, and exhibit a cost profile of sufficient difference, the InEK may (following a period of ZE) integrate the NuB permanently into the G-DRG. It should be noted that InEK makes no decision on the actual amount of "on-top" payment. This is directly negotiated between the successful hospital applicants and the SHIs. Subsequent introduction into a DRG often means broader uptake at reduced costs.
- In 2014 the InEK issued a list with a total of 618 products / procedures, for which NuB applications were received. The list solely states the products / procedures and which NuB status they were given. It was used to analyze NuB subgroups, which were subsequently sorted according to key therapeutic indications.

NuB status 1-4 status → negotiation on reimbursement with SHI. InEK considers inclusion of product / procedure for the next version of the DRG catalogue.

NuB status 2, 3, 4 status → incomplete application to different degree. Re-application necessary to be reconsidered.

- Three aspects within the InEK list were analysed and detailed below:
  1. split between (a) drugs and (b) procedures/medical products
  2. split within the above two mentioned subgroups as to success rate of NuB1 status
  3. split into indications of successful NuB1 status (drugs)
- In parallel, NuB1 drugs that went through the AMNCG process were analysed, determining the degree of additional benefit attested for the respective drugs.

RESULTS

- Out of 618 NuB submissions, 133 (22%) were classified as drugs and 485 (78%) as procedures/medicinal products.
- In total, 114 (18%) of all NuB applications received NuB1 status, out of these 43 (38%) were drugs.
- The leading therapeutic area of NuB1 status drugs was oncology with 28 drugs (65%), followed by 5 ophthalmic products (12%).
- NuB2 status was given to 465 (75%) NuB applications out of which 82 (18%) were drugs.
- The analysis shows that, the success rate to receive NuB1 status is relatively low. Chances to receive a successful NuB1 status stands at one in three for drugs, however only one in six for procedures/medicinal products.
- Out of 43 drugs that were given NuB1 status, 24 (55%) already passed through the German AMNCG process (according to an analysis: June 2014). Detailed analysis showed that AMNCG classifications for these products ranged from significant additional benefit to no additional benefit.

CONCLUSIONS

- In 2014 drug applications were more successful than procedures and medical products in receiving NuB1 status. It is hence easier for pharmaceutical drug companies to commence negotiations with the SHI on drug reimbursement in the in-patient setting.
- In 2014 NuB applications came from three main therapeutic areas: Oncology, Ophthalmology, Rheumatoid Arthritis.
- Oncology products show the highest success rate, which in part certainly derives from the fact, that pharmaceutical pipelines have a focus on oncology and continue to launch innovative therapies in Germany.
- Oncology products are often highly priced therapies and use the NuB system to enter the G-DRG system for future reimbursement.

2. Informationen nach § 6 Abs. 2 KHEntgG für 2014: Neue Untersuchungs- und Behandlungsmethoden: [http://www.g-dr-g.de](http://www.g-dr-g.de) (last visit Oct 13th, 2014)