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Physicians' Decision Making on Adoption of New Technologies and Role of Coverage with Evidence Development: A Qualitative Study

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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. Although this is a paradigm shift, the German approach is limited to some few specific technologies for which reimbursement is requested. As physicians encounter this regulatory instrument, the aim of the study was to understand physicians' decision making regarding the adoption of new medical technologies and to identify their perspectives on the evidence base and financing with additional reimbursement systems. **Methods:** From April to August 2017, semistructured interviews with chief and senior physicians of vascular surgery and cardiology in inpatient care in Germany were conducted (N = 23). The interviews were carried out by one researcher in one-to-one appointments or via telephone. Data were analyzed inductively to identify factors and generate thematic categories using qualitative content analysis. **Results:** We identified 52 factors in eight categories influencing physicians' adoption of new technologies. The evidence base for new technologies was criticized (e.g., lack of available studies). Physicians' knowledge of the regulation of market approval and innovation payments varied. They recommended the utilization of new technologies in certain specialist centers and the facilitation of observational studies. **Conclusions:** Physicians saw the need for the new approach and supported its aim. However, its design and implementation appeared to be questionable from their medical perspective. The provision of summarized information on the benefit of technologies might be a possibility to assist physicians' decision making.

Keywords: adoption of technologies, coverage with evidence development, evidence, innovation, inpatient care, physician.

Introduction

When new medical technologies enter the market, their time of adoption is a key point in patient care, as evidence and experience regarding their utilization often differ in their extent [1]. With the aim of maximizing patient benefit and reducing risks [2], many new technologies can lead to better outcomes in patients' treatment and diagnosis; however, there might be uncertainty regarding their effectiveness and risks because at the time of market approval only little or no evidence may be available [3,4]. Thus, the adoption and utilization of new technologies is necessary to gather knowledge and real-world evidence. This is the case for medical devices, especially in the European Union, where requirements to obtain market approval are generally lower than, for instance, in the United States [5].

Regarding new technologies used in inpatient care, the primary adopters are physicians, as they assess treatment options and decide, sometimes within teams, whether to adopt a new technology or to use established alternatives. A variety of studies have investigated factors influencing physicians' 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 have highlighted that adoption decisions are based on financial and social pressures, while evidence is often limited [12,13]. Different dimensions to categorize factors influencing decision making have been developed, broadly differentiating among adopter-specific, technology-related, and external factors [14–18]. However, most of these studies used previously developed categories and fill the existing ones, which may undermine relevant aspects that do not fit into the model used.

In particular, the trade-off between time of adoption and evidence base is highly relevant for physicians with regard to

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technology adoption decisions but also for health care systems. In light of limited resources and high health expenditures, a large share of which 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 benefit. The main idea is to link the coverage decision and price setting for a technology to its value [4]. Owing to the often low level of available evidence on the effectiveness of new technologies, the approach of *coverage with evidence development* (CED) has been developed, in which a technology is covered by health insurers while further post-market evidence is obligatorily generated. This approach was originally implemented for Medicare in the United States [20] and has been adapted in France [21], Germany [22], Sweden, and the Netherlands [23], among other countries. Although these CED approaches exhibit common elements (e.g., clear legal foundation and preference for high-quality study designs), their specific features depend on the underlying health system in each country. Differences exist with regard to the types of technologies being assessed (i.e., drugs, procedures, or medical devices) [22]. Compared to those in 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]) of a particular group of medical devices. Furthermore, the approach has been linked to the concept of inpatient innovation payments (see Methods for detailed information), and is a further step in a paradigm shift for the medical device industry, patient care, and inpatient physicians adopting these technologies.

As no international literature is available on the German health policy reform and its relevance for clinical practice, we aimed to fill this gap. Accordingly, the term "new technologies" in this article refers to medical devices as well as diagnostic and treatment methods, but excludes pharmaceuticals. The aim of this study was, first, to describe the German CED scheme to gain a more in-depth insight into the decision making of physicians adopting new technologies, and, second, 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 for adopting a new technology in patient care?
II. What experiences and constructive remarks do physicians have regarding the evidence base and financing of new technologies?

Methods

Brief Overview of 2016 German CED Reform

The aim of this study and, consequently, the development of the interview questionnaire focused on the German health policy reform of the CED; thus, the approach will be introduced in this section, clarifying why the reform especially affects physicians (e.g., responsibility to provide further information on a medical device or its exclusion from reimbursement).

Before 2016, approved new technologies could generally be used in German inpatient care without a prior external assessment (§137c SGB V). In 2012, the CED was first introduced for diagnostic and therapeutic methods (§137e SGB V), for which the German Federal Joint Committee (G-BA) had passed a directive for the conduction of clinical trials to gather additional data on effectiveness and safety [22]. The reform of 2016 focuses on new diagnostic and therapeutic methods whose technical application is based essentially on a medical device of high-risk class (i.e., "high-risk medical device"). According to the SGB V, "high-risk medical devices" 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/EEC,[1] whose (2) application possesses a highly invasive character. "New diagnostic and therapeutic methods" are thereby defined as medical procedures using a new theoretical and scientific concept. The term "method" involves procedures in terms of a "physician-led treatment concept" characterized by a certain degree of complexity. These are thus different 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 of the method has to differentiate it from others [24]; that is, 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 used in inpatient care. An example of a method that was considered for assessment so far is coronary lithoplasty for the treatment of coronary heart disease (CHD). This is different from, for example, rotablation, which is utilized in the treatment of CHD using another mode of action for coronary plaque ablation [25].

Figure 1 provides a schematic overview of the new CED approach [26]. The starting point of an early benefit assessment is the hospitals' first application on innovation payments for new technologies, so-called New Diagnostic and Treatment Methods. Innovation payments are separate from the system of diagnosis-related groups (DRGs) in that they 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, or (3) 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 end points (e.g., mortality, morbidity, or patient's quality of life) compared to placebo or comparator interventions [29].

Study Design and Participants

As the complexity of adoption processes is well known [17], we applied qualitative content analysis to adequately examine this organizational phenomenon [30]. This study was approved by the ethical committee of the Technische Universität Berlin via a fast track procedure. We collected data using in-depth semistructured interviews, enabling us to ask additional context-driven questions [31]. The questionnaire covered the following subject areas: (I) factors influencing physicians' decisions 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 the comprehensibility and appropriateness of the questions, a pilot test was conducted with two physicians [32]. The interviews of the pilot study were not included in the analysis.

To identify medical disciplines where a variety of new and higher priced technologies compared to standard technologies are used, the lists of requested innovation payments in Germany (2011–2015) were screened. As a result, we conducted all interviews in the disciplines of vascular surgery and cardiology or other designated areas, also carrying out interventions in those fields, for example, 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 at a small size permits having all physicians interviewed by the same researcher, preventing bias resulting from different researchers [33]; (2) Berlin, as a populous city with a high hospital density, and Brandenburg, consisting of suburban and rural regions, offer a variety in hospital sizes and

[1]As of May 25, 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.