SUCCESS FACTORS FOR §137h SGB V ASSESSMENT OF MEDICAL DEVICES IN GERMANY

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Background

In Germany, the Federal Joint Committee ("G-BA") is commissioned to assess examination and treatment methods for the inpatient sector, if

I. a hospital applies for reimbursement of a new examination and treatment method ("NUB-submission") with the Institute for the Hospital Remuneration System ("InEK"),
II. the method is primarily based on the use of a medical device with high risk class and
III. the method does represent a new theoretical-scientific concept.

If all of the above mentioned § 137h requirements are met, the benefit of the method is assessed by the G-BA. The legal basis for this benefit assessment is the § 137h Social Insurance Code Volume V (SGB V) procedure, which was introduced in 2015.

Objective

Definition of success factors of achieving a benefit or a potential as the outcome of a G-BA benefit assessment according to § 137h SGB V for high-risk medical devices in Germany.

Methods

Evaluation of resolutions and justifications for all §137h assessments publicly available on the G-BA website by November 1st, 2018. Evidence was screened on procedural level and analyzed by two individual reviewers. Data was extracted into an a priori developed extraction sheet and descriptively analyzed. Success factors where analyzed with regard to submitted level of evidence in the NUB-submission.

Results

The Evaluation of resolutions and justifications for §137h identified 23 procedures[1]. Thereof 12 procedures were assigned the status "consultation completed", 8 procedures showed the status "assessment completed" while two were "completed without assessment" and one procedure had the status "preparation of resolution" (Figure 1).

Nearly half of the procedures met the §137h SGB V requirements whereas 10 procedures did not meet requirements (Figure 2). Of those procedures which had met §137h requirements and had the status "assessment completed" (n=8), only two where awarded with a "potential" and none received a "benefit" rating as the outcome of the §137h procedure (Figure 3). For those procedures which did not meet §137h requirements, three reasons where identified: First, the medical device could not be classified as a medical device with high-risk class (5/10). Second, the medical device did not represent a new theoretical scientific concept (4/8). Third, the NUB-submission was not initial, so that a §137h procedure was already in place (1/8) (Figure 4).

In all procedures with completed G-BA assessment, non-comparative study design (level of evidence = IV-V, G-BA rules of procedure[2]) was predominantly submitted in the NUB-applications whereas randomized controlled trials or comparative cohort studies were available in three procedures, two of which were accepted by G-BA and received a "potential" as the outcome (Figure 5).

Overall, the G-BA did slightly favor comparative evidence when awarding a potential as the outcome of the §137h procedure – However, results are limited by small sample size. Arguments for why the G-BA decided on "no potential" did vary. In most cases, the reason was insufficient and insecure data.

Key Findings

While limited by a small sample size, early findings suggest that §137h SGB V outcome is dependent on the evidence level of studies. Therefore, medical device manufactures are increasingly compelled to provide comparative evidence to meet the high demands of the German §137h assessment.

Figure 1 - Status of §137h procedures according to G-BA

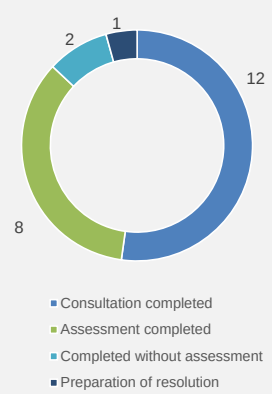


Figure 2 - § 137h requirements fulfilled/ not fulfilled according to G-BA

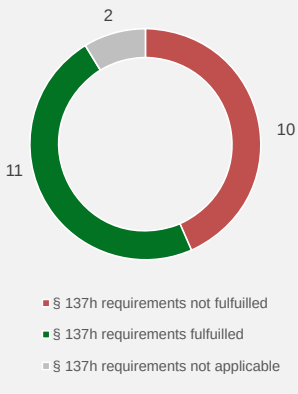


Figure 3 - Outcome of §137h procedures with the status "Assessment completed" according to G-BA

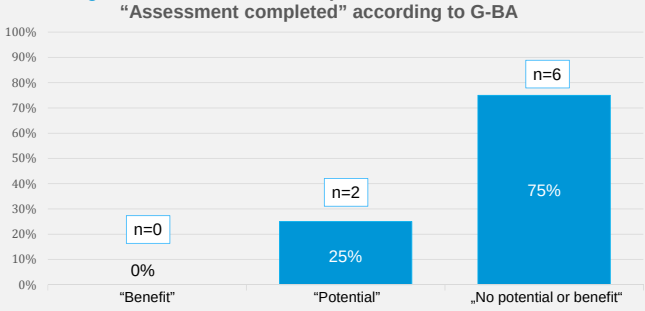


Figure 4 - Procedures with "§137h requirements not fulfilled" –reasons for exclusion by G-BA

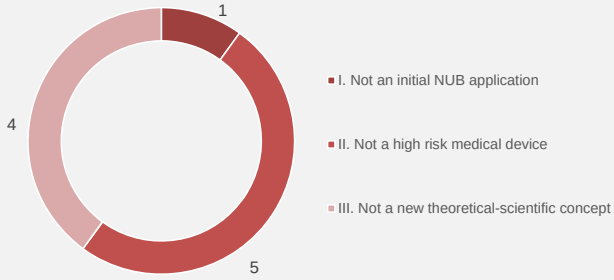
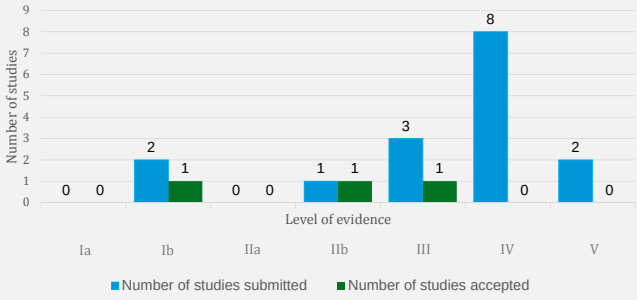


Figure 5 - Number of studies submitted in NUB-applications and number of studies accepted by G-BA to proof "potential"



Sources:
1. G-BA (2018). Database: Procedures according to § 137h SGB V. Accessed under: https://www.g-ba.de/informationen/verfahren-137h. Last access date: 01.11.2018.
2. G-BA (2017): G-BA rules of procedure. Accessed under: https://www.g-ba.de/downloads/62-492-1614/VerfO_2018-03-16_iK-2018-07-05.pdf. Last access date: 01.11.2018

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