Implementation of Innovative Medical Technologies In German Inpatient Care: Patterns of Utilization And Evidence Development

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Abstract

Background: Innovative medical technologies are commonly associated with positive expectations. At the time of their introduction into care, there is often little evidence available on their benefits and harms. Thus, it happens that some health innovations with a lack of evidence are used widely until or even though adverse study results emerge. Others with strong scientific support remain underused. The study aims at examining the diffusion patterns of innovative medical technologies in German inpatient care between 2005 and 2017 while simultaneously considering evidence development.

Methods: Based on a qualitatively derived typology and a quantitative clustering process of the adoption curves, a representative sample of 21 technologies was selected for further evaluation. Published scientific evidence on efficacy and safety of the technologies was identified and extracted in a systematic approach. Derived from a two-dimensional classification according to the degree of utilization and state of scientific evidence, the diffusion processes were then assigned to the categories "Success" (widespread/positive), "Hazard" (widespread/negative), "Overadoption" (widespread/limited or no), "Underadoption" (cautious/positive), "Vigilance" (cautious/negative) and "Prudence" (cautious/ limited or no).

Results: Overall, we found limited evidence regarding both the quantity and quality of published randomized controlled trials. Thus, the categories “Prudence” and “Overadoption” together account for nearly three-quarters of the years evaluated, followed by “Success” with 17 percent. Even when evidence is available, the transfer of knowledge into practice seems inhibited.

Conclusions: The successful implementation of innovations into practice requires substantial further efforts by policymakers to strengthen systematic knowledge generation and translation. Creating an environment that encourages the conduct of rigorous studies, promotes knowledge translation, and rewards innovations according to their added value are prerequisites for the diffusion of valuable innovations in the health care sector.

Contributions To The Literature

- Previous research has found that the implementation and diffusion of innovations is shaped by perceived advantages, organizational and environmental factors.
- The relationship between adoption of new technologies and scientific evidence has been studied mostly for individual technologies.
- This study presents a novel methodological approach for categorizing adoption patterns based on hospital utilization data, selecting a balanced sample of technologies for analysis, and analyzing the relationship between diffusion and scientific evidence.
- Insights from a comprehensive sample of 21 technologies highlight that in several cases, there is overadoption (widespread use despite limited evidence), which entails risks for patients and health

Background

Medical innovations are commonly accompanied by positive expectations. In fact, they may reduce pain and/or contribute to patients' full recovery, improve health-related quality of life and well-being and, in addition, create economic benefits by reducing health care expenditures in the long run [1]. As a result, an initially uncritical adoption behavior often prevails [2]. However, it is not uncommon that these high expectations prove to be unrealizable. This does not only put patients at risk of suffering health damages, but can also mean unwarranted high expenses for health systems [3].

Many innovations – both therapeutic and diagnostic – are procedures, in which medical devices constitute a central component. Medical devices in the European Union (EU) must undergo a conformity assessment demonstrating that they fulfil regulatory requirements of quality, safety and performance to obtain a Conformité Européene (CE) mark, which certifies their approval for marketing. In other countries, such as the US, an additional demonstration of efficacy may be required depending on the risk of the device [4]. The U.S. Food and Drug Administration (FDA) published several examples of high-risk medical devices that were approved only in Europe and resulted in major health damages or were later found to be ineffective. For example, the drug-eluting stent CoSTAR was withdrawn in Europe when an approval trial in the United States showed increased rates of reinterventions and heart attacks [5]. Despite the increased rigor of the marketing authorization process introduced by the Medical Device Regulation (Regulation (EU) 2017/245), the requirements for the pre-market evaluation of medical devices remain less strict than those for pharmaceuticals [6], although the potential for harm is not necessarily lower.

In various countries, an evaluation of (cost-)effectiveness is required before new technologies can be reimbursed in the statutory health system [7]. This is generally not the case for the utilization of new technologies in German inpatient care, including those which use a medical device as a central component. New certified medical devices may be utilized in inpatient care, unless they are explicitly excluded by the Federal Joint Committee (G-BA), the highest decision making body in the German health care system [8]. New technologies that cannot yet be appropriately billed via per-case flat rates and additional charges of the German Diagnosis Related Groups (G-DRG) system used to pay for hospitals may be reimbursed by additional extrabudgetary innovation payments if hospitals are permitted to negotiate prices with health insurers (see Henschke et al. [9] for details on this process). The negotiated amount does not depend on the technology's effectiveness or risk-benefit profile. In 2016, the concept of the innovation payments was supplemented by a structured obligatory early benefit assessment for certain high-risk new diagnostic and treatment methods (Neue Untersuchungs- und Behandlungsmethoden, NUB) [10]. Nevertheless, the decision to utilize these new technologies, and consequently their diffusion rate, is largely the responsibility of hospitals. Thus, the implementation of health innovations is not necessarily based on evidence-based recommendations [11]. It happens that some health innovations are utilized widely despite a lack of supporting evidence while others with strong scientific support remain underused [12, 13].

Research on the diffusion of innovation was largely shaped by Rogers [14], who argued that it is facilitated by the perceived relative advantage of new technologies; their compatibility with previous experience, values, and needs; their subjective complexity; and their trialability [14, 15]. However, the perceived relative advantage to current practice seems to be the subjective result of debate among health professionals and not a rational assessment based on credible evidence [12, 16]. Indeed, previous research demonstrates that the implementation and diffusion of innovations depends only to some extent on scientific evidence [17] and is shaped by many intra- and extra-organizational factors [18, 19], not least environmental factors such as financial incentives [20].

Because the adoption and diffusion of innovative technologies are important drivers of value-based health care [13], it is important to understand the optimal timing for them to be (de)adopted in healthcare, particularly in relation to the availability of robust scientific evidence. Considering the fast pace of innovation in health care and the resulting broad range of new technologies, it is also important to recognize that diffusion patterns will differ, and that exploring this relationship should strive to capture this variability. Therefore, this study had two aims:

a) To develop a methodological approach for categorizing diffusion patterns of medical innovations based on hospital utilization data and available scientific evidence, in order to select a varied sample for further investigation, and

b) to investigate how these diffusion patterns relate to the underlying scientific evidence on safety and efficacy/effectiveness in the German health system, which is characterized by low entry requirements for utilization in inpatient care.

Methods

In a first step, innovations reimbursed in German inpatient care between 2005 and 2017 were identified using a database annually published by the German Institute of the Hospital Remuneration System (InEK), and those with a relevant number of cases were pre-selected for consideration. Data on utilization numbers between 2005 and 2017 were drawn from the German DRG statistics [21] and used to plot diffusion curves and determine the number of cases treated with appropriate alternatives. The diffusion curves were grouped in seven progression types, and a minimum number of technologies per type was selected for investigation, also considering available evidence. The maximum sample for investigation was set at 30 technologies, to balance representativity with feasibility. The diffusion curves were subsequently juxtaposed to systematically identify randomized controlled trials (RCTs) over the observation period. Figure 1 visualizes the methodical approach in a flowchart. Each step is described in detail below. Since steps 1 to 5 serve as preparation for the analysis in step 6, their outcomes are described here and not separately in the results section.

(1) Determining the initial technology pool

To identify the initial technology pool, the following steps were taken:

i) The lists of new medical diagnostic and treatment methods published annually by the InEK between 2005 and 2012 were scrutinized. These lists include all new medical diagnostic and treatment methods, which are significantly based on the application of a medical device for which hospitals have requested permission to negotiate innovation payments with health insurers (as they are not adequately reimbursed by current DRGs). The time window was chosen to ensure that data would be available for at least five years ahead of the start of this research. Consequently, the observation period for this study spans the years 2005 to 2017.

ii) The “DRG statistics” dataset, which includes hospital claims data reported annually to the German Federal Office of Statistics, was used to determine the number of hospitals using the technology and the total number of cases. DRG statistics capture anonymized information for all inpatient treatments.

iii) The following criteria were applied for selection based on the information from i) and ii):

- Permission to negotiate an innovation payment for the technology was requested by more than ten hospitals and granted for at least one year between 2005 and 2012,
- Case numbers and numbers of hospitals using the technology were available for at least four years,
- 100 cases or more were billed for at least one year.

Overall, 59 technologies were included following these selection criteria, and are listed in Table 1 (Table 1 also shows the final selection of 27 technologies based on the process described in step 4, below). They can be classified into ten groups according to the anatomical region of application. More than two-thirds of the technologies (41 of 59) concern the cardiovascular system.

(2) Grouping technologies empirically based on adoption curve progression

Based on the DRG case data described above, adoption curves were plotted for all 59 technologies (visualized in Additional file 1). We subsequently empirically developed seven curve progression types in order to select a varied sample for further analysis. The types evolved by grouping curve progressions that were as homogeneous as possible; this was achieved in two steps.

First, a qualitative clustering was performed aiming at an unambiguous assignment of the curve progressions. The gradients of the curves over time, changes in the gradient, and the approach of the curve to a saturation point were considered. The operationalization of these criteria and the resulting groups can be traced in Table 2 (types I-V). According to this approach, 28 of the 59 technologies could not be assigned to any of the five types. These were initially grouped together in a further group (VI) under the keyword "complex".

To obtain further differentiation of this residual group of curve progressions, a quantitative cluster analysis [22] was applied in a second step using the statistical software RStudio (version 1.3.1093). Details are presented in detail in Additional file 2. Based on the resulting target number of two clusters, the 28 technologies in curve progression type VI were distributed into two groups of 23 (type VI.a) and 5

technologies (type VI.b), respectively. Table 2 summarizes the types of progression curves, the operationalization of the criteria and the distribution of technologies to the types.

(3) Identifying baseline information on available scientific evidence

The aim of this step was to gather baseline information on the state of scientific knowledge for each technology to ensure that the selected sample covers different types of adoption curves, but also different results derived from the available evidence (i.e., evidence supporting utilization with or without restrictions, evidence not supporting utilization). For this purpose, we screened reports of the Medical Review Board of the Federal Association of Sickness Funds (Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen – MDS) for the 59 technologies described above. These reports are prepared upon request to evaluate technologies for which the negotiation of innovation payments has been permitted by the InEK.

Since the reports are confidential, detailed results cannot be reported. A total of 45 reports were identified for 56 of the 59 included technologies. We developed a structured template to extract information on methodology (e.g., year, PICOS criteria), included studies (e.g., level of evidence), reported outcomes (mortality, morbidity, quality of life), results of included studies, and the conclusions of the MDS appraisal. Based on the latter, we classified each technology into one of the evidence groups "has potential without limitations" (1), "has potential for certain patients" (2), and "no potential" (3). It is important to note that these initial assessments were not necessarily identical to the results of the systematic identification of evidence described under step 5, below.

(4) Selecting a balanced sample for further analysis

Of the 59 technologies pre-selected in step 1, we decided to further select a maximum of 30 technologies of all curve progression types and evidence classifications. Within these groups we chose those technologies that were most relevant to care based on high case numbers and high rates of increase in case numbers. The conjunction of these two parameters was translated into a multiplicative criterion for each technology *i* from all available data years *j*:

$$Crit._i = (\text{Maximum number of cases}_i) \cdot (\text{Largest rate of change}_i)$$

$$= \max_{j \in [1,13]} \{f_i(t_j)\} \cdot \max_{j \in [1,13]} \left\{ \left| \frac{f_i(t_{j+1})}{f_i(t_j)} - 1 \right| \right\}$$

Within each type of curve progression, all technologies were sorted by size based on $Crit._i$ in descending order. To achieve a sample of 28 (as a multiple of the seven groups), the four top technologies were selected from each group (i.e., I-V, VI.a and VI.b). However, since curve types II, III, and V each contain fewer than four technologies, the final resulting sample included only 22. To further diversify the sample

and balance the selection of evidence classifications, the remaining technologies were filtered according to the following scheme.

First, technologies that are used in the context of an indication already strongly represented in the sample of 22 were excluded. Then, three and two additional technologies were selected from the evidence groups "has potential without limitations" and "no potential", respectively, as these were the least represented. This results in an almost even distribution across the groups: 55 % (6 of 11) selected from group 1, 60 % (3 of 5) selected from group 2, and 57 % (4 of 7) selected from group 3. This sample also achieved a balance between groups with clear and unclear evidence (13 vs. 14 of 27). Again, selection was based on curve progressions: candidates were compared qualitatively and those that appeared to be particularly complementary to the technologies already selected were included. The final sample of 27 technologies is shown in the last column of Table 1.

(5) Systematically identifying published evidence for included technologies

Subsequently, published evidence on the selected technologies was systematically identified, selected, and evaluated. For this purpose, bibliographic biomedical electronic databases (Medline and Embase via OVID, PubMed, the Cochrane Library), clinical trial registries (Clinicaltrials.org, WHO International Clinical Trials Registry Platform (ICTRP)) and selected Health Technology Assessment (HTA) databases and agencies (LBI-HTA, IQWiG/G-BA, CRD HTA/ INAHTA Database, DIMDI-DAHTA, EUnetHTA) were searched between May and September 2019. Search strategies with high sensitivity were used and restriction on the study designs was included. However, only RCTs are considered for the purpose of this article; an overview of all evidence types is presented elsewhere [23].

The results of the searches were imported into the literature management program EndNote (version x9, Clarivate). Explicit inclusion and exclusion criteria were formulated for each technology; inter alia, studies were included if they were published in the 2-year period before the first documented hospital case through the end of the observation period (2017). Due to the number of included technologies and the high number of hits resulting from the sensitive searches, for the selection of relevant citations a so-called rapid review approach was adopted [24]. After duplicate removal, a random sample of 10 percent of all hits (at least 100) was drawn for each technology, and a title-abstract screening was carried out by two researchers independently. In case of discrepancies, the inclusion and exclusion criteria were discussed and adjusted, involving a third researcher if necessary. Subsequently, the remaining hits per technology were screened by one person (title/abstract screening followed by full-text screening as per standard systematic review methodology). Data from included publications were extracted using a standardized extraction sheet.

Based on the conclusion of the authors, each publication was labelled based on its key message:

- Positive: The authors' conclusions are consistently positive regarding efficacy and safety, and across patient groups. When a neutral (e.g., "equally safe") and a positive (e.g., "effective") statement were combined, the publication was considered positive.

- Negative: The authors' conclusions are consistently negative regarding efficacy and safety, and across patient groups. When a neutral (e.g., "safe") and a negative (e.g., "less efficacious") statement were combined, this publication was classified as negative.
- Neutral: The authors conclude no difference between intervention and comparative intervention.
- Inconclusive: The authors conclude that no definite statement can be made.

(6) Grouping and analyzing adoption processes according to diffusion rate and evidence

In a final step, the diffusion of innovations into the German health care system was examined against the background of available scientific evidence in order to identify successful and failed adoption statuses and possible changes therein. For this purpose, we adapted the grid design for classification of innovations from Denis et al. [12]. The expressions of available scientific evidence and utilization are combined in a 6-field table (see Table 3). In the case of positive scientific support, widespread utilization is described as "Success", whereas cautious utilization implies "Underadoption". We extended the initial matrix by Denis et al. [12] to include the case of negative scientific support, where widespread utilization results in "Hazard" and restrained application represents "Vigilance". Limited or lacking evidence may indicate "Overadoption" or, on the contrary, "Prudence".

The state of evidence is divided into (1) strong direct or moderate evidence with positive conclusions, (2) strong direct or moderate evidence with negative conclusions and (3) limited or no evidence. We categorized the evidence for each year and each technology using a modified version of the World Health Organization/Health Evidence Network criteria [25, 26] based on identified RCTs (see Table 4). Included RCTs were assessed regarding risk of bias according to the procedural rules of the G-BA [27]. A high potential for bias led to a downgrade within the grading scheme from strong to moderate evidence. The color coding for the different grades of evidence shown in Table 3 is further explained in Table 4.

The utilization, on the other axis of the classification grid in Table 3, is divided according to the diffusion rate in percent based on Roger's Diffusion of Innovation Model [14]. Accordingly, we set a threshold at 16 percent of the target population for each technology. Below this threshold, adoption of the technology is considered "cautious", or commensurate with the risk of a novel technology due to lack scientific support. Above the threshold, utilization of the technology was classified as widespread. It is important to note that Rogers' model uses health care providers as the unit of analysis, with the first 16 percent corresponding to the group of innovators and early adopters, and beyond that to the (early) majority. We considered this threshold to be transferrable for the categorization of adoption based on case numbers, which offer an overarching view of technology diffusion; we note the lack of other models for such an exercise in the literature.

To determine the target population for each technology, we identified the predominant (gold) standard intervention for each indication in the literature. We subsequently accessed the "DRG statistics" dataset remotely via the Research Data Center of the German Federal Statistical Office (see Step 1 for information on the dataset). For six out of 27 technologies (PECLA/iLA, MVAC, BVS, DCB-AV, IABC and FDT) no [illegible]vailable, so these were excluded from further analysis. For the

other technologies, we cumulated the case numbers to transform the adoption curves (see Additional file 1) into diffusion curves (see Fig. 2). The cut-off value was formed for each year as 16 percent of the sum of the case numbers of the comparator and the technology itself.

For each of the remaining 21 technologies, adoption statuses were evaluated per year based on the grid in Table 3. In the subsequent analysis, we view the adoption of innovations as dynamic, allowing and accounting for change in status.

Results

Figure 2 shows the diffusion curves of the 21 technologies and the underlying evidence, as well as the threshold value and its intersection point with the diffusion curve. This defines the change from cautious to widespread utilization. Five technologies (LVRC, IET-MICRO, ACT, ACD, MRD) were already applied to more than 16 percent of the total population in the first documented year of use. Eight (EL-P/ICD, ER-ABL, SE-BMS, FD-ULV, DES-ULV, EABO, F-TUR, HCO) do not reach this threshold during the entire period of observation.

For the majority of technologies (16 of 21), no relevant study of acceptable scientific quality as defined for this work was available at the time of introduction. For more than the half, no (6 of 21) or only limited (5 of 21) evidence was identified over the entire observation period. The evidence on four further technologies (TAVI, DCB-ULV, DCB-LLV, ACD) was downgraded to “limited” at the end of the period because of conflicting study results. In contrast to the sparse evidence base, 13 out of 21 technologies were utilized widely over time. In relation to the years evaluated across all technologies, the proportion of no available (127 of 246 data years) or limited evidence (63 of 246 data years) predominate (see Fig. 3). Thus, the statuses “Prudence” and “Overadoption” together account for nearly three-quarters of the years evaluated, followed by “Success” with 17 percent. The “Vigilance” status (cautious utilization in light of negative evidence) was not assigned at all. From the perspective of technologies, a successful diffusion was observed for eight out of 21 in at least one year (Fig. 4). Strong direct positive or negative evidence was identified for only one technology each (LVRC and IET-MICRO). All other identified RCTs showed high potential for bias. While moderate positive evidence was present in about 20 percent of all data years, there were no data years with moderate negative evidence.

For the technology “anticoagulation with citrate during dialysis (ACD)”, moderate positive evidence was already available at the time of its introduction into German inpatient care. Therefore, the process can initially be considered a successful diffusion. However, this changed over time to “Overadoption” due to inconsistent findings in several studies. Moderate positive evidence was also available for the procedure “Fluorescence-assisted transurethral resection (F-TUR)” even one year before its introduction. However, throughout the entire observation period, the procedure was utilized cautiously in a fraction of the target population.

Figure 5 visualizes the change in statuses between the start and end point of the observation period for

Only four technologies have made a desirable shift from a

potential “Overadoption” (LVRC) or “Prudence” (pVAD, DES-LLV, DEB-TACE) to widespread utilization with supporting evidence. Five technologies (TAVI, DCB-IV, DCB-AV, DCB-ULV, DCB-LLV) shifted from cautious to widespread utilization while the state of evidence was either downgraded, or no evidence was identified. On the contrary, the procedure “implantation of a drug-eluting stent in upper leg vessels (DES-ULV)” reached only a fraction of the target population although positive scientific support prevailed at the end. Overall, adoption behavior is changing from a focus on "Prudence" to "Overadoption". While the statuses “Hazard” and “Underadoption” are each assigned one technology more at the end of the observation period, “Success” acquires the second most, from 1 to 4.

All technologies together were applied to a total of 775,410 and a mean of 36,924 cases during the observation period. The group of technologies for which no credible or even negative evidence was available in 2017 was applied to an average of 46,565 cases (in total to 698,479), while those with positive study results were only applied to an average of 12,822 cases (in total to 76,931). The three technologies most relevant to care overall as determined by cumulative cases (ACD with 338,123 cases; DCB-ULV with 111,727 cases; and TAVI with 106,392 cases), all result in "Overadoption".

Discussion

This study aimed to explore the adoption of new technologies in German inpatient care, focusing on the relationship between diffusion and available scientific evidence. To understand technology adoption, an in-depth exploration of factors related to the technology itself, its potential adopters, and the context is necessary [28, 29]. The importance of considering elements such as previous experience of users and financial incentives has been established [18, 20, 30]. However, the (potential) influence of scientific evidence on the technology’s safety and effectiveness has largely been explored theoretically, or only for isolated examples of technologies. The main strengths of this study lie in the clear methodological approach for exploring this relationship empirically, and in the varied sample of more than 20 technologies.

Previous research has found a gap between existing rigorous evidence and lack of application of new technologies [19, 31, 32]. In the present study, however, we observe rather the opposite phenomenon. On the one hand, we found an overall sparse evidence base in terms of quantity and quality for the majority of technologies investigated. Despite that, most investigated technologies were widely utilized in German inpatient care. This widespread diffusion entails a considerable risk for some technologies, particularly for invasive procedures such as the implantation of “self-expanding bare metal stents in coronary vessels (SE-BMS)” or “drug-coated balloon catheter in intracranial vessels (DCB-IV)”. During the study’s observation period, German hospitals treated a total of about 700,000 cases with technologies without rigorous scientific support. However, the status of scientific evidence is subject to rapid change. Accordingly, an initially positive evaluation may be followed by contradictory study results (see TAVI, DCB-ULV, DCB-LLV, ACD), e.g., if the target group of the technology is widened to include further population subgroups. Nevertheless, this does not imply that the benefit of the technology is negated lication, study results must be diffused to reach potential

adopters, and subsequent user response seems inhibited for some technologies. For example, the only technology with strong direct negative evidence in the sample (IET-MICRO) had already been applied to almost 25,000 patients by 2017. For ACD, after initial successful diffusion, the evidence base changes in 2013 due to an RCT showing negative effects of the technology. However, the adoption rate continues to steadily increase instead of being inhibited (see Additional file 1). This can partially be explained by the momentum in the diffusion of an innovation: the more hospitals adopt a technology, the more popular it becomes [15]. On the other hand, there are also positive examples of technologies in the sample (TAVI, pVAD, DES-LLV, ACD, DEB-TACE), where the change to a widespread utilization is accompanied by the turn in positive evidence with only one year of divergence. However, these findings also need to be considered cautiously: for instance, there is ongoing debate about the diffusion of transcatheter aortic valve implantation (TAVI) in Germany, as adoption rates are very high in the international comparison, against a backdrop of inconclusive evidence [33]. In general, it should be noted that most years evaluated are assigned to “Prudence”. According to Denis et al. [12], cautious utilization in the case of limited or lacking evidence can even be considered a success.

Concerning the change of adoption statuses over time, we see both an increase in successful diffusion but also cases of users becoming more courageous in their utilization of technologies whose benefits remain unclear. The decision for or against an innovation is often revised, especially during the last phase of the adoption process, known as confirmation, which is used to verify the adoption decision made [14]. Thus, for some of the technologies studied here, there appear to be malfunctions of innovation diffusion contradicting previously formulated principles. Accordingly, the current paradigm of scientific literature publication leads to information overload and inhibits evidence from being implemented adequately and timely [11, 13]. Moreover, Neilson et al. [11] observed that interpretations of “evidence-based” may differ.

A successful innovation process should maximize patient benefit and minimize potential risks. Ideally, the transfer of innovative medical technologies into practice should be guided and accompanied by the existing scientific evidence and induce the systematic generation of new data [34]. As only little or no evidence may be available at the time of market approval, evidence generation during the application of new technologies in routine care is necessary in order to obtain scientific knowledge [8]. However, the observed diffusion of innovations in German health care system fails to generate comprehensive and reliable evidence. The current reimbursement system for inpatient care aims to enable fast access to innovation. According to our analyses, there is little need to accelerate innovation processes as only eight percent of the years analyzed show an underadoption of technologies. However, this swift introduction of innovations without proof of benefit should be accompanied by meaningful clinical studies to evaluate these technologies as they are used [20]. This requires high personnel and financial resources, de facto limiting the conduct of clinical trials to large (university) hospitals. In this context, it is the responsibility of policymakers to establish structures and targeted incentives of adequate bureaucracy to enable appropriate hospitals to participate in evidence generation. At the same time, knowledge must be available to hospitals in a timely and systematized manner.

In addition to clinical studies, the use of medical device registries offers the possibility of generating "real-world evidence". Making the use of registries mandatory for innovative technologies could further enhance the evaluation of effectiveness and risks under routine practice conditions and provide insight into mid- and long-term outcomes. Thus, registries offer valuable information for improving quality of care when incorporated into decision making for (de)adopting new technologies [35]. What is more, the linkage of clinical trials and registries (“registry-embedded clinical trials”) can accelerate the availability of robust evidence [36].

As mentioned, the level of reimbursement significantly influences the utilization of new technologies in German healthcare [20, 33]. Thus, the diffusion of innovative technologies could be managed if reimbursement of technologies were determined according to the benefit they provide. Approaches such as “Coverage with Evidence (CED)” have already been implemented in many countries [37]. In the German health care system, the introduction of § 137h Social Code Book V in 2016 established a pathway for the scientific evaluation of a technology’s benefit and harm as soon as hospitals request innovation payments for the first time [34]. However, only a fraction of all new technologies is affected by this regulation: “new diagnostic and treatment methods whose technical application is based essentially on a medical device of a high risk class with a particularly invasive character and a new theoretical-scientific concept” [38]. Therefore, the present CED approach in German inpatient care does not meet its goals due to lack of comprehensiveness and complexity [10, 37]. Also, in light of this study’s findings, there is potential for reconsideration.

Limitations

It is plausible that the following limitations may have influenced the results of this study. Despite best efforts, it is possible that the systematic review missed relevant studies. Furthermore, the two-dimensional evaluation scheme lacks consideration of other factors relevant to the diffusion of innovations beyond scientific evidence. The analysis is based on a sample obtained through defined criteria and an empirical selection process. Even though this was designed to yield a sample that was both varied and feasible, it is possible that a different sample would have resulted in different findings. In any case, results for the investigated 21 technologies are not generalizable for all innovations in an overarching way. The selection criterion of being most relevant to care does not imply that non-selected innovations are irrelevant and should not be investigated or addressed. The sole focus on RCTs may have resulted in the loss of important results from other study designs. Furthermore, it should be noted that the approaches to determine the state of scientific evidence as well as the degree of utilization are subject to methodological limitations and may not accurately reflect the care situation. Furthermore, both evidence and diffusion are dynamic, so the present analysis constitutes a snapshot illustrative only of the observation period.

Conclusions

This study substantially contributes to research on the diffusion of innovations in German inpatient care. We analyzed diffusion patterns and evidence development of 21 technologies using quantitative and qualitative methods. We observe that the diffusion rate of new technologies is often not in line with the state of the evidence. At the end of the observation period, the share of overadopted technologies predominates which may have consequences for patients (harm) and the statutory health care system (inefficiencies). Overall, there is a lack of evidence regarding the (clinical) effectiveness and benefit of innovative medical technologies utilized in German inpatient care. Even in cases of available evidence, the transfer of knowledge into practice seems inhibited. The successful diffusion of innovation requires substantial further efforts by policymakers to strengthen systematic knowledge generation and translation. Responsive policies must facilitate the diffusion of valuable technologies in healthcare and curb the spread of potentially dangerous and ineffective technologies. Creating an environment that encourages the conduct of rigorous studies, promotes knowledge translation, and rewards innovations according to their added value are prerequisites for the diffusion of ‘true’ innovations in the health care sector.

Abbreviations

ACCS	Antibody coated coronary stent
ACD	Anticoagulation with citrate during dialysis
ACT	Adjustable continence therapy
BRA	Baroreceptor activation
BS-PV	Insertion of coated (covered) stents with bioactive surface for peripheral vessels
BS-VSAV	Insertion of coated (covered) stents with bioactive surface for visceral and supraaortic vessels
BVS	Bioresorbable vascular scaffold in coronary vessels
CBS	Coronary bifurcation stents
CE	Conformité Européene
DCB-ARTV	Drug-coated balloon catheter in artificial vessels
DCB-AV	Drug-coated balloon catheter in abdominal vessels
DCB-CV	Drug-coated balloon catheter in coronary vessels
DCB-IV	Drug-coated balloon catheter in intracranial vessels
DCB-LAV	Drug-coated balloon catheter in lower arm vessels
DCB-LLV	Drug-coated balloon catheter in lower leg vessels
DCB-OTHV	Drug-coated balloon catheter in other vessels
DCB-SUAV	Drug-coated balloon catheter in shoulder and upper arm vessels
DCB-TV	Drug-coated balloon catheter in thoracic vessels
DCB-ULV	Drug-coated balloon catheter in upper leg vessels
DCB-VV	Drug-coated balloon catheter in visceral vessels
DEB-TACE	Drug-eluting beads for transarterial chemoembolization
DES-LLV	Implantation of a drug-eluting stent in lower leg vessels
DES-SAA	Drug-eluting stents for the treatment of lesions of the supraaortic arteries
DES-ULV	Implantation of a drug-eluting stent in upper leg vessels
EABO	Endoaortic balloon occlusion with extracorporeal circulation
EBV	Endobronchial valve
EL-P/ICD	Excimer laser extraction of pacemaker and defibrillator electrodes
ER-ABL	Cardiac event recorder after ablative measures for atrial fibrillation / atrial tachycardia

ACCS	Antibody coated coronary stent
EU	European Union
EVCT	Ex vivo chemosensitivity testing
FDA	Food and Drug Administration
FD-IV	Flow-diverter (Hemodynamically effective implant for endovascular treatment) in intracranial vessels
FDT	Fetoscopic drainage therapy
FD-ULV	Flow-diverter (Hemodynamically effective implant for endovascular treatment of peripheral aneurysms) in upper leg vessels
FE-AAA	Fenestrated endoprostheses for abdominal aortic aneurysms
F-TUR	Fluorescence-assisted transurethral resection
G-BA	Federal Joint Committee
G-DRG	German-Diagnosis Related Groups
HCI	Hybrid cochlear implant
HCO	Dialysis with high cut-off dialysis membrane
IABC	Bioactive coils for intracranial aneurysm therapy
IABC-EL	Bioactive extra-long coils for intracranial aneurysm therapy
IAELC	Extra-long coils (3D) for intracranial aneurysm therapy
IAHEI	Intraaneurysmal hemodynamically effective implant for endovascular treatment of intracranial aneurysms.
IAVC	Volume coils for intracranial aneurysm therapy
IET-MICRO	Intracranial endovascular thrombectomy (microwire retriever)
InEK	German Institute of the Hospital Remuneration System
LVRC	Lung volume reduction by insertion of coils
MDS	Medical Review Board of the Federal Association of Sickness Funds
MESI	Esophageal sphincter implant, magnetic
MRD	Molecular monitoring of residual tumor burden
MR-PTC	Percutaneous transluminal clipping for mitral valve regurgitation
MVAC	Mitral valve annuloplasty with clamp
MVR	Minimally invasive operations on heart valves (implantation of a mitral valve replacement)

ACCS	Antibody coated coronary stent
NEURO	Neurostimulator for stimulation of the spinal cord or peripheral nervous system, rechargeable
PECLA/iLA	Pumpless Extracorporal Lung Assist/ Interventional Lung Assist
pVAD	Percutaneous ventricular assist device (Microaxial blood pump)
PVR	Minimally invasive heart valve surgery (endovascular implantation of pulmonary valve replacement)
RCT	Randomized Controlled Trial
SCO-MAGN	Therapy of scoliosis by means of magnetic-controlled rods
SE-BMS	Self-expanding bare metal stents in coronary vessels
SE-DES	Coronary stent, self-expanding (at least two stents, drug-eluting)
S-ICD	Defibrillator with subcutaneously implantable electrode
SP-ENDOST	Endovascular implantation/repair of a stent prosthesis using an endostapler
TAVI	Transcatheter aortic valve implantation
UD-DJMS	Double J metal stent for urinary diversion in ureteral strictures
VEPTR	Vertical Expandable Prosthetic Titanium Rib

Declarations

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Consent for publication: Not applicable.

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Authors' contributions: MB, HeE, SF, HaE, HL, TR, RB, CH and DP all contributed to the conceptualization of the overall project. MB, HeE, SF, HaE, HL, TR, CH and DP were involved in the identification, selection and analysis of published evidence. The analysis presented in this article was conceptualized by MB with support from CH and DP. The subsequent analysis regarding diffusion patterns was done by MB. MB wrote the Manuscript with contributions from CH and DP. All authors read, commented and approved the final manuscript.

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References

1. Fuchs VR, Sox HC. Physicians' views of the relative importance of thirty medical innovations. Health Aff (Millwood). 2001;20:30–42. doi:10.1377/hlthaff.20.5.30.
2. Deyo RA, Patrick DL. Hope Or Hype: The Obsession With Medical Advances And The High Cost Of False Promises. New York: Amacon; 2005.
3. Grimes DA. Technology Follies. JAMA. 1993;269:3030. doi:10.1001/jama.1993.03500230112038.
4. Henschke C, Panteli D, Perleth M, Busse R. Taxonomy of Medical Devices in the Logic of Health Technology Assessment. Int J Technol Assess Health Care. 2015;31:324–30. doi:10.1017/S0266462315000562.
5. FDA. Unsafe and Ineffective Devices Approved in the EU that were Not Approved in the US; May 2012.
6. van Norman GA. Drugs and Devices: Comparison of European and U.S. Approval Processes. JACC Basic Transl Sci. 2016;1:399–412. doi:10.1016/j.jacbts.2016.06.003.
7. Hartz S, John J. Public health policy decisions on medical innovations: what role can early economic evaluation play? Health Policy. 2009;89:184–92. doi:10.1016/j.healthpol.2008.05.011.
8. Felgner S, Ex P, Henschke C. Physicians' Decision Making on Adoption of New Technologies and Role of Coverage with Evidence Development: A Qualitative Study. Value in Health. 2018;21:1069–76. doi:10.1016/j.jval.2018.03.006.
9. Henschke C, Bäumler M, Weid S, Gaskins M, Busse R. Extrabudgetary ('NUB') payments: A gateway for introducing new medical devices into the German inpatient reimbursement system? Journal of Management Marketing in Healthcare. 2010;3:119–33. doi:10.1179/175330310X12665793931221.
10. Ex P, Busse R, Henschke C. Die Nutzenbewertung von nichtmedikamentösen Untersuchungs- und Behandlungsmethoden. GuS. 2016;70:48–55. doi:10.5771/1611-5821-2016-2-48.
11. Neilson E, Smith KC, Steinwachs D, Phelan-Emrick DF, Lawrence RS, Bowie JV, Cohen B. Moving research into practice: the diffusion of evidence-based recommendations through professional societies. Implement Sci. 2015. doi:10.1186/1748-5908-10-S1-A52.
12. Denis J-L, Hébert Y, Langley A, Lozeau D, Trottier L-H. Explaining diffusion patterns for complex ...nagement review. 2002;27:60–73.

13. Balas EA, Chapman WW. Road Map For Diffusion Of Innovation In Health Care. Health Aff (Millwood). 2018;37:198–204. doi:10.1377/hlthaff.2017.1155.
14. Rogers EM. Diffusion of Innovations. New York. USA: The Free Press: A Division of Simon and Schuster Inc.; 1962.
15. Cain M, Mittman R. Diffusion of innovation in healthcare: iHealth Reports Oakland. California: California Healthcare Foundation; 2002.
16. Fitzgerald L, Ferlie E, Wood M, Hawkins C. Interlocking Interactions, the Diffusion of Innovations in Health Care. Hum Relat. 2002;55:1429–49. doi:10.1177/0018726021287822 13.
17. Urquhart R, Kendell C, Geldenhuys L, Ross A, Rajaraman M, Folkes A, et al. The role of scientific evidence in decisions to adopt complex innovations in cancer care settings: a multiple case study in Nova Scotia, Canada. Implement Sci. 2019;14:14. doi:10.1186/s13012-019-0859-5.
18. Barnett J, Vasileiou K, Djemil F, Brooks L, Young T. Understanding innovators' experiences of barriers and facilitators in implementation and diffusion of healthcare service innovations: a qualitative study. BMC Health Serv Res. 2011;11:342. doi:10.1186/1472-6963-11-342.
19. Fitzgerald L, Ferlie E, Hawkins C. Innovation in healthcare: how does credible evidence influence professionals? Health Soc Care Community. 2003;11:219–28. doi:10.1046/j.1365-2524.2003.00426.x.
20. Ex P, Henschke C. Changing payment instruments and the utilisation of new medical technologies. The European journal of health economics: HEPAC: health economics in prevention care. 2019;20:1029–39. doi:10.1007/s10198-019-01056-z.
21. Research Data Centre of the Federal Statistical Office and Statistical Offices of the Federal States. DRG statistics, survey years 2005–2017, own calculations: RDC of the Federal Statistical Office and the statistical offices of the Länder (RDC).
22. Wolf C, Best H. Handbuch der sozialwissenschaftlichen Datenanalyse. Wiesbaden: VS Verlag für Sozialwissenschaften; 2010.
23. Authors redacted for peer review. Utilization of Innovative Medical Technologies in German Inpatient Care. Does Evidence Matter? Submitted for review; 2021.
24. Garritty C, Gartlehner G, Nussbaumer-Streit B, King VJ, Hamel C, Kamel C, et al. Cochrane Rapid Reviews Methods Group offers evidence-informed guidance to conduct rapid reviews. J Clin Epidemiol. 2021;130:13–22. doi:10.1016/j.jclinepi.2020.10.007.
25. Øvretveit J. What are the best strategies for ensuring quality in hospitals?: Health Evidence Network Report. WHO Regional Office for Europe; 2003.
26. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. The milbank quarterly. 2004;82:581–629.
27. Gemeinsamer Bundesausschuss. Verfahrensordnung des Gemeinsamen Bundesausschusses: State: 25. Februar 2021; 2021.

28. Dearing JW, Cox JG. Diffusion Of Innovations Theory, Principles, And Practice. Health Aff (Millwood). 2018;37:183–90. doi:10.1377/hlthaff.2017.1104.
29. Abrishami P, Boer A, Horstman K. Understanding the adoption dynamics of medical innovations: affordances of the da Vinci robot in the Netherlands. Soc Sci Med. 2014;117:125–33. doi:10.1016/j.socscimed.2014.07.046.
30. Barrenho E, Miraldo M, Propper C, Walsh B. The importance of surgeons and their peers in adoption and diffusion of innovation: An observational study of laparoscopic colectomy adoption and diffusion in England. Soc Sci Med. 2021;272:113715. doi:10.1016/j.socscimed.2021.113715.
31. Berwick DM. Disseminating innovations in health care. JAMA. 2003;289:1969–75. doi:10.1001/jama.289.15.1969.
32. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50. doi:10.1186/1748-5908-4-50.
33. Merkel S, Eikermann M, Neugebauer EA, Bandemer S von. The transcatheter aortic valve implementation (TAVI) - A qualitative approach to the implementation and diffusion of a minimally invasive surgical procedure. Implement Sci. 2015;10:140. doi:10.1186/s13012-015-0330-1.
34. Olberg B, Fuchs S, Matthias K, Nolting A, Perleth M, Busse R. Evidence-based decision-making for diagnostic and therapeutic methods: the changing landscape of assessment approaches in Germany. Health Res Policy Syst. 2017;15:89. doi:10.1186/s12961-017-0253-1.
35. Hoque DME, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM. Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. PLoS One. 2017;12:e0183667. doi:10.1371/journal.pone.0183667.
36. Mikita JS, Mitchel J, Gatto NM, Laschinger J, Tcheng JE, Zeitler EP, et al. Determining the Suitability of Registries for Embedding Clinical Trials in the United States: A Project of the Clinical Trials Transformation Initiative. Ther Innov Regul Sci. 2021;55:6–18. doi:10.1007/s43441-020-00185-5.
37. 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. 2014;117:135–45. doi:10.1016/j.healthpol.2014.04.018.
38. Wolf K, Dettloff M, Egger B. Hochrisiko-Medizinprodukte in der GKV: Was ist eine innovationsfreundliche Gesundheitspolitik? GuS. 2017;71:75–83. doi:10.5771/1611-5821-2017-3-4-75.

Tables

Table 1: Included innovative technologies

Type	Technology	Abbreviation	Selection via adoption curve progression type no. or evidence cross-check
Procedures on nervous system			
	Neurostimulator for stimulation of the spinal cord or peripheral nervous system, rechargeable	NEURO	
	Baroreceptor activation	BRA	
Procedures on ear and mastoid process			
	Hybrid cochlear implant	HCI	
Procedures on respiratory system			
	Lung volume reduction by insertion of coils	LVRC	4
	Endobronchial valve	EBV	
	Pumpless Extracorporal Lung Assist/ Interventional Lung Assist	PECLA/iLA	Evidence cross-check
Procedures on cardiovascular system			
	Percutaneous transluminal clipping for mitral valve regurgitation	MR-PTC	
	Transcatheter aortic valve implantation	TAVI	1
	Minimally invasive heart valve surgery (endovascular implantation of pulmonary valve replacement)	PVR	
	Mitral valve annuloplasty with clamp	MVAC	5
	Minimally invasive operations on heart valves (implantation of a mitral valve replacement)	MVR	
	Percutaneous ventricular assist device (Microaxial blood pump)	pVAD	6.1
	Excimer laser extraction of pacemaker and defibrillator electrodes	EL-P/ICD	3
	Defibrillator with subcutaneously implantable electrode	S-ICD	
	Cardiac event recorder after ablative measures for atrial fibrillation / atrial tachycardia	ER-ABL	6.2
	Coronary bifurcation stents	CBS	
	Antibody coated coronary stent	ACCS	

	Bioresorbable vascular scaffold in coronary vessels	BVS	4
	Self-expanding bare metal stents in coronary vessels	SE-BMS	2
	Coronary stent, self-expanding (at least two stents, drug-eluting)	SE-DES	
	Drug-coated balloon catheter in coronary vessels	DCB-CV	3
	Drug-coated balloon catheter in intracranial vessels	DCB-IV	6.2
	Extra-long coils (3D) for intracranial aneurysm therapy	IAELC	
	Volume coils for intracranial aneurysm therapy	IAVC	
	Intraaneurysmal hemodynamically effective implant for endovascular treatment of intracranial aneurysms.	IAHEI	
	Bioactive coils for intracranial aneurysm therapy	IABC	Evidence cross-check
	Bioactive extra-long coils for intracranial aneurysm therapy	IABC-EL	
	Flow-diverter (Hemodynamically effective implant for endovascular treatment) in intracranial vessels	FD-IV	
	Intracranial endovascular thrombectomy (microwire retriever)	IET-MICRO	6.2
	Drug-coated balloon catheter in visceral vessels	DCB-VV	
	Insertion of coated (covered) stents with bioactive surface for visceral and supraaortic vessels	BS-VSAV	
	Drug-eluting stents for the treatment of lesions of the supraaortic arteries	DES-SAA	
	Drug-coated balloon catheter in thoracic vessels	DCB-TV	
	Fenestrated endoprostheses for abdominal aortic aneurysms	FE-AAA	
	Drug-coated balloon catheter in abdominal vessels	DCB-AV	1
	Insertion of coated (covered) stents with bioactive surface for peripheral vessels	BS-PV	
	Drug-coated balloon catheter in shoulder and upper arm vessels	DCB-SUAV	
	Drug-coated balloon catheter in lower arm vessels	DCB-LAV	
	Flow-diverter (Hemodynamically effective implant for endovascular treatment of peripheral aneurysms) in upper leg vessels	FD-ULV	5

Drug-coated balloon catheter in upper leg vessels	DCB-ULV	1
Drug-coated balloon catheter in lower leg vessels	DCB-LLV	1
Implantation of a drug-eluting stent in lower leg vessels	DES-LLV	6.1
Implantation of a drug-eluting stent in upper leg vessels	DES-ULV	6.1
Drug-coated balloon catheter in artificial vessels	DCB-ARTV	
Drug-coated balloon catheter in other vessels	DCB-OTHV	
Endovascular implantation/repair of a stent prosthesis using an endostapler	SP-ENDOST	
Endoaortic balloon occlusion with extracorporeal circulation	EABO	Evidence cross-check
Procedures on digestive system		
Esophageal sphincter implant, magnetic	MESI	
Procedures on urinary system		
Adjustable continence therapy	ACT	4
Double J metal stent for urinary diversion in ureteral strictures	UD-DJMS	
Fluorescence-assisted transurethral resection	F-TUR	6.2
Anticoagulation with citrate during dialysis	ACD	6.1
Dialysis with high cut-off dialysis membrane	HCO	Evidence cross-check
Obstetric procedures		
Fetoscopic drainage therapy	FDT	Evidence cross-check
Procedures on musculoskeletal system		
Vertical Expandable Prosthetic Titanium Rib	VEPTR	
Therapy of scoliosis by means of magnetic-controlled rods	SCO-MAGN	
Antineoplastic procedures		
Drug-eluting beads for transarterial chemoembolization	DEB-TACE	4
Diagnostic procedures		
Ex vivo chemosensitivity testing	EVCT	
Molecular monitoring of residual tumor burden	MRD	3

Table 2: Types of adoption curves and associated technologies

Type	Criterion	Technologies (No.)
(I) Continuous increase	$\frac{\mathrm{d}f(t)}{\mathrm{d}t} =: m\,(t) > 0$ $\forall\ t \in [2006; 2017]$	HCI, MR-PTC, S-ICD, IAHEI, SCO-MAGN, BS-PV, SE-DES, TAVI, BS-VSAV, DCB-SUAV, DCB-LAV, DCB-AV, SCB-ULV, DCB-LLV, DCB-ARTV (n = 15)
(II) Continuous decrease	$\frac{\mathrm{d}f(t)}{\mathrm{d}t} =: m\,(t) < 0$ $\forall\ t \in [2006; 2017]$	SE-BMS (n = 1)
(III) Reaching a saturation	$\frac{f(2015)}{f(2014)} < 1.1 \wedge$ $\frac{f(2016)}{f(2015)} < 1.075 \wedge$ $\frac{f(2017)}{f(2016)} < 1.05 \wedge$ $f(2015) > f(t)\ \forall\ t < 2015$	EL-P/ICD, MRD, DCB-CV (n = 3)
(IV) "Local maximum": Continuous increase followed by continuous decrease	$m(t_I) > 0 \wedge$ $m(t_{II}) < 0$ $t_I \in [t_i; t_j], t_{II} \in [t_j; t_k]$ $t_i, t_j < t_k$	FE-AAA, ACT, ACCS, DEB-TACE, LVRC, BVS, BRA, IABC, MVR, FD-IV (n = 10)
(V) "Local minimum": Continuous decrease followed by continuous increase	$m(t_I) < 0 \wedge$ $m(t_{II}) > 0$ $t_I \in [t_i; t_j], t_{II} \in [t_j; t_k]$ $t_i, t_j < t_k$	MVAC, FD-ULV (n = 2)
(VI) Complex	NA	
(VI.a)	according to hierarchical-agglomerative clustering method	PECLA/iLA, pVAD, EVCT, CBS, ACD, VEPTR, IAELC, UD-DJMS, DES-LLV, EABO, HCO, IAVC, SP-ENDOST, FDT, DES-SAA, MESI, EBV, NEURO, IABC-EL, DES-ULV, PVR, DCB-TV, DCB-OTHV (n = 23)
(VI.b)	according to hierarchical-agglomerative clustering method	IET-MICRO, F-TUR, DCB-IV, DCB-VV, ER-ABL (n = 5)

Table 3: Six-field table for the classification of adoption statuses based on utilization and evidence

		EVIDENCE		
		Strong direct evidence (positive)	Strong direct evidence (negative)	Limited Evidence
		Moderate evidence (positive)	Moderate evidence (negative)	No Evidence
UTILIZATION	Widespread	Success	Hazard	Overadoption
	Cautious	Underadoption	Vigilance	Prudence

Source: Authors' own, adapted from Denis et al. [12]

Table 4: Categorization of evidence

Categories		Description
(1) Strong direct evidence		
positive consistent (i.e., only positive, neutral and /or indecisive findings based on the conclusion of the authors)	negative consistent (i.e., only negative, neutral and /or indecisive findings based on the conclusion of the authors)	Consistent findings in two or more empirical studies of appropriate design and high scientific quality (i.e., RCTs with low potential for bias)
(2) Moderate evidence		
positive consistent (i.e., only positive, neutral and /or indecisive findings based on the conclusion of the authors)	negative consistent (i.e., only negative, neutral and /or indecisive findings based on the conclusion of the authors)	Consistent findings in two or more empirical studies of less appropriate design and/or of acceptable scientific quality (i.e., RCTs with high potential for bias)
(3) Limited evidence		Only one study of appropriate design and acceptable quality available, or inconsistent findings in several studies
(4) No evidence		No relevant study of acceptable scientific quality available

Source: Authors' own, adapted from Øvretveit [25] and Greenhalgh et al. [26]

Figures

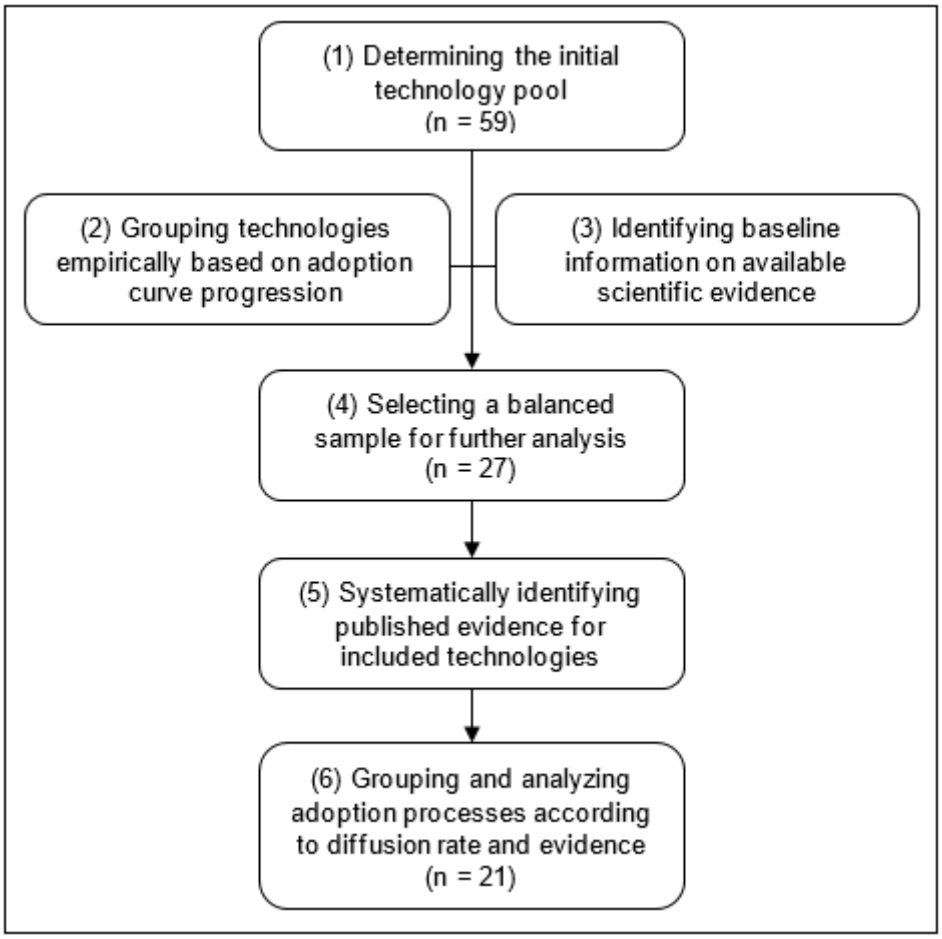

Figure 1

Flowchart of the methodology

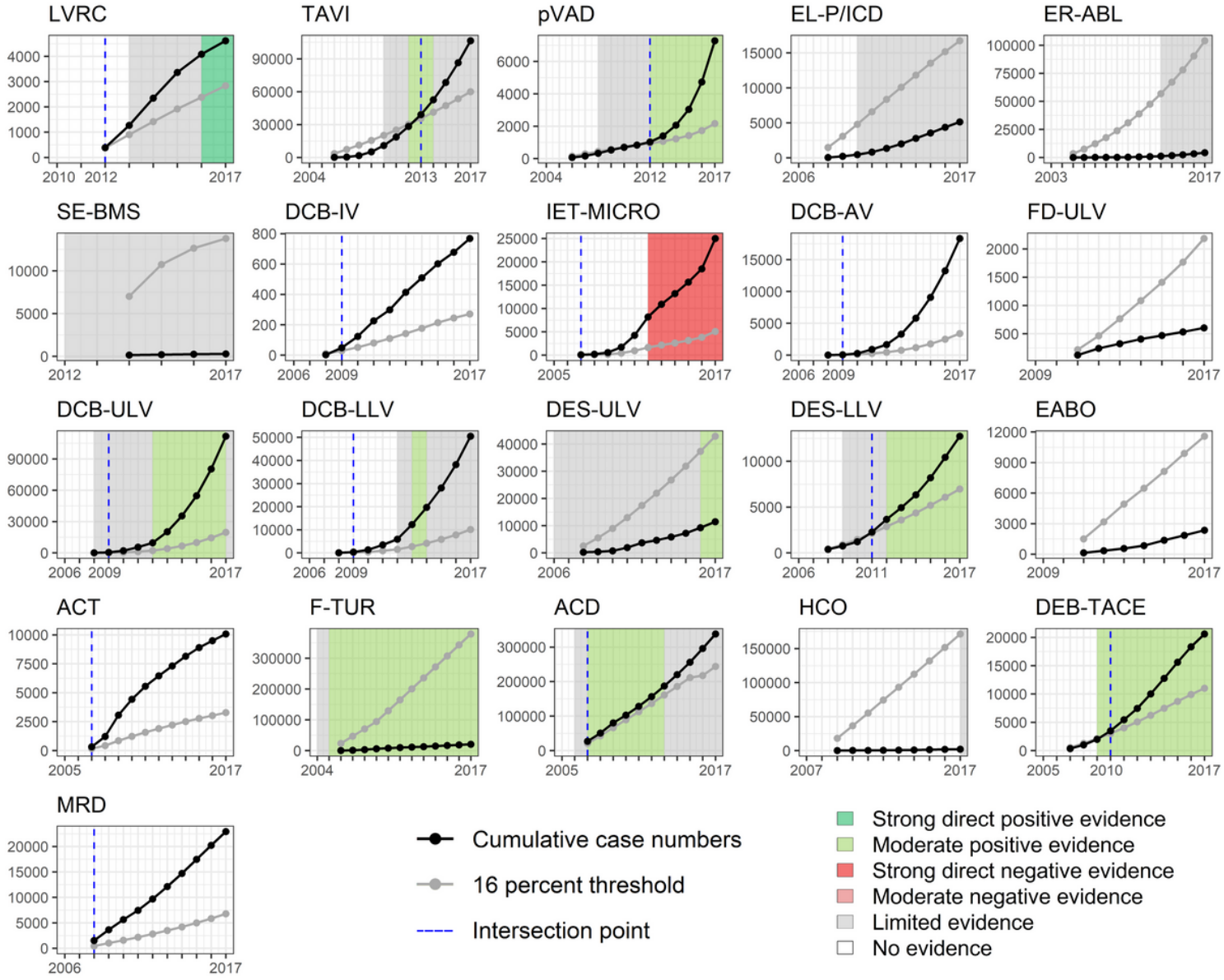

Figure 2

Diffusion curves and identified evidence

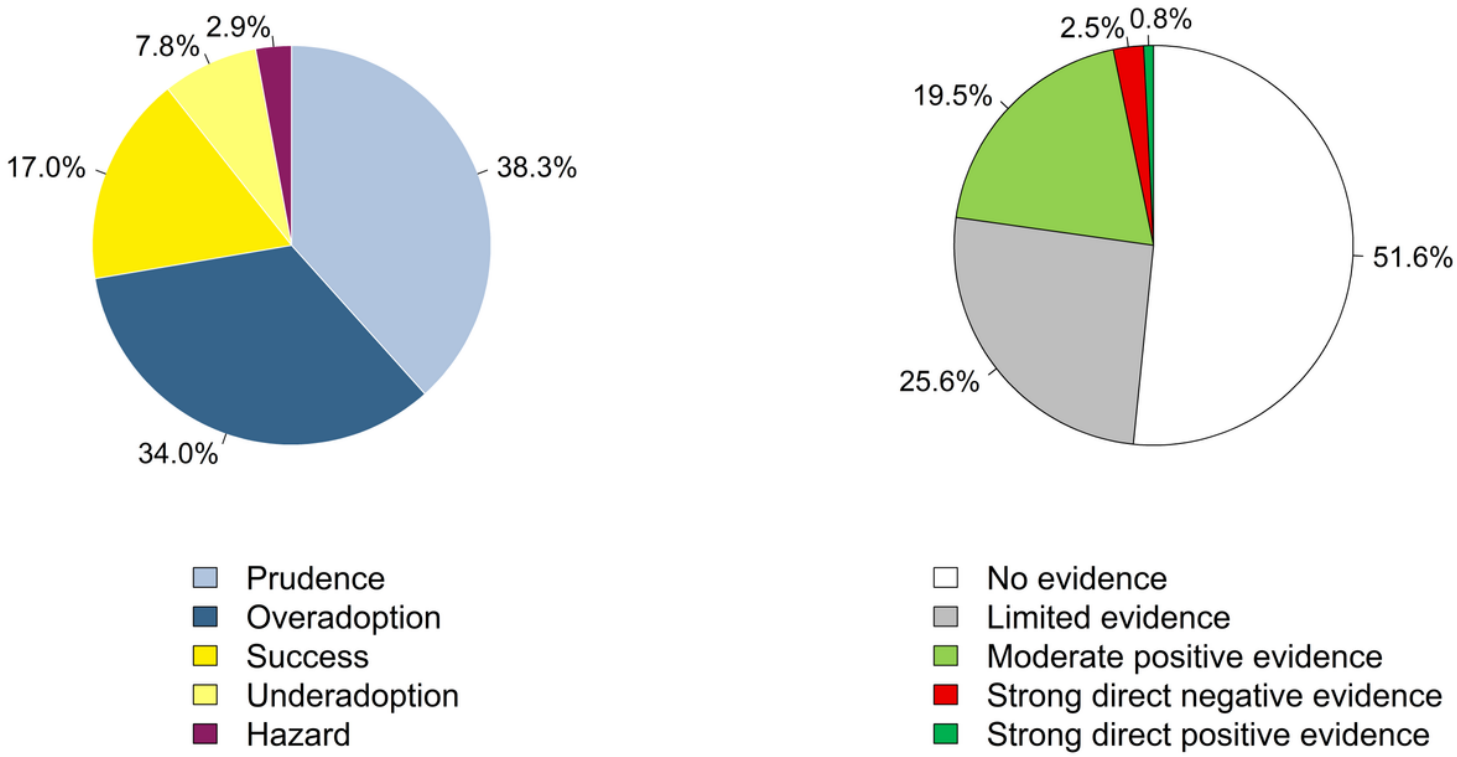

Figure 3

Distribution of adoption and evidence statuses based on evaluated data years across considered technologies

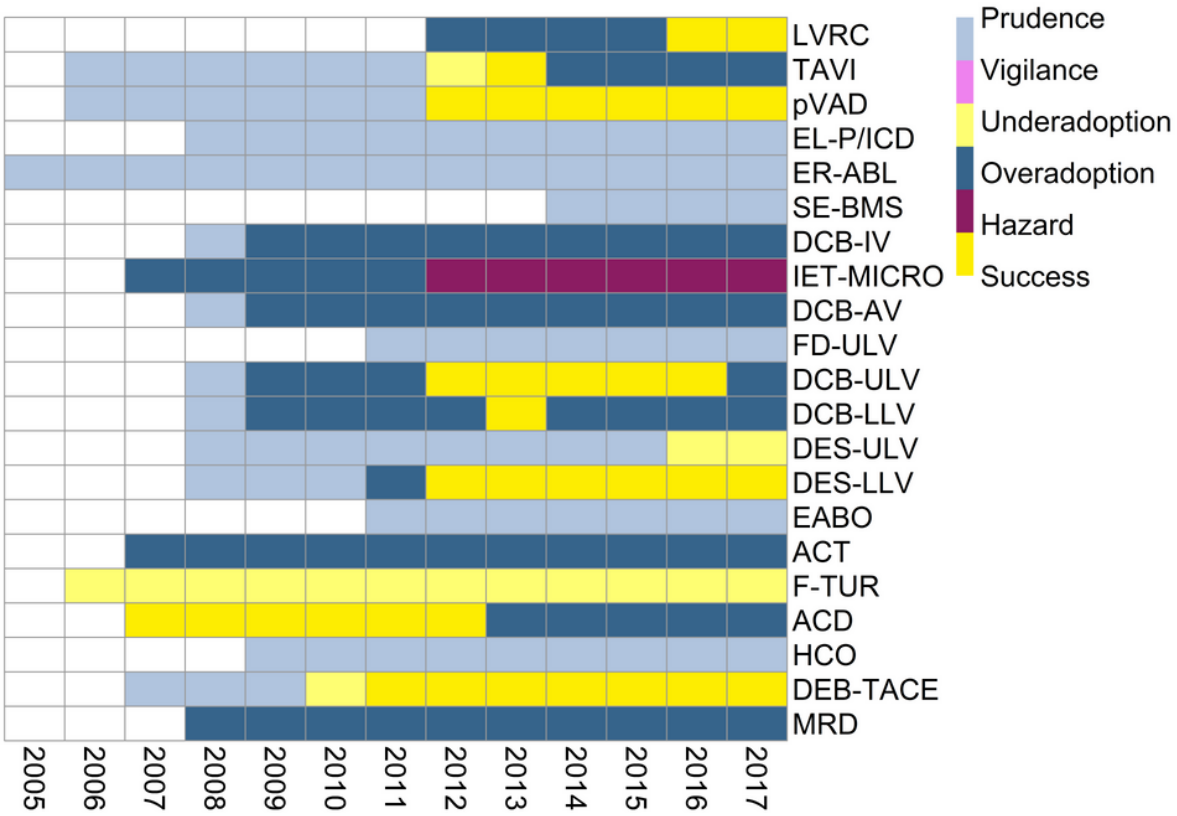

Figure 4

Heatmap of adoption statuses

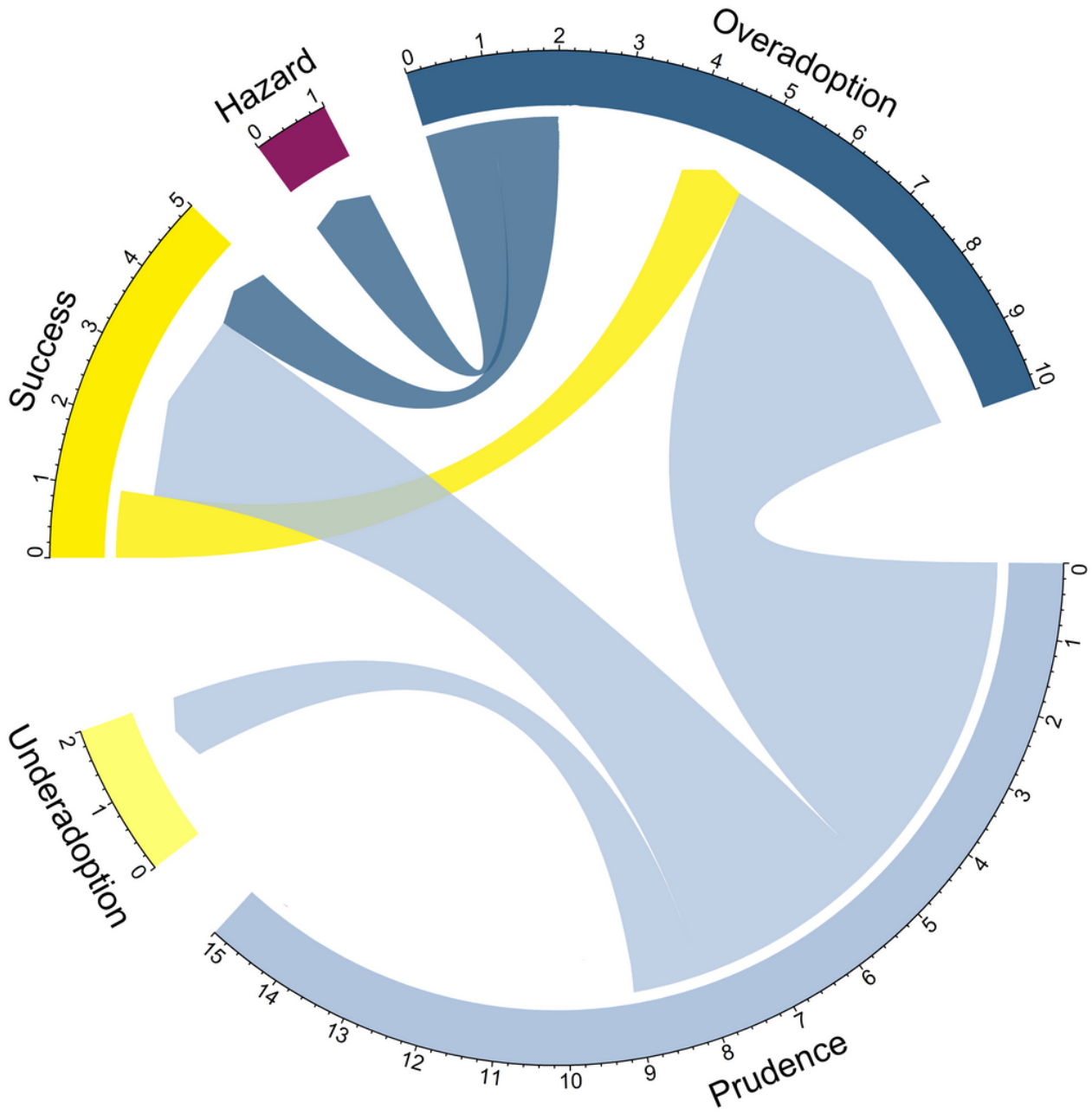

Figure 5

Status changes between start and end points of the observation period for considered technologies

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