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# Obstacles to Prosthetic Care—Legal and Ethical Aspects of Access to Upper and Lower Limb Prosthetics in Germany and the Improvement of Prosthetic Care from a Social Perspective

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**Abstract:** Prosthetic technology for people with missing limbs has made great progress in recent decades. However, acceptance rates and user satisfaction are not only dependent on technical aspects, but also to a great extent on social and psychological factors. We propose that these factors should receive greater attention in order to improve prosthetic care and give recommendations how to incorporate the findings from social science in research and development (R&D) and in care practice. Limited access due to high costs of new prosthetic technology combined with rising costs in health care systems in general is a further issue we address. Our legal and ethical analysis of the reimbursement process in Germany shows that this issue requires further empirical investigation, a stakeholder dialogue and maybe even policy changes. Social science knowledge and participatory methods are of high relevance to answer questions about the benefit of prosthetics for users, based on individual needs and preferences, which should be at the core of debates on ethical resource allocation.

**Keywords:** prosthetics; disability; reimbursement; regulation; HTA; ELSI; (just) resource allocation in health care; clinical practice guidelines; equity; inclusion

## 1. Introduction

Artificial limb prostheses have become more sophisticated, with improved performance and decreased weight due to the use of latest material science and engineering technologies. Nevertheless, acceptance and usage rates vary strongly between different patients. While performance is one acceptance factor and may be objectively measured, there are more subjective factors relating to social aspects that appear to strongly influence the single person in his or her attitude to accept or reject the use of an artificial limb[1].

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An important research aim of ours was thus to produce an overview of social acceptance factors from the literature. As a focus for the present article, we selected the cost factor, as an international study [1] found that it has a high impact on usage rates and satisfaction of users. The authors of this study had concluded that analyses of national legal frameworks and empirical studies in different countries are needed to better understand the situation of prosthetic care with regard to reimbursement matters. Accordingly, our second research question for this paper was how the German reimbursement system works for prosthetics and whether injustices with regard to access might result from it.

The consideration of costs of prosthetics leads inevitably to the ethical problem of health care resource allocation and rationing in general. In this respect, Germany is a particularly interesting case: Explicit, open rationing of health services based on cost-effectiveness analysis is avoided for ethical reasons in Germany [2] but not in other countries [3]. However, ethicists think that explicit rationing is inevitable in the long term also in a rich country such as Germany and that it is in any case preferable to implicit rationing [3–5]—which, as a matter of fact, already taking place in many ways also in the German health care system [5].

In the present article, we discuss two basic alternative solutions for the resource allocation problem (which may however be combined in reality). The first solution would be to make prosthetic care more efficient in order to alleviate the financial burden from health care systems (and individual users in case their insurance does not reimburse the whole price). Here, we ask how this could be achieved. The second solution would be to find just processes and criteria for explicit rationing. One key prerequisite would then be to assess the benefit of prosthetics, ideally in an objective way, set it in relation to costs, and at the same time incorporate individual, subjective user preferences and needs into the equation.

With respect to the latter, we specifically ask which role Health Technology Assessment (HTA) could play to help meet this requirement. HTA is a branch of Technology Assessment (TA), which is exclusively concerned with health technologies, and has its very specific and own methods, functions and institutions if compared to other areas of TA. There is a worldwide network of national HTA institutions today (Health Technology Assessment International, HTAi). In Germany, the IQWiG (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, i.e., Institute for Quality and Efficiency in Health Care), assesses mostly pharmaceuticals, but also medical devices. Benefits are assessed in comparison to an existing, standard treatment for the same medical indication, in order to inform policy and other decision makers about the additional benefit of new products, and also as a basis to negotiate prices between manufacturers and the insurances [6]. The evidence base which is used to assess a new treatment option are clinical studies, which analyse what effects relevant to the patient, if any, a medical device or pharmaceutical has, for example for the patient's quality of life, a blood parameter, or the capability to walk or grasp objects. The methods used for HTA reports are similar in different countries, but their function may differ according to the national regulatory framework in place [7].

The paper is structured as follows. Based on a review of some of the most important social factors for acceptance and successful use of prosthetics, as found in the social-scientific and psychological literature (2.), we make some recommendations for an improvement of prosthetic care (3.). We then (4.) give an overview of the reimbursement process for prosthetics for upper and lower limbs in Germany and discuss ethical implications of this process. This overview is based on documents from online sources, grey literature and academic publications from several disciplines (law, social sciences, prosthetic care research, HTA, health ethics and economics). Concluding the paper (5.), we reflect on the role of HTA and more generally value or benefit assessment of prosthetic technology and care for reimbursement decisions.

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which improve the quality of life of its users by more intuitive human–technology interaction, whilst ethical, legal and social aspects are researched in order to increase acceptance and distribution of new prosthetic technologies.

We will argue that prosthetic care is so important for the overall health of users that it is economically beneficial for health insurances to deliver the best possible care. This has already been pointed out in some studies [8,9], but is still not widely acknowledged by insurances, in Germany also due to the short-term budget allocation scheme in the health care system [10] (p. 61). We posit that there are ways to efficiently improve prosthetic care, minimising the burden on the health care budget, in particular social aspects of acceptance are taken more systematically into account.

Furthermore, we argue that the current reimbursement process for prosthetics in Germany is prone to injustices, and that a stakeholder dialogue is urgently needed to approach this issue. As a starting point for this dialogue, we propose ideas for a role of HTA in the processes and adapted ways of cost and effectiveness evaluation of prosthetics and assessment of individual needs and preferences of its users.

## 2. Social Acceptance Factors

In the following, we will review acceptance factors for prosthesis use from a social science perspective, i.e., beyond pure technical performance measurements. We will then draw recommendations from this research for improvement of prosthetic care.

### *2.1. Social Environment*

The acceptability of assistive technology is dependent not only on its efficiency, but also on the reactions it elicits in people surrounding the user, as people with limb loss themselves have rated social outcomes as more important for assessing quality of life outcomes than their physical impairment [11,12]. Good social support has been identified as a predictor for not only the perceived quality of life, but also the functional outcome after amputation [13,14]. The very definition of disability is highly dependent on the environment defining this term, which further solidifies the need to pay more attention to a patient's surroundings and their place therein. People with limb loss reported that they experienced a "disabled" identity mostly through the reactions of others [15]. Perception of functional outcomes in relation to prostheses use have repeatedly been linked to the social environment of a patient, with higher satisfaction and lower anxiety levels if prosthesis users felt accepted by their social surroundings [16–18]. Therefore, the understanding of the social realities of prosthesis users does not only allow for more empathy, but it can maximise the potential for positive outcomes of prosthesis fitting [13].

### *2.2. Psychosocial Adjustment, Expectations and Personal Significance*

When trying to assess factors related to prosthesis usage, the overarching theme of potentially traumatic limb loss needs to be addressed. The experience of losing a limb, through either trauma or disease, can have a significant impact on a person's psychological reality. In addition to, potentially significant, pain, people with limb loss commonly experience reduced self-worth, heightened anxiety in social situations, depression, and even post-traumatic stress disorder [19]. Thus, how well people adjust to the experience of limb loss itself has a significant impact on their ability to later accept and integrate a prosthesis into their lives [13,15]. Psychosocial adjustment is defined as an individual's response to events having a significant impact on their lives, which require adaptation. Influential factors on positive psychosocial adaptation have not been explored widely [20], despite the fact that it seems like this adaptation is one of the most powerful facilitators of later prosthesis use and a high quality of life [12,20,21]. There is, however, some evidence that factors such as an active coping style, as well as general (dispositional) optimism, a tendency for "downwards social comparison", as well as the feeling that one has some control over one's own situation, are all favourable indicators for good psychosocial adjustment [15,22]. Widehammar et al. hypothesised that the care patients receive in early rehabilitation stages can be a significant contributory factor to the development of effective coping [12]. Thus, this specific goal might need to receive more attention in mainstream rehabilitation protocols.

Expectation management is another factor of vital importance in early rehabilitation stages. Several studies found that setting realistic expectations is not only important to avoid disappointment, but that there is also a positive correlation between meeting the initial expectations that users had and reported satisfaction at later stages [17,23–25]. However, the degree to which this is practiced appears to be insufficient at times. Interview participants in a study by Uytman mentioned that they felt insufficiently informed about how quick their progress would be [26].

On the other hand, one important and often overlooked factor is the enthusiasm that can be created by providing a patient who lost a limb with a functional replacement [15,27]. Experiencing positive change in their abilities might actually be the first step to install a positive feedback cycle that in the end leads to a successful incorporation of the prosthesis into their lives. If initial positive experiences are reinforced and kept in focus, users can be more motivated to continue training with their devices. The plus in experience in operating the prosthesis in turn leads to a more natural way and ease of use, encouraging users to keep expanding the repertoire of activities they can facilitate with their system. Murray found that such positive association is frequent if users see their prosthesis as an enabling tool for valued activities that they associate with their personality [17]. These can be of social nature, such as participating in dance classes or going out to clubs at night, playing with or helping their children, or enabling greater proficiency at their workplace. Users who place special emphasis on their autonomy are likely to integrate a prosthesis into their lives successfully if they make the experience that the device can enable them to perform more tasks without the help of others. One of the experiences that has been rated as one of the most liberating in connection with both upper and lower prosthesis use is driving a car, which most users experienced as highly valuable [12,16,28].

### *2.3. Individual Choice of a Prosthesis and Communication with Prosthetists and Peer Networks*

Research focussing on the relationship between user and prosthetist has found that good communication between the two is a key factor in facilitating favourable outcomes [22,29–31]. Recognising that shared decision-making requires input from both sides could thus be a first step to facilitate better relationships between the users of prostheses and those who provide them.

Especially, individual choice of the prosthesis itself is one of the few factors that have consistently been found to be important for prosthetic acceptance [32]. Biddiss and Chau point out that users who were involved in the selection process for their system are eight times more likely to continue to use it later on [33]. One reason for this is certainly that users have different priorities and goals. Whilst some users value function and reliability, others appreciate aesthetically pleasing design features or customisable prosthetic covers [18,20]. These personal values will not only affect which type of prosthesis users will find particularly useful in their everyday life. They also have a strong impact on the emotional associations that they have with specific systems [20].

As lack of involvement can lead to issues if patients later feel that the decisions made were not the right ones, recognising one's own responsibility to partake in decision-making is one important step. To aid in this collaborative endeavour, a prosthetist should always provide as much information as the user needs to make an informed decision about the choice of the prosthesis and other steps in the rehabilitation process. Research has shown that health care professionals frequently underestimate just how much information patients need or desire for this purpose [29,30], so a heightened awareness of the vital role this knowledge transfer plays would likely improve outcomes favourably. Not only does the mere involvement of patients in the prosthesis selection process in itself produce higher instances of continued use, but good communication between prosthetist and user is also the basis for many other factors related to the successful integration of a prosthesis into a user's life. This entails, for example, setting realistic expectations, taking goals and wishes into account, encouraging users to persevere through the initially frustrating training phases, as well as providing a stable and trusted fix point in case issues emerge.

However, it is worth considering that the relationship between a prosthesis user and their health care professionals cannot always provide the support, reassurance and knowledge exchange that

the patients desire. Thus, other, more experienced prosthesis users can be an invaluable resource. Gallagher and Maclachlan found that contact with other users of prostheses at an early stage after amputation can greatly enhance patients' confidence by reassuring them that initial uncertainties and difficulties are normal and can be overcome [25]. The participants in their study who were given such an opportunity all rated it as highly beneficial, and others expressed they had wished to be given the possibility to do so. Given that prosthesis acceptance seems to be a long-term process, meeting someone who can confirm from first-hand experience that mastering one's system is doable and worth it can install confidence and hope in new users [15,28]. The participants in Hamill et al.'s study rated the exchange with others who had gone through the same experience as their strongest "support connection", seeing them as persons whom they could consult with respect to questions they might have felt uncomfortable to ask the medical staff.

## 3. Improvements of Prosthetic Care from the Perspective of Social Science Research

It is important to translate knowledge about social acceptance factors into practice. By doing so, probably not only quality of life may improve but also resources may be allocated more efficiently by reducing long-term negative side effects of failed prosthetic care such as a lack of acceptance of and adaptation problems with prostheses as well as by reducing costs in its research and development phase. It has already been shown, for example, that prosthetic care for high-cost knee prostheses is beneficial for the insurance budget in the long term, if compared to the use of such prostheses without care [8,9]. Biddiss et al. point out that there are possibilities to reduce costs of prosthetic limbs by technical means like computer-aided design and manufacturing, and due to new market opportunities [1]. In recent years, this aspect already received significant attention in the media where technical means of rationalisation are often focused. 3D printing, for example, is expected to increasingly provide solutions for bringing prosthetic care to poor world regions. We think there might also be chances to improve prosthetic care in Germany and make it more efficient by giving social research a more relevant role. In the following, we will describe further specific recommendations with regard to both, current practice and future research directions.

### *3.1. Development of Prosthetic Technology*

Patient engagement in the development of new therapies is an important pillar of translational research [34]. Recently, this kind of "citizen science" or "patient science" has been increasingly promoted and supported by policy makers and others. However, it is well known from biomedical research that it is challenging to make use of experiential knowledge in the research and development (R&D) process [34]. Methodically, it is challenging to give users a rich impression of what the innovation could look like. Furthermore, it is difficult to link the experiential knowledge of users to the envisioned innovation [34].

In respect to the development of prostheses, developers indicated that there are relatively few opportunities for them to communicate directly with users about prosthesis design and functionality [35]. Studies about user preferences and wishes regarding prosthesis design and functionality do exist, but sometimes have limited validity for direct implementation in practice, for example when only doctors are asked on users behalf [36]. Also, in qualitative and explorative studies users with diverse kinds of amputations and models are asked about limitations of prostheses and design priorities without dividing them into subgroups due to the small number of participants [37]. Generally, however, such studies can deliver valuable guidance for R&D in order to improve usability and usefulness of prostheses. There are different ways of asking about preferences and development needs, from direct and open questions about wishes of users in qualitative studies via more indirect and less open investigations. These may include research into functional (technical) rejection factors, the ranking of suggested features which should be improved [37] and of the relevance of daily tasks which are difficult with current prostheses [38,39]. For prosthetic technology which bears a risk, e.g., invasive control techniques, questions about the acceptance of trade-offs of functional benefits and invasiveness may be

asked [40]. Open questions about wishes may bring new ideas and perspectives into development. However, a limitation of this kind of questioning may be that users acquire an attitude of being satisfied with the status quo. In addition, some developments that are planned by innovative prosthesis makers may not occur to users and, when they are presented for evaluation in a questionnaire, may be unimaginable for users when they cannot test a prototype. As Benz et al. put it, "it is difficult for users to map technical advances or specific device features to their individual experiences with a prosthesis" [37] (p. 288). A more regular interaction of developers and users is needed, and in different steps of the development process. During the course of a prosthesis development project, numerous design and functional decisions are being made every few weeks or months. However, users are often only indirectly, if at all, incorporated in these decisions. They may then only asked to test demonstrators when months of work have already been invested for the development; and product descriptions are often too vague for users to evaluate the prostheses in a valid way. Generalisability increases with the diversity of test users, and shorter cycles of iterative user feedback and progression in the development can diminish the gap between users wishes and developers imagination.

### 3.2. Cooperation between Professions in Research and Practice

There is a need for more communication between professions within prosthetic care. For example, it has been pointed out that systematic research by prosthetists would be important, but is rather done in clinical settings or by researchers who are themselves no practitioners in the field [41]. The British Association of Prosthetists and Orthotists describes the contribution to research as an explicit and mandatory role of prosthetists [42] (p. 3). Research conducted by practitioners would help to represent real-world settings like patient diversity in a study as closely as possible and thus increase generalisability. An established research culture within practice at the same time makes sure that results are noticed by practitioners and implemented more widely. The direct communication of acceptance research results to the practitioners might also be an option. In any case, more exchange of expertise is needed between social science and acceptance researchers on the one hand and prosthetists on the other.

### 3.3. Guidelines

Besides informal communication channels from practitioners to researchers and back, systematic research results may also reach practice via CPGs (Clinical Practice Guidelines).

Numerous such CPGs can be found published online for different kinds of prosthetic care, providing advisory information for practitioners. For example, for knee prosthetics there is a CPG informing about the specific advantages of microprocessor-controlled vs. other prosthetic knees and conclusions that can be drawn for knee selection for a user [43]. This information can guide the decision of the doctor whether a user might benefit from microprocessor-controlled knees. CPGs are used as guides for prescription choice (e.g., also [44]), but can also include more detailed best practice recommendations for all phases of rehabilitation and its organisation [45] (pp. 6–7), [46] (pp. 55–56). CPGs tend to be rather heterogeneous guideline documents [47], which may be produced by (national) medical associations and health organisations or departments [45,46,48], but also othe players in the health care system such as hospitals [43,49] and insurance companies [44]. In any case, they are not binding for care providers however. Different methods may be used to create CPGs, including Delphi surveys with professionals [44,48] and focus groups with patients [45,46]. It would be desirable to have (nationally standardised) guidelines covering all aspects of prosthetic care and amputation types, using input not only from practitioners but also users.

The basis of CPGs is mostly evidence according to standards of HTA and practitioners' experience [50] (p. 5). With respect to Germany at least, we think that there are options to improve prosthetic care by taking research on social acceptance factors more systematically into account in guidelines for such care. At present, some socio-psychological aspects already receive attention in some guidelines [45,46]. A German guideline on amputation of lower limbs, for example, states that

the user and not its stump should be at the centre of rehabilitation and that the social environment should be included in the rehabilitation process [48] (p. 15). It also recommends to evaluate quality of life of users and support psychological coping mechanisms [48] (p. 21). These incorporations of socio-psychological aspects in current CPGs are a significant improvement if compared to simple prescription guidelines focusing solely on physiological and technical aspects—but they are still not very detailed or a very prominent part in the guidelines.

Guidelines could address the criteria for an adequate individual choice of a prosthesis by taking into account personal factors other than age, physiology and activity levels, such as the extent to which a user values aesthetics. While for prosthetists, this knowledge is acquired during practice and can be transmitted from experienced to less experienced prosthetists, doctors might be not so much aware of these important acceptance factors. The latter have to prescribe prostheses but are not involved in the following supervision of their use, although it is of crucial importance, also with regard to reimbursement, that they prescribe the "right" prosthesis in the first place. Last but not least, CPGs could also address communicational aspects of care such as the frequency of informational exchange with the prosthetist, or the opportunities of access to peer networks (as is the case in one US guideline) [45] (p. 76).

### 3.4. Education and Training of Professionals

We already mentioned the benefits of practicing prosthetists being able to do research or work with researchers conducting evaluation tests with individual users [42] (which may entail outcome assessment as a task for prosthetists). In order to reach their intended audience, the results of social science research on prosthetic care should be included in education curricula for prosthetists. They accompany users from the first fitting process on, and sometimes in their entire future life, as changes in prostheses or fitting of new prostheses have to be done every few years. It is self-evident that prosthetists should thus be aware of all relevant acceptance factors like social factors and psychosocial adjustment processes in order to help the user, for example with prosthesis choice and adaptation processes. Research results that are so far rarely used in everyday practice could be an additional helpful resource of knowledge for them. Also, the British Association of Prosthetists and Orthotists names integration of best available evidence into practice as an explicit and mandatory role of prosthetists [42] (p. 3).

In Germany, the usual qualification of a professional prosthetist is not an academic but a rather practically and technically oriented trade education. The few academic courses (Master) on prosthetics have a strong focus on engineering. Therefore, there is a kind of professional gap of acceptance and understanding between the more hands-on prosthetists and the engineers with a university background. Thus, it would make sense to incorporate a more interdisciplinary approach, including optional courses on psycho-social aspects, in the education of German prosthetists that may allow for a more holistic view of prosthetics and the users of prostheses.

### 3.5. Peer Networks

With regard to the reimbursement issue, users can inform each other about their experience and help to distribute the knowledge about insured user's rights more widely. Peer networks created via online tools, events in prosthetic care houses or personal mediation can bring users together. This is however only a work-around for a profound regulatory, ethical and communicative problem that should be discussed between all stakeholders including developers and users, policymakers and insurances.

Peer networks are also invaluable for informing users about prosthesis choice. Not only the pros and cons of different prosthesis types but also personal accounts of more experienced users can generate more realistic expectations. Health care professionals cannot always provide the support, reassurance, and knowledge exchange a patient desires. In some cases, patients even reported some reluctance to ask the medical staff about the consequences of amputation if they felt like the question

might be "stupid" or if the answer might be frightening and unpleasant to cope with [15,22]. Within a peer-network however, asking an individual who has already dealt with these topics first hand might reduce the initial hurdles to address them. As such, participants of Hamill et al.'s 2010 study rated other individuals with limb loss as the most credible source of information regarding the consequences of amputation due to their status as "insiders" with personal experience [15]. They act as a role model and guide others.

### 3.6. Communication between User and Prosthetist

Good communication between the prosthesis user and their prosthetist is vital, as important decisions such as which prosthesis model to choose, how to optimise them for the individual user, as well as the kind of training required, are made between the two. However, not all patients favour the same level of involvement. Ideally, all decisions should be made collaboratively, taking into account the patient's wishes, as well as considerations about what is medically feasible. However, especially new users might struggle with partaking in the decision-making process due to the gap in knowledge and experience. To enable patient-centred decision-making models, communication between patient and medical staff needs to be effective and informative enough to grant patients access to relevant information surrounding the decisions to be made. Most prosthesis users have a strong interest in finding the best long-term solution for their specific case and all communicative efforts to enable this best possible solution should be made.

### 3.7. User Choice

Acknowledging patient preferences is a general aim in health care and should also be taking into account for prosthetics [51]. The kind of physical activities a user would like to engage in, as well as the wide range of subjective rehabilitation goals users might have, can have a significant impact on how appropriate a certain type of prosthesis might be. Prosthesis users should be able to choose between several options based on their knowledge of the drawbacks and benefits of a specific prosthesis in combination with their own preferences and goals. Ideally, this knowledge is acquired by testing the prosthesis for a sufficient time period, but could be substituted for the best available information provided by a prosthetist and other users.

## 4. Cost as an Acceptance Factor and Access to Prosthetic Care in GERMANY

In the following, we will point out that cost is an important acceptance factor for prosthetics besides technological, social and psychological factors, and make a deeper analysis of the legal background and ethical implications of the reimbursement process in Germany.

### 4.1. Cost as an Acceptance Factor

An international study on the role of affordability in selection and wear of upper-extremity prostheses showed that 37% of prosthesis wearers were not fully reimbursed for their expenses and that 48% of non-wearers considered the cost an influential factor in their decision not to wear prostheses [1]. The survey results also suggest that prostheses are sometimes selected based on affordability and that multiple device access is highly appreciated but also dependent on financial support [1]. Fear of damage and resulting repair costs were cited by 34% of those who reported reasons for non-wear, which can hamper participation in social life and activities [1].

The fitting time is another acceptance factor which may be relevant independently from the reimbursement process but is often directly linked to it. In case of procedural hurdles for getting a prosthesis reimbursed, the insured may choose not to buy a prosthesis at their own expense in case their application fails. This may lead to a considerable time lag between the prescription and first use of the prosthesis of several months. In this context, it is relevant that early fitting both for congenital and acquired limb loss seems to increase the prevalence of sustained prosthesis wear [18,33,52–55].

Biddiss and Chau found that users who were fitted within six months of amputation were 16 times more likely to continue use than those fitted later [33].

As systematic data for reimbursement of prosthetics in Germany is missing, it is difficult to estimate the scale of this issue. We do however have anecdotal evidence from conversations with prosthesis users, as well as prosthetists and device producers, which leads us to assume that the problem of insufficient reimbursement and a lack of transparency still exist. Some years ago, the reimbursement process has already been discussed as one important factor to be improved for optimized care with medical aids by the German Association for Rehabilitation [56]. It was stated by professionals in the field that there is unequal treatment in reimbursement or prosthetic legs [57], that claims for medical aids, in general, are intransparent and may require high extra payments for the insured [58]. Thus, studies are needed to systematically analyse the scale of this issue. Biddiss et al. recommend the conduct of empirical studies in other countries to analyse the specific national reimbursement regulations [1], which we will do now.

### *4.2. Reimbursement Practice and Regulation*

Paving the way back into everyday life after amputation requires collaborative efforts between the amputees, their social circle and different professional groups such as doctors, physiotherapists, nurses and orthopedic technicians. Other actors to consider are case reviewers and employees at the responsible insurance companies. The prosthetist is probably the most central person for the amputee: He or she will accompany them during rehabilitation and will remain the decisive contact person and confidant later on. The prosthetist is in charge of all aspects of prosthetic care, such as suggesting specific models, as a large number of different prostheses and individual components are available. The prosthetist is also at the interface between doctor, health insurance company and the patient. They prepare a cost estimate based on the medical prescription, which has to be approved by the responsible health insurance company.

On the legal side, the situation in Germany is quite complex [59]. The Federal Participation Act (Bundesteilhabegesetz) is intended to implement the UN *Convention on the Rights of Persons with Disabilities*. It is intended to enable people with disabilities to participate as fully as possible in all areas of society. Furthermore, reimbursement of medical devices is regulated in the Social Code Book (SGB, Sozialgesetzbuch), according to which those covered by insurance are entitled to the provision of aids, including prostheses, "in order to ensure the success of the medical treatment, to prevent an impending obstruction or to compensate for a disability" (§ 33, Abs.1 SGB V). Aids to compensate for a disability are covered by § 33 SGB V if they are needed to satisfy the basic needs of daily life. The Federal Social Court (Bundessozialgericht, BSG) has defined the following activities as basic needs: Walking, standing, sitting, lying, grasping, seeing, hearing, excreting, eating, basic body care, independent living, as well as the development of a certain physical and mental freedom [60]. Claims to statutory health insurance providers are also based on the so-called economic efficiency principle, i.e., they are limited to those measures which are to be regarded as sufficient, expedient and economical according to objective standards, as well as not exceeding the measure of what is necessary (§12, Abs.1 SGB V). Practically, the BSG states that considerable additional costs for a more modern and state-of-the-art prosthesis do not play a role if there are advantages compared to the previous prosthetic care. Rejection solely on the grounds that a medical aid is too expensive is not permitted by law. "Significant additional costs are only relevant if the additional benefits of using a new aid in everyday life are rather low and the associated costs are disproportionately high compared to a standard of care that has previously been considered sufficient" [61]. To prove that a user actually is able to benefit from a prosthetic, typically a video or personal demonstration is given to the health insurance fund or the Medical Service of the Health Insurance Funds (Medizinischer Dienst der Krankenkassen, MDK).

### *4.3. Ethical Reflection on the Legal and Practical Reimbursement Situation in Germany*

It may occur that insurances reject the initial application for a prosthesis. The reasons they give for a rejection are contradictions in the prescription of the doctor and the demand of the insured, or insufficient explanation of the needs of the insured and of why the prosthesis chosen should meet these needs. The insured can then appeal and the insurance can review its initial decision. If the review does not lead to a revision of the decision, the insured has the possibility to file a lawsuit against the insurance at the social court. In the majority of cases, the social courts decide in favour of the insured [62,63]. However, costs for a lawyer have to be paid by the insured [63] and financial and administrative hurdles in the reimbursement process may represent a considerable or even decisive barrier for people in need of prostheses. Especially in cases where the reimbursement decision is made in social court, laborious paper work and emotional distress can be expected. To buy a prosthetic without insurance can cost as much as several tens of thousands of Euros and they are thus not affordable for a large part of the population. From an ethical perspective, there are two strands of arguments that call for a change of this situation.

The first is that disabled persons should have equal chances to pursue a life in dignity and to its full potential. There are a number of literature studies that show how important a successful prosthetic rehabilitation can be for reestablishment of a positive body image, self-esteem and reintegration in social life [12,13,18,27]. Studies show also that a significant percentage of people with acquired limb loss have difficulty returning to work, and those who do usually require job modifications to be successful, and use and acceptance of upper limb prosthetics are positively correlated with employment [64] (p. 114). Special sports prostheses are mostly not reimbursed, based on the argument that sports is not a basic need, especially when the user did not do this sport before his/her amputation. However, it is obviously an important part of many people's lives and grants quality of life, and also health, and may be an important aspect of social inclusion. Thus, criteria such as need and equity should play a bigger role in addition to benefit and efficiency considerations for reimbursement decisions. These principles, ranked in importance in the order from need to benefit to efficiency, should be balanced, though it is difficult to generalize how exactly they should be balanced or weighted [4].

In 2007, the German Central Ethics Commission on medicine (Zentrale Ethikkommission, ZEKO) drafted recommendations on just criteria for prioritisation of health care, followed by the German Ethics Council (Deutscher Ethikrat) in 2011. Prioritisation means that certain medical indications or people are preferably treated due to cost and/or medical effectiveness reasons. Explicit rationing on the macro-level of the health care system (e.g., denying reimbursement of an expensive cancer treatment for all patients, or a group of patients with specific medical characteristics) is avoided in Germany based on ethical grounds. Prioritisation is however implicitly taking place also in the rich German health care system, through individual prescription decisions doctors, or, as in the case of prosthetics, reimbursement decisions by state insurances.

The criteria the ZEKO recommends with regard to the process of prioritisation are transparency, justification, evidence-basedness, consistency, legitimacy, openness and balance of conflicts of interest, legal protection, and regulation [4]. For prosthetic care, there are strong hints that the criteria transparency/openness, justification/legitimacy, evidence-basedness, and consistency are not fulfilled. Initial rejections of the reimbursement applications are not justified in every case, as a considerable number of insured in need of a prosthesis go to social courts and win the lawsuit against their insurance. It can be assumed that there is also a high number of insured who do not veto the initial insurance decision, which leads to unequal access based on the capability to seek legal aid. It can also be doubted that decision criteria for the initial rejection or approval of reimbursement of prostheses are consistent across all insurances within the state-funded insurances in Germany (Gesetzliche Krankenversicherungen, GKV), as they have their own service catalogues. Thus, it cannot be excluded that certain groups of insured are discriminated against with regard to access to prosthetics. Starting in 2017, the medical aid catalogue will be reworked/updated based on scientific evidence and quality criteria by the GKV according to the *Gesetz zur Verbesserung der Heil- und Hilfsmittelversorgung* [65].

Also, insurances are obliged to inform insured better about their contract details on medical aids. However, this law does not touch the decision capacity of insurances based on individual cases and according to their internal rationales, improving little if at all the transparency and evidence-basedness of reimbursement decisions.

Discussions about the question whether it is ethically justified to ration health care at all are very controversial. Some politicians even condemned proposals of this sort as against human dignity. However, it has also been argued for a long time now by ethicists that rationing is inevitable in the long term and implicit/non-transparent rationing shall be avoided, and general ethical criteria for rationing have been proposed [4,5,66]. However, the more serious this proposal is taken, the more specific criteria have to be found for every health care item. As every spending drains resources from another item in the health system, a systemic view is needed, and measures be found that make items comparable (with regard to whatever criteria are chosen, be it benefit, cost, equity, need, or others, and their relations).

Prosthetic care is a comparatively small financial item within the entire health care budget. This does not mean that expenses are justified in any case, as this in a way would discriminate insured who belong to groups affected by diseases, which are using a larger part of the health care budget. It is beyond the scope of this article to discuss this broader ethical dilemma of just allocation of resources in a health care system with limited resources. Public debate regarding the possibility of explicit rationing or redistribution of federal budget may have to take place. The point we want to make here is simply that currently, prosthetic care is implicitly rationed and therefore unfairly distributed in Germany. The costs of a more fairly distributed prosthetic care in Germany (where everyone would get the same chance to get an optimal prosthesis according to his/her needs) may be higher or lower than current costs for prosthetic care (where some insured don't get the prosthesis they want) is a fairly open question. There are only few studies regarding this question for the US, suggesting that in the long term, prosthesis prescription even could save money [9]. While Section 2 of this paper dealt with the question of how prosthetic care could be made better by social innovation and changes, but possibly at the same time more efficient in order to circumvent this problem to a certain extent, we will now turn to the more complex question or an alternative solution. What would have to be done if explicit rationing shall indeed become reality in the future, in order to conduct it in transparent, just and evidence-based (and thus ethically justifiable) ways?

## 5. Health Technology Assessment (HTA) in the Reimbursement of Prostheses

In the following, we will propose directions for the evaluation of prosthetic care as one requirement to solve the broader ethical problem of just resource allocation in health care systems.

### *5.1. HTA—Assessment of Costs and Benefits and the QALY Concept*

General process and content criteria for prioritisation as defined by the German ethics committee on medicine [4] are a first prerequisite to make reimbursement more just. Though it is contested how and if at all, one can optimise the benefit across the whole population in a just manner, the effectiveness of prosthetics should play some role for distribution of resources. After all, it is the primary goal of health care to improve quality of life of people, and non-effective treatments will drain resources from other areas of health care where people may benefit. The next and probably more laborious step towards just reimbursement would thus be to find methods for effectiveness evaluation of specific technologies. Biddiss et al. see the evidence-based evaluation of prosthetic practices and outcomes as a prerequisite for reimbursement policy change [1].

Deciding about the reimbursement of prosthetics based on benefits and costs is in fact one (simple) way of interpreting the criterion of being based on evidence, which the ZEKO defined. This refers to the term "evidence-based medicine" (EBM), which stands for the principle to use the best evidence at hand, ideally the statistically significant outcome of prospective randomized controlled trials, and summarize it according to a certain standard systematically in order to inform approval decisions by regulatory

bodies. An evidence-based evaluation has been suggested to be highly beneficial for prosthetic care specifically, both to empirically justify prescription of high cost prostheses [67], but also to improve quality and raise efficiency [41]. In Germany, evidence-basedness of reimbursement means that only such medical treatments are reimbursed which have a benefit going beyond alternative treatments [2].

For pharmaceuticals, the benefit gain of the new treatment in comparison to existing treatments, and their respective prices, are used to negotiate the price of a new treatment between manufacturer and GKV [2]. This procedure has the advantage that nothing is being withheld from patients based on costs, but still some form of limiting the rising costs for pharmaceuticals is achieved.

This limit is however quite arbitrary as the "starting price" for a specific indication is taken mostly as pre-given and can basically be determined by the manufacturer who puts the first treatment for a certain indication on the market [2,66] (p. 45). An assessment of benefit and costs of prosthetic technology could be not only a quality and cost control mechanism within a specific health care sector, but also a first step towards a comparability of treatments across sectors, like cancer and prosthetic care.

In the UK, there is now a regulation in place which sets a limit of Euros a Quality adjusted life year (QALY, a measure of gains in both quality and length of life) may cost in order to be reimbursable. Above a certain limit (around 25,000 £/QALY), reimbursement is not excluded but demands specific justification [50] (p. 23). Though methodologically difficult, there are studies asking the general public for their willingness to pay for one QALY, with the aim of democratically legitimising such a number [68]. There are only few attempts to evaluate cost-effectiveness of prostheses up to now. Two studies evaluating the same prosthesis came to very different results of 3000 vs. 35,000 Euros/QALY [69], which shows that it is still a methodological challenge to measure QALYs, besides ethical objections [66] (pp. 64–65). But at least all three studies found Euro/QALY amounts below the assumed Euro/QALY limit of the UK, a result that might suffice as a legitimisation for reimbursement.

Whether a health care system uses an approach with QALYs like in the UK or negotiates prices based on additional benefits of a treatment like in Germany, it is important to have an evidence base in the form of reliable studies. Without scientific evidence, the uptake and diffusion of health technologies is likely to be influenced by a range of social, financial and institutional factors, resulting in suboptimal health outcomes and inefficient use of resources [50]. For prostheses, the evidence base is rather scarce (for microprocessor controlled knees one can at least find several studies, see [69–71]), and only a few HTA studies can be found for upper limb prostheses [72]. This may be a critical point explaining insurance providers' unwillingness to provide more expensive prosthetics. It also makes it difficult to change regulations in a way incorporating the evidence-basedness criterion of the ZEKO and thus make it more difficult for insurance providers to proceed with implicit rationing. One more option would of course be to give insured access to prosthetics without any interference option by insurance providers. The past has shown, however, that in a profit driven medical sector, this is in general not the best option. Without quality control mechanisms like a systematic, manufacturer independent benefit evaluation in place, it may result in high prices for medical products with low quality, thus worsening the financial problems of the health care system and not necessarily fostering the development of good products and patient care.

Also, while an inclusion of social aspects as discussed above might alleviate the health care budget problem by making prosthetic care supposedly more efficient, this has to be assessed in some objective way, e.g., by HTA, as well. We will consider prosthetic care evaluation from a broader, multidisciplinary perspective rather than a narrow perspective focusing on (objectively measurable) physiological parameters and direct costs of the prosthetic technology. This is why we come back to our findings from the social science literature here as well.

Overall, we try to bring socio-economic/HTA, ethical and social perspectives on limb prosthetics together in a so far unique way. Furthermore, we give some policy recommendations with regard to starting the process of discussing the reimbursement process and regulation and possible changes.

### *5.2. Hurdles for HTA-Based Reimbursement*

There are three intertwined hurdles for developing HTA-based reimbursement criteria for prosthetics. One is that guidelines or standards on evidence-based evaluation of prosthetic care (and medical devices generally) are lacking so far [10] (p. 10). HTA agencies state that the available studies they had to base their assessment on were generally small and methodologically weak [69]. The available number of HTAs is very low. Also, the studies which the HTAs are based on were mostly sponsored by manufacturers and patients were often fit and healthy adults, which means a low generalisability of results [69]. Outcome measures are heterogeneous and thus difficult to summarise or compare between studies [71], and only some studies assess quality of life, but most of them rely on functional outcomes like speed, balance, gait biomechanics, and energy expenditure [69].

One reason for the scarcity of clinical studies and HTAs is the legal framework for medical devices in Germany and the EU. Medical products of low risk (class I and IIa), there is no obligation for manufacturers to make a benefit evaluation at all [10,73]. The sole requirement to gain market access is the CE mark which is basically a certificate for compliancy with safety standards [10] (p. 58). The Federal Social Court (BSG—Bundessozialgericht) decided in 2015 that if a medical aid (prostheses are also classified as medical aids, which is crucial for reimbursement regulation) is innovative, insurances are not allowed to reimburse it without further investigations on benefit [74]. For new prostheses that are not seen as "innovative" by the G-BA (Gemeinsamer Bundesausschuss), there is no incentive for producers to conduct more studies on effectiveness than necessary for CE mark purposes. Rather, this would be a financial burden and a risk in case of negative study results. Thus, to encourage the conduct of studies according to standards of evidence-based medicine (EBM), a more demanding legal framework is needed. At the same time, care has to be taken that small and medium-sized companies (SME) are not overburdened with complex, costly and time-consuming requirements [10] (p. 10). Currently, the framework in Germany is insufficient in this regard, and policymakers can produce innovation impulses by helping to develop evaluation processes [10] (p. 11). The question of who has to finance studies has also to be solved [75].

The third issue is that there are methodological difficulties with the evaluation of medical devices in general, as they are characterised by complexity, incremental innovation and dependency of effectiveness on the care provider (as discussed in depth in [73]). Medical device manufacturer associations in Germany are calling for the development of scientific guidelines for a transparent benefit evaluation of new medical products [64]. Otherwise, uncertainty and complexity of the regulatory framework may hinder the realisation of new ideas in medical technology development in Germany [10] (p. 11).

Methods and regulation of benefit evaluation should ideally be innovation-friendly, user-centred, mirroring real-life care settings [76,77] and satisfying the demands of insurances who wish to legitimize their decisions based on good evidence [75]. There is a huge breadth of possibilities concerning the evaluation of prosthetics. One has to choose the point in time (before or after market access, right after fitting or after a time period for letting the user adapt), number of users and prosthetic models studied in every user, mode of study (registry or clinical study, case studies) and most importantly, measurement instruments/outcomes.

The ZEKO gives only very general hints with regard to evaluation of prosthetic technology: Benefit evaluation of medical treatments should be both evidence-based and patient-oriented, and evidence has to be gained systematically [4]. A general conclusion from that is that it is important to include quality of life as a criterion for reimbursement and not only a functional evaluation (as, for example, asking whether the user is able to walk a certain distance with the prosthesis in a certain manner).

### *5.3. The Role of Social Factors for the Assessment of Prosthetics*

Social acceptance factors interact with technical aspects of the prosthesis, as shown in the first part of this paper. Thus, it is not reasonable to measure or predict benefit based solely on surrogate parameters like functionality at a certain time point, only because they are easier to measure and

quantifiable. Other non-quantifiable values like patient preferences, acceptability, equity concerns and indirect benefits and costs should be accounted for in HTA assessments if they are used as a basis for reimbursement decisions [50].

In addition, the context of evaluation can be crucial for the result. Opinions and experiences of health care professionals and individual users are needed to understand the real-world benefit of a technology [50]. For example, when a user has not been involved in choosing the prosthesis, the evaluation result will be misleading regarding the potential of the technology (it would have in an optimal care and social setting). Thus, social acceptance research is important to consider when thinking about how, when, in which setting, and by whom prostheses should be evaluated to get valid results that are transferable to future users. However, a conclusion might also be that prosthetic care success is to such an extent individual and the context so decisive for the benefit of a prosthetic technology that no prediction regarding an individual could or should be drawn from the general population of users. If this is true, it might not be an unavoidable obstacle for prosthesis evaluation, as wearing a prosthesis has no such acute or irreversible side effects as pharmaceuticals and implants.

Though social aspects of prosthesis acceptance are crucial, new technological developments also have to be taken into account when thinking about policies of prosthetic evaluation and reimbursement. Individual designs, e.g., with 3D printing of prosthetics (or Lego Limbs) can boost acceptance and are assumed to contribute to a positive self-image, particularly in children. The personalization/individualization of medical treatments which is discussed for medical substances as a challenge for effectiveness testing methods [10] (p. 10), and there might be critical voices not accepting this kind of aesthetic demands as medically strictly necessary. Further research is thus needed on this specific aspect of aesthetics and related regulatory questions around individualized medical products, both regarding safety [78] and reimbursement. Reimbursement regulation for individualised medical products is generally complex and intransparent in Germany [10] (p. 11).

One approach would be a systematic evaluation with questionnaires conducted directly by the care providers (doctors or prosthetists) and collected in registries. With regard to a suitable method, a prosthesis evaluation questionnaire (PEQ) is available to measure quality of life of people with limb loss and quantify the benefit of using a prosthesis [79]. It was used to assess one microprocessor-controlled knee in a US study. However, in Germany, there are no medical registries for people with limb loss and the authors could not find published studies using the PEQ. Tools like PEQ are needed and should be validated further, as well as anchored in guidelines and teaching in prosthetics.

An individual evaluation per case by the care providers in this manner could open up possibilities for testing a new and diverse set of prostheses for every user in order to make the best individual choice and at the same time produce data that could be aggregated to generate more general conclusions about benefits of specific prosthesis models for specific user groups. Testing the benefit of prostheses under real-world conditions improves the reliability of the evaluation. Another advantage is the fact that evaluation after market access is generally innovation friendlier. Products can be sold while in the testing phase, users can get access to potentially beneficial technology, but at the same time it is guaranteed that products without sufficient benefit are deselected based on the collected data. Of course, safety-testing is still needed before market access. A drawback of this approach is that a full evaluation for every user would need extra time resources on behalf of the prosthetic technician and the user him/herself.

### *5.4. Early Stakeholder Dialogue and Implementation of Reimbursement Recommendations*

We described a possible approach for evaluation and made reference to a validated method from the literature here. However, this is only a suggestion, and pros and cons for this and other approaches as well as combinations thereof (like randomized controlled trial combined with registry data [77]) have to be discussed by experts and stakeholders specifically for prosthetic care in our view. It has been argued that HTA (of effectiveness/benefit) and regulatory evaluation (of safety) should be aligned for medical products [75]. The German Academia of Engineering Sciences (ACATECH) recommends

a collaboration of representatives of clinical medicine, industry and research, as well as regulatory agencies to develop suitable guidelines for effectiveness/benefit evaluation of individualized medical products [10] (p. 11), and patient feedback on the quality criteria used [10] (p. 64). For the case of prosthetics, we would also suggest incorporating prosthetists besides users.

An important issue to think about would also be how to implement more standardised and evidence-based reimbursement criteria once they are developed and consented on. The current situation shows that there is a lot of uncertainty about the claims of prosthetic users. In the future, this uncertainty should be avoided by clear guidelines on reimbursement, which are open and understandable for professionals and insurance employees involved in the process.

A possibility might be to use existing practice guidelines as a platform. Insurances are not obliged to reimburse practices which are recommended in guidelines. However, if resulting in better and more efficient care, insurances should in their own interest support the implementation of (best practice) guidelines. The NHS (National Health Service of England) proposes that with a standardised practice related outcome evaluation (of orthotics) one could develop practical guidelines that could improve quality of care and save money [70]. The impact of prosthetic guideline implementation has to be evaluated in order to prove such claims [47]. Reimbursement decision (bodies) (in Germany G-BA and GKV), practical guideline developers (clinicians and prosthetists) and HTA assessment bodies are however separated [50] (p. 5). A closer collaboration might help in aligning best practice and prescription guidelines with reimbursement decisions of insurances.

## 6. Conclusions and Future Research Directions

The reimbursement process in Germany may pose an insurmountable hurdle for people in need of a prosthesis and decrease prosthesis acceptance and quality of life of users. Non-optimal prosthetic care resulting from this may have negative impacts on social inclusion [12,13,18,27] and working capabilities [38,64] (p. 114), thus having broader societal effects beyond the individual well-being. Our analysis shows that prostheses are implicitly rationed to some extent, which contradicts German disability law as well as BGB/SBG, which gives amputees the right to get the best available prosthesis that may benefit them, according to their own subjective evaluation [62]. To overcome this issue, regulatory changes, the development of adequate cost-effectiveness evaluation methods for medical products (taking into account the "social side" of prosthetic care), and ethical discussions about the justification of prioritisation or budget reallocations are needed. With our exemplary analysis of what implicit rationing of health care may mean for individuals, we hope to contribute to the broader discussion and to help raise public and political awareness for this pressing problem. More quantitative and qualitative studies on reimbursement experiences and effects are needed.

Translational research requires (1) cooperation between the involved professions. Starting points for tangible improvements, which may be promoted in CPGs, could be the (2) inclusion of research findings in guidelines and (3) curricula for prosthetic technologists, both in order to more strongly link academic research to practice. Furthermore, R&D should (4) be conducted in a user-centric way from the early stages. This allows incorporating a social and personal experience perspective on the technology, in addition to the instrumental and functionality-centred perspective developers have. Empowerment of users through the chance of (5) individual choice of prostheses and (6) through communication with peers and (7) prosthetists is also crucial, due to the complexity of prosthetic care and individual preferences and needs. In order to make CPGs more inclusive and to adequately incorporate social aspects in them, patient views need to be systematically included in the development process. A further step would be to couple CPGs with reimbursement regulation.

We may draw several conclusions from our analysis. First, we posit that improvements in prosthetic care that are based on insights from social science will decrease rather than further increase pressure on the health care budget. This hypothesis should be tested in studies on prosthetic care spending and on benefits for users by means, making use of HTA methods. The development of adequate cost-effectiveness evaluation methods for medical products (taking into account the "social

side" of prosthetic care) is a prerequisite for that. Much work has been conducted in this area and discussions are ongoing, but there are still many open methodological and regulatory issues. In the future, more encompassing studies on prosthetic care may be conducted, in order to evaluate prosthetic devices but also organisational and social measures to improve prosthetic care (with respect to a broader understanding of efficiency in activities of daily living).

HTA may help to make reimbursement decisions more transparent and based on evidence, e.g., also on quality of life gains through prosthetic technology. However, this requires new forms of collaboration between HTA agencies and professionals and users in the field, new study designs (focusing on real-world evidence and patient preferences), and of course, financial resources.

To start and guide an improvement process, the interests of all stakeholders should be taken into account and ideally be discussed in a dialogic format. Some years ago, an attempt has already been made to discuss reimbursement issues in a multi-stakeholder setting that included representatives of insurances, producers, health economics, prosthetists, and doctors. However, it had a rather narrow focus on a specific prosthetic leg model and had little tangible or broader impact so far [57]. In our point of view, strong efforts should be made to continue with such processes, making it even more inclusive by taking into account the users themselves as well as representatives from regulation and health technology assessment.

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