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Physician decision making on new technologies and the role of coverage with evidence development

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Abstract

Objectives: To foster value-based pricing and coverage with evidence development in Germany, certain new diagnostic and treatment methods have been subject to a benefit assessment since 2016 to determine their reimbursement. While this is a paradigm shift, the German approach is limited to some few specific technologies that request reimbursement. As physicians are encountered with this regulatory instrument, the aim of the study is to understand physician decision making regarding the adoption of new medical technologies and to identify physicians' perspectives on the evidence base and the financing with additional reimbursement instruments.

Methods: From April to August 2017 semi-structured interviews with chief and senior physicians on vascular surgery and cardiology in German inpatient care were conducted (n=23). The interviews were carried out by one researcher in one-to-one appointments or via telephone. Data was analysed inductively to identify factors and generate thematic categories using qualitative content analysis.

Results: We identified 52 factors in eight categories influencing physicians in their adoption of new technologies. The evidence base of new technologies was criticised (e.g. the lack of available studies) while the knowledge of physicians varies concerning the regulation of market approval and innovation payments. They recommend utilisation of new technologies in certain specialist centres and facilitating observational studies.

Conclusions: Physicians see the necessity of the new approach and support its aim. However, the design and implementation seems to be questionable from their medical perspective. The provision of summarised information on the benefit of technologies might be a possibility to assist physicians' decision making.

Introduction

When new medical technologies enter the market, the time of adoption is a key point in patient care as evidence and experiences regarding its utilisation differ in their extent [1]. Many new technologies are capable of leading to better outcomes in patients' treatment and diagnostic.

However, there might be uncertainty and risks regarding the effectiveness of these technologies as at the time of market approval only little or no evidence is available [2, 3]. Thus, the adoption and utilisation of new technologies is necessary in order to gather knowledge and real-world evidence. This is especially the case for medical devices in the European Union (EU) where requirements to gain market approval are generally lower than, for instance, in the United States (US) [4].

When focusing on new technologies that are used in inpatient care with the aim of maximising patient benefit and avoiding risks [5], the primary adopters are physicians. They assess treatment options and decide, sometimes within team decisions, whether to adopt a new technology or to use established alternatives. A variety of studies have investigated factors that influence physicians in their decision making. Several quantitative studies have evaluated the influence of hospital characteristics [6, 7], external factors (e.g. financing systems and reimbursement) [8, 9] and technology-related factors of particular technologies [10, 11]. Qualitative studies highlight that adoption decisions are based on financial and social pressures while evidence is often limited [12, 13]. Different dimensions to categorise factors influencing the decision making have been developed broadly differentiating between adopter specific, technology-related and external factors [14–18]. However, most of these studies use previously developed categories and fill the existing ones, which may undermine relevant aspects that do not fit into the used model.

Especially, the trade-off between the time of adoption and the evidence base is highly relevant for physicians with regard to technology adoption decisions, but also for health systems. In the light of limited resources and high health expenditures, from which a large share is spent on technologies, health care systems and payers are under pressure to control their expenditures [19]. Many countries, therefore, have introduced schemes to reimburse only those new technologies that have shown a benefit. The central idea is to link the value of a technology to its coverage decision and price setting [3]. However, due to the often low level of available evidence on new technologies' effectiveness the approach of *coverage with evidence development* (CED) has emerged. The technology is covered from health insurers, while obligatory generating further post-market evidence. The approach was originally implemented for Medicare in the US [20] and has been adapted in France [21], Germany [22], Sweden and the Netherlands [23], just to name a few. While these CED approaches exhibit common elements (e.g. a clear legal foundation and a preference for high quality study designs), their specifics depend on the underlying health system of the countries. Differences exist with regard to the types of technologies being assessed (i.e. drugs, procedures or medical devices) [22]. Compared to other countries the German approach, introduced in 2016, is based on an early benefit assessment (§137h in combination with §137e Social Code Book V (SGB V)) that focuses on a particular group of medical devices. Furthermore, the approach has been linked to the concept of inpatient innovation payments (see the 'Methods' section for detailed information). It is a further step in the paradigm shift for the medical device industry, for patient care, and for inpatient physicians adopting these technologies.

Since no international literature is available on this German health policy reform and its relevance in clinical practice, we aim to fill this gap. Based on this focus, the term 'new

technologies' includes medical devices and also diagnostic and treatment methods, but excludes pharmaceuticals.

The aim of this study is to

- (1) depict the German CED scheme, in order to gain more in-depth insights into the decision making of physicians adopting new technologies, and
- (2) to explore physicians' perspectives on the trade-off between evidence base and reimbursement of new technologies.

Our research has been led by two research questions:

- I. How do physicians describe their decision criteria whether to adopt a new technology in patient care?
- II. What experiences and constructive remarks do physicians have on the evidence base and the financing of new technologies?

Methods

Brief overview on the German CED reform in 2016

Because this study's aim and consequently the interviews' questionnaire's development was based on the German health policy reform on CED the approach will be introduced in this chapter. It clarifies why the reform especially affects physicians, which is e.g. the responsibility to deliver further information on a medical device or its exclusion from reimbursement.

Before 2016, approved new technologies generally could be used in German inpatient care without a prior external assessment (§137c SGB V). In 2012, CED was first introduced for diagnostic and therapeutic methods (§137e SGB V) for which the German Federal Joint Committee (G-BA) have passed a directive for the conduction of clinical trials to gather

additional data on effectiveness and safety [22]. The reform of 2016 focusses on new diagnostic and therapeutic methods whose technical application is based essentially on a medical device of high risk class (in short: ‘high-risk medical device’). ‘High-risk medical devices’ according to the SGB V are (1) medical devices of risk class IIb or III in line with the Directive 93/42/EEC or active implantable medical devices in line with the Directive 90/385/EEC¹ whose (2) application possess a highly invasive character. ‘New diagnostic and therapeutic methods’ thereby are defined as medical procedures with a new theoretical and scientific concept. The term ‘method’ includes procedures in terms of a ‘physician-led treatment concept’ characterised by a certain degree of complexity. It is thus distinct from other medical devices, such as medical instruments or appliances, that are used for one-step procedures [24]. The underlying new theoretical and scientific concept has to differentiate the method from others [24]; i.e., according to §137h SGB V, the new method’s mode of action or its field of application needs to differ substantially from systematic approaches already introduced in inpatient care. One example for a method that has been considered for assessment so far is the Coronary Lithoplasty for the treatment of Coronary Heart Disease (CHD). It is set apart from, e.g., the Rotablation, that is utilised in the treatment of CHD using another mode of action for coronary plaque ablation [25].

Figure 1 provides a schematic overview of the new approach [26]. Starting point of an early benefit assessment is a first application on innovation payments for new health technologies, so called ‘New Diagnostic and Treatment Methods’ (‘NUB’). Innovation payments are separate from the DRG system that involve additional funding (i.e., are paid on a fee-for-service basis) and are negotiated locally [27, 28]. The benefit assessment of a method leads to one of the following results: 1) sufficient proof of benefit, 2) no sufficient proof but potential of benefit, 3)

¹ As from 25 May 2017 the new Medical Device Regulation (MDR) came into force. Regulation (EU) 2017/745 will replace the directives concerning medical devices and active implantable devices after a transitional period of 3 years.

no sufficient proof of benefit. According to the Institute for Quality and Efficiency in Health Care (IQWiG), ‘benefit’ is defined as valid positive effects of methods concerning patient-related endpoints (e.g. mortality, morbidity or patients’ quality of life) compared to placebo or comparator interventions [29].

[Figure 1 about here.]

Design and participants

As the complexity of adoption processes is well known [17], we applied qualitative content analysis to adequately consider this organisational phenomenon [30]. The study was approved by the ethical committee of the Technische Universität Berlin via fast track procedure. We collected data based on in-depth semi-structured interviews, enabling us to ask context-driven additional questions [31]. The questionnaire covered the following subject areas: (I) Factors influencing physicians in their decision to adopt new technologies, (IIa) physicians’ assessment of the evidence base and (IIb) physicians’ assessment of the concept of innovation payments in clinical practice. With the aim of testing comprehensibility and appropriateness of the questions, a pilot test was conducted with two physicians [32]. The interviews of the pilot study were not part of the analysis.

In order to identify medical disciplines encompassing a variety of new and higher priced technologies compared to standard technologies, the German lists of requested innovation payments (2011-2015) were screened. As a result we conducted all interviews in the disciplines of vascular surgery and cardiology or other designation also carrying out interventions in these fields, e.g. internal medicine. We identified all relevant inpatient hospitals in the city of Berlin and the federal state of Brandenburg limiting the regional area for the following reasons: (1) Keeping the area of investigation small sized enables us to interview physicians by the same

researcher preventing bias of different researchers [33]. (2) Berlin as a populous city with a high hospital density and Brandenburg depicting the suburban and also rural region give a variety in hospitals' sizes and provider types [34, 35]. The recruitment process was realised from March to July 2017 contacting n = 173 physicians. The overall response rate was about 20% (n = 33). However, ten physicians rejected the invitation due to a lack of time or interest.

The semi-structured interviews were carried out in one-to-one appointments or via telephone from April to August 2017, were audio-taped and lasted between eleven and 33 minutes. After conducting 23 interviews, no fundamentally new information or arguments emerged. As this indicates the point of saturation was reached [36], no further physicians were recruited.

Data editing and analysis

The recordings were transcribed verbatim by an external office and the transcripts were anonymised by two researchers. With the aim to prevent information processing bias and to ensure a systematic analysis of qualitative data, we used the analytical software tool Atlas.ti (version 8.0) for coding [37]. All relevant text passages were coded separately by two researchers while directly deriving code titles from the text data [38]. Two rounds of analysis were conducted: A first set of codes was developed based on a discussion with the option of adding or amending codes for further analysis. With the aim to harmonise the analysis, we compared the final results after the second round to reach consensus [39]. In case of disagreement, a neutral researcher was consulted and codes were discussed. For answering the first research question all codes representing factors that influence physicians in their decision making were pooled in thematic categories using the bottom-up-approach [40]. To answer the second research question codes were systematically ordered.

Results

The data set consists of 23 in-depth semi-structured interviews with chief and senior physicians on vascular surgery and cardiology in inpatient care. The interviewed physicians have practiced in mean 24.7 years and 8.6 years in their current position. The departments have a mean of 50.5 beds. Table 1 gives an overview of the physicians' characteristics, the departments and hospitals.

[Table 1 about here.]

Factors influencing physicians' decision on the adoption of new technologies

In the interviews, a total of 52 individual factors were identified that physicians described as an influence in their decision to adopt a new technology. We grouped these factors into eight thematic categories, representing influences through (1) the technology, (2) the evidence base, (3) the state of medical care, (4) the manufacturer, (5) regulation, (6) the hospital, including its institutional characteristics and its strategy, (7) the individual, and (8) the patient. Figure 2 displays these categories including the influencing factors.

[Figure 2 about here.]

Technology-related factors include the handling of a medical device experienced by physicians, its durability and extent of improvement, and if it reduced the invasiveness of a treatment. Due to the diversity of technologies, a single comparison of an individual characteristic is not possible, forcing physicians to make an overall assessment considering a variety of aspects. Physicians also assess the *evidence base* when deciding whether to adopt a technology. They are aware of a low evidence base of medical devices after their market authorisation, in particular in the EU. However, some physicians view this as an opportunity to adopt a technology carefully in a hospital setting. Others reported that this might nevertheless lead to an excessive proliferation of

new technologies. They criticised that available studies are often based on a very small patient cohort and are biased with regard to manufacturer interests.

Furthermore, physicians' decision to use new technologies includes the *state of medical care*.

Interviewees value the level of care in their discipline as excellent with regard to the quality and availability of options. Thus, they set high standards for new technologies to compete against that. On the contrary, if few or no alternatives exist in an indication, such as in the case of rare diseases, physicians are willing to utilise certain new technologies despite lacking evidence. They cited guidelines as an important point of reference.

Manufacturer-related factors are mentioned as a further factor influencing physicians in their decision to adopt new technologies. They described the influence of manufacturers' sales activities, ranging from no interaction to using interactions as basically only source of information and criticised the focus on marketing activities. Furthermore, physicians consider the service provided by the manufacturers in their decision making. Another factor mentioned, was the manufacturer price and the cost-benefit-ratio, i. e. the manufacturer's pricing strategy of a technology in relation to the expected benefits. They observe, that prices decrease after initial market launch; some report to wait until prices declined.

In the context of *regulation*, relations between different factors of adoption play a significant role: reimbursement decisions and price developments are relevant in physicians' decision making whether to adopt new technologies. Some physicians expressed to be able to utilise a technology even if they have to cross-finance it from other DRGs.

Regarding *hospital*-related factors influencing the adoption, physicians distinguish between characteristics of the *institution*, such as the size and the type of provider, and *strategic* decision making of the hospitals. Interviewed physicians of non-university hospitals mentioned, that

university hospitals and specialist centres might have more possibilities of refinancing and thus should adopt new technologies first. They also reported to not have sufficient patient numbers in a certain indication to utilise new technologies. *Strategic* aspects of hospitals include internal processes regarding central purchasing, logistical efforts and coordination with administrative colleagues. Also, strategic hospital decisions such as to increase patient numbers and quality in patient care play a role in physicians' decisions whether to adopt new technologies as also reputation and patient satisfaction. Many physicians mentioned that they do not feel under pressure to be the first to adopt a technology. Instead, they would wait for other clinicians to utilise the technology first in order to adopt it at a later stage when more experiences have been acquired.

Regarding *individual*-related factors, physicians report their interest in something new and extraordinary as one driver to utilise new technologies, which is closely related to their personality. However, career and urge to publish articles constitutes a motivation, which the physicians assessed as a dominating incentive at times. Being familiar with a product can even set a certain barrier to not use new technologies.

Regarding the *patient*-related factors that affect the decision to adopt new technologies physicians mention patients' overall health and the compatibility of a technology with individual patients. While some physicians said they utilised new technologies primarily in young patients, others reported the opposite. Besides, some physicians are also willing to consider patient preferences for a certain technology, even in the context of implantable devices, while others do not. A selection of physicians' statements on the determinants regarding the adoption decision of new technologies are listed in Table 2.

[Table 2 about here.]

Physicians' experiences and remarks regarding evidence base and financing of new technologies

With regard to the second research question physicians overall expressed a trade-off between early adoption and the possibility to utilise innovative technologies, in particular in the case of new technologies without treatment alternatives. They criticised that the evidence base at point of market entry is scarce. Therefore, they sometimes prefer to wait for additional evidence. Many physicians complained, that some new technologies are financed too early by innovation payments. They additionally reported that the process of requesting and receiving an innovation payment is too complicated and inflexible. Table 3 gives an overview of the physicians' experiences and remarks. Statements on the evidence base at the time of adoption were divided into comments regarding market authorisation, utilisation, and study situation. Physicians' experiences and expectations about innovation payments consider issues with regard to the technology, the process of requesting and negotiating additional payments as well as the effects of this financing system.

[Table 3 about here.]

Discussion

This study gives detailed information on factors determining the adoption of new technologies from clinicians' point of view. The lack of evidence of individual values and attitudes of local innovators was previously highlighted by Varabyova [18]. Additionally, Hatz and colleagues conclude in their analysis of adoption decisions that the behaviour of physicians differs according to the length of time a cardiovascular medical device has been on the market. They thus differentiate between 'new' and 'old' medical technologies [17]. We contribute to the research on

the adoption of new technologies by picking up these differences and the identified research lacks and additionally investigated the role of innovation payments in combination with the introduction of a new regulatory approach for high-risk medical devices in Germany.

Our in-depth analysis of physicians' decision making whether to adopt new technologies generates eight thematic categories relevant for their utilisation. The study results show similar categories of influencing factors in German inpatient care as defined in previous literature [14–18]. The category *regulation* refers to previously defined structural, contextual and environmental factors, depending on the wording [14–18]. Organisational factors known from the literature [14, 16–18] are presented through *hospital*-related factors split into *institutional* and *strategic* factors. A particularity in health care is the structure of demand, as physicians use technologies in patient care, but actually the patient is the end user. Thus, we decided to split adopter-specific factors into (a) the *individual* category including factors of the physicians themselves and (b) the *patient* category covering patient-relevant adoption factors. Lastly, our results typically comprise *technology*-related factors.

However, new thematic categories evolved. Further categories have to be defined supplementing the existing literature-based dimensions. Firstly, the *state of medical care* plays an important role in adopting decisions, i.e. the availability of alternative treatments, the existence of different technology generations, the availability of a follow-up treatment for certain technologies, etc. Most studies, do not consider these factors. The same holds true for the activities of the *manufacturer*, which have been described, but rarely occur in studies examining physicians' adoption behaviour. Hatz and colleagues could show for the group of 'new' technologies that a perceived support of the manufacturer is associated with a higher probability of adoption [17]. Our results show that physicians expect a high service availability while they take a critical view on studies with regard to possible influences of manufacturers. High service availability might

improve device-operator interactions as it generates learning curve effects by gaining experiences within the utilisation of technologies. Learning curve effects might affect the technologies' effectiveness [41], as shown by Varabyova et al. for endovascular aneurysm repair (EVAR), a minimally invasive treatment method for abdominal aortic aneurysms, emphasising the need of training with medical devices [42]. Additionally, physicians discuss the available evidence extensively. Hatz et al. did not identify perceived medical evidence as a major driver of adoption. Our results show that the evidence base, depending on the availability of treatment alternatives, is a factor influencing adoption decisions. Interviewed physicians assess studies and their evidence base on their own. However, there are also statements that the manufacturer serves as the basis for decision making. As the *evidence base* did not fit properly into either of the defined categories, we established an extra category. Indeed, physicians consider this aspect as an important issue to influence their decision.. Our results indicate that physicians experience the evidence base at the time of market entry usually to be scarce. In particular, the interviewed physicians criticise a lack of studies overall, a small number of patients in approval studies and a supposed influence of manufacturers in studies. Furthermore, they noted a lack of studies investigating the effectiveness of technologies compared to their alternatives, highlighting that such studies are not required for medical devices in the EU. They view the additional benefit as a relevant indicator, since in their experiences many technologies had some minor improvements opposed to several complications and the overall uncertainty. Regarding financing of new technologies, many of the interviewed physicians have the power within the hospital to choose the product and manufacturer they prefer, even if it is more expensive than the calculated costs in the reimbursed rates. Nonetheless, physicians feel a personal responsibility to support the economic wellbeing of the hospital or the goal of breaking even. Therefore, the clinicians try to

act within the scope of DRGs. This supports the notion that the diffusion of new technologies is steered by their reimbursement.

Due to scarce evidence and the requirement of additional reimbursement, the physicians overall support the aim and objectives of the health policy reform. However, the design of the approach and its implementation is criticised. With regard to medical decision making based on evidence of effectiveness, this regulatory instrument will fall short. Additional evidence may be gathered only for a small group of technologies with the following prerequisites: (i) hospitals' first request of innovation payment, (ii) defined as 'high-risk medical device', (iii) underlying 'new theoretical and scientific concept', (iv) status 'potential'. Many technologies do not fall under this approach as it is currently designed (e.g. high-risk technologies without requests of innovation payments)

Although this study allows a unique insight into physicians' perspectives using the qualitative approach limitations need to be mentioned [43]: Besides researchers' individual conclusions in analysis, study results might not be representative for all physicians [44, 45]. Additionally, using telephone interviews implies disadvantages compared to an appointment in person (e.g. a lack of interaction between interviewer and participant) [46]. However, conducting telephone interviews offered some assets (e.g. high response rate, low costs) [47]. Furthermore, we interviewed chief and senior physicians only, professionals in a certain hierarchical and thus experience level. Since years in practice of physicians were found to be negatively associated with the adoption of new technologies [48, 49], clinicians in other positions also should be considered in further analysis. Overall, as the analysis is based on 23 interviews used to identify a wide range of factors influencing physicians' adopting decisions, further quantitative studies are necessary to investigate factors according to their relevance in adopting decisions and their relations.

Conclusions

This study offers an in-depth understanding of factors influencing the decision making of clinicians to adopt new technologies. We identified 52 factors that are allocated in eight thematic categories and depict the overall trade-off that physicians have to handle in their adoption decisions. All interviewed physicians supported the general notion of conducting benefit assessments and, if necessary, generating additional evidence. However, they criticize the design and implementation of the German approach. They appreciate improvements in receiving summarised information. Therefore, a further step and a challenge for policy makers and payers could be, to bring together country specific evidence on the effectiveness of new technologies on European level to build up a transnational overarching database. A central provision of summarised evidence might assist physicians in their decision whether to use new technologies. Overall, the results of the 23 interviews analysed based on qualitative content analysis should be verified via quantitative studies in a further step to investigate factors according to their relevance in adopting decisions and their relations in more detail.

References

- [1] Rothery C, Claxton K, Palmer S, et al. Characterising Uncertainty in the Assessment of Medical Devices and Determining Future Research Needs. *Health economics* 2017;26 (Suppl.1):109–23.
- [2] van de Wetering EJ, van Exel J, Brouwer WBF. The Challenge of Conditional Reimbursement: Stopping Reimbursement Can Be More Difficult Than Not Starting in the First Place! *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 2017;20:118–25.
- [3] Walker S, Sculpher M, Claxton K, et al. Coverage with evidence development, only in research, risk sharing, or patient access scheme? A framework for coverage decisions. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 2012;15:570–9.
- [4] van Norman GA. Drugs and Devices. Comparison of European and U.S. Approval Processes. *JACC: Basic to Translational Science* 2016;1:399–412.
- [5] Greer AL. Adoption of medical technology. The hospital's three decision systems. *International journal of technology assessment in health care* 1985;1:669–80.
- [6] Blank JLT, Valdmanis VG. Technology diffusion in hospitals: a log odds random effects regression model. *The International journal of health planning and management* 2015;30:246–59.
- [7] Bech M, Christiansen T, Dunham K, et al. The influence of economic incentives and regulatory factors on the adoption of treatment technologies: a case study of technologies used to treat heart attacks. *Health economics* 2009;18:1114–32.

- [8] Sorenson C, Drummond M, Torbica A, et al. The role of hospital payments in the adoption of new medical technologies: an international survey of current practice. *Health economics, policy, and law* 2015;10:133–59.
- [9] Cappellaro G, Ghislandi S, Anessi-Pessina E. Diffusion of medical technology: the role of financing. *Health policy (Amsterdam, Netherlands)* 2011;100:51–9.
- [10] Cutler DM, Huckman RS. Technological development and medical productivity. The diffusion of angioplasty in New York state. *Journal of Health Economics* 2003;22:187–217.
- [11] Sloan FA, Valvona J, Perrin JM, et al. Diffusion of surgical technology. *Journal of Health Economics* 1986;5:31–61.
- [12] Gold HT, Pitrelli K, Hayes MK, et al. Decision to adopt medical technology: case study of breast cancer radiotherapy techniques. *Medical decision making : an international journal of the Society for Medical Decision Making* 2014;34:1006–15.
- [13] Ubel PA, Asch DA. Creating value in health by understanding and overcoming resistance to de-innovation. *Health affairs (Project Hope)* 2015;34:239–44.
- [14] Kimberly JR, Evanisko MJ. Organizational Innovation. The Influence of Individual, Organizational, and Contextual Factors on Hospital Adoption of Technological and Administrative Innovations. *Academy of Management Journal* 1981;24:689–713.
- [15] McCullough JS. The adoption of hospital information systems. *Health economics* 2008;17:649–64.
- [16] Chaudoir SR, Dugan AG, Barr CHI. Measuring factors affecting implementation of health innovations: a systematic review of structural, organizational, provider, patient, and innovation level measures. *Implementation science* 2013;8:22.

- [17] Hatz MHM, Schreyögg J, Torbica A, et al. Adoption Decisions for Medical Devices in the Field of Cardiology: Results from a European Survey. *Health economics* 2017;26 Suppl 1:124–44.
- [18] Varabyova Y, Blankart CR, Greer AL, et al. The determinants of medical technology adoption in different decisional systems: A systematic literature review. *Health policy (Amsterdam, Netherlands)* 2017;121:230–42.
- [19] Banta HD, Russell LB. Policies toward medical technology: an international review. *International journal of health services : planning, administration, evaluation* 1981;11:631–52.
- [20] Tunis SR, Pearson SD. Coverage options for promising technologies: Medicare's 'coverage with evidence development'. *Health affairs (Project Hope)* 2006;25:1218–30.
- [21] Martelli N, van den Brink H, Borget I. New French Coverage with Evidence Development for Innovative Medical Devices: Improvements and Unresolved Issues. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research* 2016;19:17–9.
- [22] Olberg B, Perleth M, Busse R. The new regulation to investigate potentially beneficial diagnostic and therapeutic methods in Germany: up to international standard? *Health policy (Amsterdam, Netherlands)* 2014;117:135–45.
- [23] Ferrario A, Kanavos P. Dealing with uncertainty and high prices of new medicines: a comparative analysis of the use of managed entry agreements in Belgium, England, the Netherlands and Sweden. *Social science & medicine (1982)* 2015;124:39–47.
- [24] Olberg B, Fuchs S, Matthias K, et al. Evidence-based decision-making for diagnostic and therapeutic methods: the changing landscape of assessment approaches in Germany. *Health research policy and systems* 2017;15:1–11.

- [25] Gemeinsamer Bundesausschuss, G-BA (Federal Joint Committee). Tragende Gründe zum Beschluss des Gemeinsamen Bundesausschusses über die Einschlägigkeit des Verfahrens gemäß 2. Kapitel § 33 Absatz 1 Verfahrensordnung: Koronare Lithoplastie bei koronarer Herzkrankheit 2017. Available from: https://www.g-ba.de/downloads/40-268-4664/2017-11-17_137h_BAh-17-004_Lithoplastie_TrG.pdf. [Accessed January 22, 2018].
- [26] Ex P, Busse R, Henschke C. Die Nutzenbewertung von nichtmedikamentösen Untersuchungs- und Behandlungsmethoden. Welche Tragweite hat die Regelung nach § 137h SGB V? Gesundheits- und Sozialpolitik 2016;70:48–55.
- [27] Sorenson C, Drummond M, Wilkinson G. Use of innovation payments to encourage the adoption of new medical technologies in the English NHS. Health Policy and Technology 2013;2:168–73.
- [28] Scheller-Kreinsen D, Quentin W, Busse R. DRG-based hospital payment systems and technological innovation in 12 European countries. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research 2011;14:1166–72.
- [29] Allgemeine Methoden: Version 5.0. Köln: Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG), 2017.
- [30] Denzin NK, Lincoln YS (Eds.). The Sage handbook of qualitative research. 3. ed. Thousand Oaks: Sage Publications, 2009.
- [31] Gill P, Stewart K, Treasure E, et al. Methods of data collection in qualitative research: interviews and focus groups. British dental journal 2008;204:291–5.
- [32] Turner DW. Qualitative Interview Design: A Practical Guide for Novice Investigators. The Qualitative Report 2010;15:754–60.
- [33] Breakwell GM (Ed.). Research methods in psychology. 3. ed. Los Angeles, Calif.: SAGE-Publ, 2007.

- [34] Porter ME, Guth C. Redefining the German healthcare system. Berlin, Heidelberg: Springer, 2012.
- [35] Klauber J, Friedrich J, Wasem J (Eds.). Schwerpunkt: Strukturwandel. Mit 98 Tabellen. Stuttgart: Schattauer Verlag, 2015.
- [36] Guest G, Bunce A, Johnson L. How Many Interviews Are Enough? *Field Methods* 2016;18:59–82.
- [37] Miles MB, Huberman AM, Saldana J. *Qualitative Data Analysis. A Methods Sourcebook*. 3. ed. Thousand Oaks: Sage Publications, 2014.
- [38] Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. *Qualitative health research* 2005;15:1277–88.
- [39] Campbell JL, Quincy C, Osserman J, et al. Coding In-depth Semistructured Interviews. *Sociological Methods & Research* 2013;42:294–320.
- [40] Webb C. Analysing qualitative data: computerized and other approaches. *Journal of Advanced Nursing* 1999;29:323–30.
- [41] Tarricone R, Torbica A, Drummond M. Challenges in the Assessment of Medical Devices: The MedtechHTA Project. *Health economics* 2017;26 Suppl 1:5–12.
- [42] Varabyova Y, Blankart CR, Schreyögg J. The Role of Learning in Health Technology Assessments: An Empirical Assessment of Endovascular Aneurysm Repairs in German Hospitals. *Health economics* 2017;26 Suppl 1:93–108.
- [43] Stewart K, Gill P, Chadwick B, et al. Qualitative research in dentistry. *British dental journal* 2008;204:235–9.
- [44] Eysenbach G, Köhler C. How do consumers search for and appraise health information on the world wide web? Qualitative study using focus groups, usability tests, and in-depth interviews. *BMJ (Clinical research ed.)* 2002;324:573–7.

- [45] Mays N, Pope C. Rigour and qualitative research. *BMJ (Clinical research ed.)* 1995;311:109–12.
- [46] Trier-Bieniek A. Framing the telephone interview as a participant-centred tool for qualitative research. A methodological discussion. *Qualitative Research* 2012;12:630–44.
- [47] Carr EC, Worth A. The use of the telephone interview for research. *NT Research* 2016;6:511–24.
- [48] Scott SD, Plotnikoff RC, Karunamuni N, et al. Factors influencing the adoption of an innovation: an examination of the uptake of the Canadian Heart Health Kit (HHK). *Implementation science : IS* 2008;3:1–8.
- [49] Choudhry NK, Fletcher RH, Soumerai SB. Systematic Review. The Relationship between Clinical Experience and Quality of Health Care. *Annals of Internal Medicine* 2005;142:260–73.