Approach to Medical Devices in Germany

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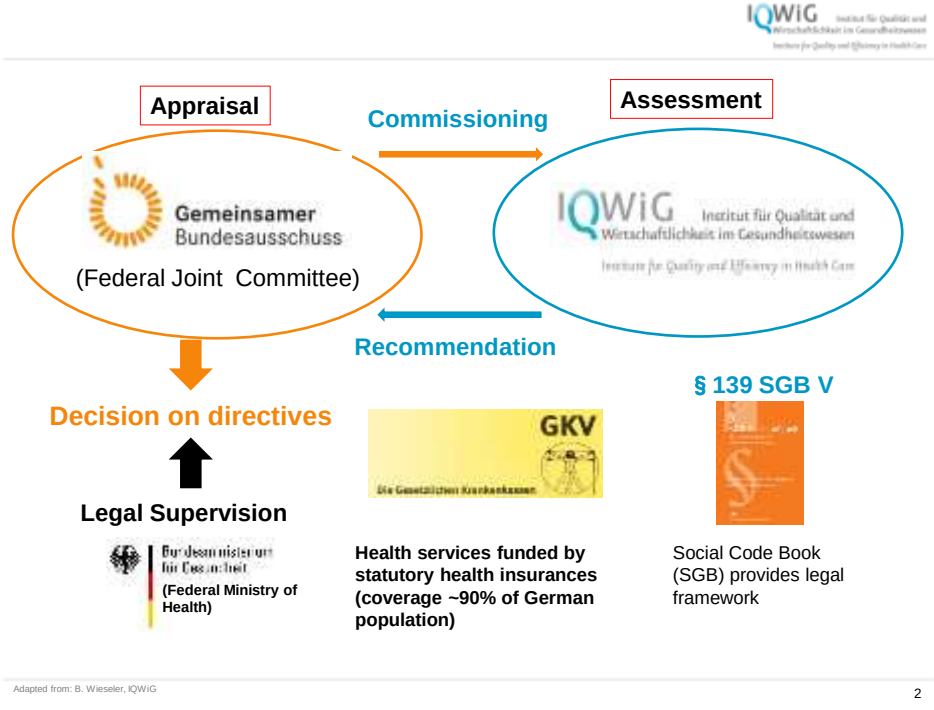
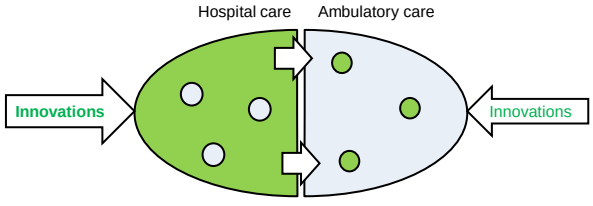


Adapted from: B. Wieseler, IQWiG

General principles of reimbursement in Germany

Different regulations for in-hospital and ambulatory care according to Social Code of Law V (SGB V):

- Innovations may be used in hospital care, unless G-BA decides against it.
- Innovations may not be used in ambulatory care, unless G-BA decides in favor of the innovation.



G-BA = Gemeinsamer Bundesausschuss (Federal Joint Committee);
SGB = Sozialgesetzbuch (Social Code of Law)

Reimbursement of medical devices in hospital care

- Reimbursement is primarily based on ~1200 DRGs (German Diagnosis-related Groups)
  - Organized by the Institute for the Hospital Remuneration System (InEK), but no assessment of effectiveness
- Two different situations:
  - New medical device is part of existing procedure ➔ may require add-on remuneration or new DRG, if costs of procedure increase
  - New medical device is key element of new procedure ➔ always requires creation of new DRG

Reimbursement of medical devices in <u>ambulatory</u> care

- Completely independent from decision for hospital care.
- Process depends on type of medical device.
- Decision of the Federal Joint Committee (GBA) required (except for medical aids and appliances)
  - Joint evaluation for both sectors in a few cases
- Depending on clinical and/or economical importance IQWiG may be asked to assess
  - clinical effectiveness or
  - clinical effectiveness and cost efficiency

Three „little“ problems with new medical devices

1. Efficacy and (added-) benefit is not necessary to get a CE certificate.
   - New products could be ineffective or even cause harm

2. No obligation to publish essential information.
   - Doctors or patients could be poorly or incorrect informed.

3. Reimbursement does not ask for data for (added) benefit.
   - Many patients receive the product partly because of „wrong“ economic incentives
   - The benefit of the “innovation“ remains unclear.

Example: stent in intracranial artery stenosis

BACKGROUND AND PURPOSE:

The purpose of this study was to assess the safety and performance of the Wingspan stent system and Gateway percutaneous transluminal angioplasty balloon catheter in the treatment of high-grade, intracranial atherosclerotic lesions in patients who had failed medical therapy.

→ **Enough for CE mark (MPG)**

METHODS:

In this prospective, multicenter, single-arm study, medically refractory patients with a modified Rankin score < or =3 and recurrent symptoms attributable to angiographically demonstrated intracranial stenosis > or =50% in a vessel 2.5 to 4.5 mm in diameter were enrolled. Intracranial lesions were predilated with an undersized Gateway balloon catheter to 80% of the native vessel diameter, followed by deployment of the self-expanding Wingspan stent to facilitate further remodeling of the atherosclerotic plaque and to maintain vessel patency. Neurologic examinations and angiograms were performed at 6 months after the procedure.

→ **No comparator (level of evidence 4)**

RESULTS:

Among the 45 patients enrolled, the degree of stenosis was reduced from a baseline of 74.9+/-9.8% to 31.9+/-13.6% after stenting and 28+/-23.2% at the 6-month follow-up. The 30-day composite ipsilateral stroke/death rate was 4.5% (2/44); at the 6-month follow-up, the ipsilateral stroke/death rate was 7.0%, the rate for all strokes was 9.7%, and all-cause mortality was 2.3%. Physician-reported follow-up in 43 patients (average of 13 months) conducted outside the study protocol (not adjudicated by the clinical event committee) reported 1 additional ipsilateral stroke.

→ **no data to medium- / long-term results**

CONCLUSIONS:

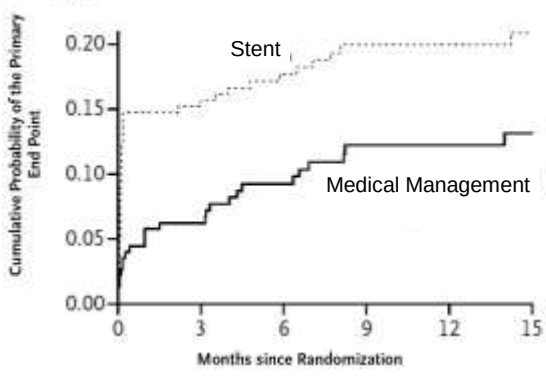
In medically refractory patients with high-grade intracranial atherosclerotic stenoses, a new treatment paradigm involving predilation with an undersized Gateway percutaneous transluminal angioplasty balloon catheter and placement of a self-expanding Wingspan stent system appears to be safe, may facilitate remodeling, and may contribute to favorable angiographic outcomes.

→ **No statement of clinical efficacy possible**

Bose A, Hartmann M, Henkes H, et al.: A novel, self-expanding, nitinol stent in medically refractory intracranial atherosclerotic stenoses: the Wingspan study. Stroke 2007; 38: 1531-7.

Stents for intracranial artery stenosis

- RCT(n= 451)
- Stroke or death (30d): 14.7% vs. 5.8% (p= 0.002)
- IQWiG-report: hint for greater harm for stroke



Chimowitz MI, et al., N Engl J Med 2011; 365: 993-1003.
IQWiG: Stents for the treatment of intracranial artery stenosis (rapid report N14-01). Cologne, 2014.

WHO
2011

http://apps.who.int/medicinedocs/documents/s21560en/s21560en.pdf

General principles of reimbursement in Germany

G-BA and IQWiG assess **medical procedures** (which may include use of medical devices).

G-BA and IQWiG do not assess classes of medical devices or individual devices.

However, it may happen that only one device is available for one procedure.

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IQWiG Methods:

Evidence based medicine (SGB V)

- **Principle of causality**
- **Bias**
- **Dramatic effect**
- **Transparency**
- **Reliability**

Todate: Version 4.2. from 22.04.2015

https://www.iqwig.de/en/methods/methods-papers/general-methods.3020.html

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IQWiG General Methods 4.2: non-drug interventions

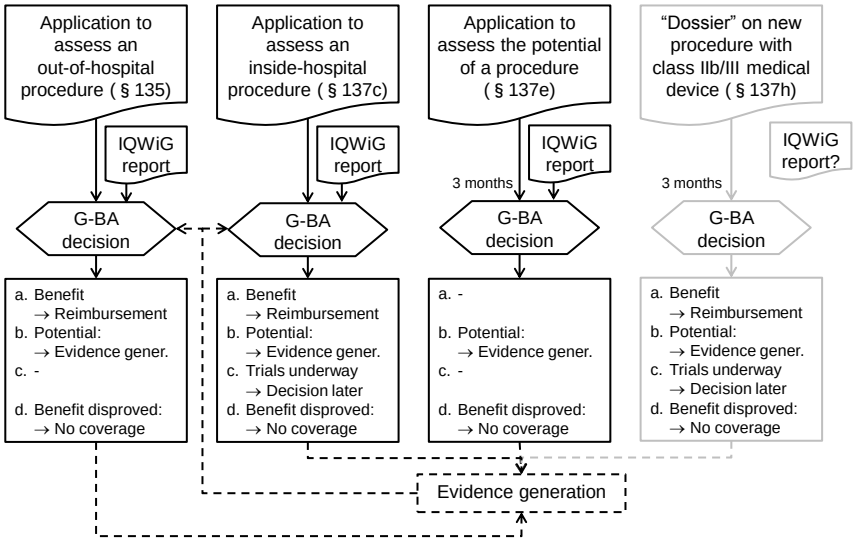
…it may therefore also be necessary to consider non-randomized studies in the assessment. Nonetheless, quality standards also apply in these studies, in particular regarding measures taken to ensure structural equality. However, such studies will usually at best be able to provide hints of a(n) (added) benefit or harm of an intervention due to their inherently lower certainty of results.

IQWiG General Methods 4.2: non-drug interventions cont.

…The inclusion of studies with lower evidence levels is consistent with the corresponding regulation in the G-BA's Code of Procedure [211]. However, the specific obligation to provide a justification is emphasized. In this regulation it is noted:

"However, in order to protect patients, recognition of a method's medical benefit on the basis of documents with lower evidence levels requires all the more justification the greater the deviation from evidence level 1 ….

§ 137h: Current and future pathways of HTA of non-drug interventions



Assessment of potential: IQWIG general methods 4.2

Lower requirements of evidence apply

- **low qualitative certainty of results:** result of a higher quality non-randomized comparative study with adequate control for confounders (e.g. non-randomized controlled studies with active allocation of the intervention following a preplanned rule,…),
- **very low qualitative certainty of results:** result of a higher quality non-randomized comparative study (see point above), but without adequate control for confounders or result of another non-randomized comparative study (e.g. retrospective comparative cohort studies, historically controlled studies, case-control studies),
- **minimum qualitative certainty of results:** result of a non-comparative study (e.g. one-arm cohort studies, observational studies or case series, cross-sectional studies or other non-comparative studies).

Conclusions

- In Germany, the borderline between in-hospital and ambulatory care is very important for reimbursement.
- G-BA and IQWiG perform HTA on medical procedures and devices, but only for a minority of innovations.
- The principles of evidence-based medicine apply. The basis of benefit is the demonstration of causality (RCT, Bias, etc.)
- The new model of CED / Potential is an additional opportunity for manufacturers to provide evidence. It has to show its usefulness in the next years.
- Some future aspects:
  - Early dialogues
  - International collaboration (i.e. EUnetHTA)


Scientists studying ants?
No. People from IQWiG. They're searching for evidence!