Improving access to prosthetic limbs in Germany: 
An explorative review

Martina F. Baumann and Maia Maria

Abstract

Background: Meeting the needs of users when it comes to accessing prosthetic limbs is an important factor in the acceptance and use of a prosthesis; the cost of such prosthetics also constitutes a potential financial challenge.

Objectives: The aim of this study was to investigate potential hurdles to accessing limb prosthetics in the German health care system, including organizational, social, economic, and regulatory issues, and to provide food for thought about ethical implications.

Methods: Sixteen German users of limb prosthetics with upper-limb and/or lower-limb amputation were recruited by means of purposive sampling. Semistructured interviews were performed, with the guiding question being as follows: “What were your experiences with the German prosthetic care and reimbursement system?” Ten stakeholders (insurance representatives, prosthetic technicians, medical service representatives, a law expert, and a lawyer) were asked about the issues they encounter in their work related to prosthetic care and reimbursement, and about ways to ameliorate these issues. A qualitative content analysis method was used to analyze the data.

Results: Half of the interviewed service users experienced hurdles to gaining a suitable prosthetic device, such as waiting times and pressure to negotiate their need for a certain prosthesis. Some of the views expressed about the issues relating to prosthetic reimbursement in Germany were common to all stakeholders, whereas some conflicted with the views of others.

Conclusions: Equitable access to prosthetics and the efficient distribution of prosthetic innovations could be improved by organizational and regulatory measures. Furthermore, a user-centered design of prostheses, a health technology assessment, monitoring of prosthetic care pathways, and a societal discussion about rationing in health care should be considered as parts of a broader approach to tackle this issue.

Keywords

ethics, resource allocation, rationing, reimbursement, societal, access, limb prosthetics, qualitative research, health provision research

Introduction

To improve the health, mobility, autonomy, ability to work, inclusion, and ultimately the quality of life of amputees, different types of limb prostheses are available on the market today, ranging from cosmetic models to extremely functional products that enable high-performance running or several dozen types of grip. Relatively low and stagnating acceptance rates for highly functional prosthetics show that technological progress alone is not enough to bring about prosthetic care improvements. Owing to their very individual physiological and personal circumstances, such as their preferences and needs, the success of prosthetic care and the benefits a user can ultimately obtain from using a prosthesis are highly dependent on several factors, including the selection of a suitable prosthesis and a good accompanying rehabilitation process, a field that is still undergoing constant development.\(^1\) The general psychological and physical health of potential prosthetic users and the support they receive from their social environment also have a considerable influence because coping with an amputation and engaging in the rehabilitation process is physically and emotionally very demanding. Depending on the health care and insurance system, reimbursement models and the costs of prostheses that are potentially borne by the user are an important factor that may affect the selection and use of a prosthesis.\(^2\)

In Germany, the Social Code provides the legal framework for the reimbursement of limb prosthetics.\(^3\) Insurers have the final say in reimbursement decisions in each individual case. Negotiations between service users and insurers may ultimately have to be resolved by the social courts, whose rulings also serve as further general orientation, for example, regarding the question of whether sports prosthetics or esthetic covers should be reimbursed. The process of reimbursement decision-making involves a range of actors with conflicting interests,\(^4\) which may have negative consequences for persons in need of prosthetics, the efficiency of prosthetic care, and ultimately for the just allocation of resources in the statutory health insurance system.\(^5,6\) Although denying reimbursement of a specific prosthesis is usually justified by insurers on the grounds of eligibility and economic feasibility, manufacturers’ organizations criticize the decisions, claiming that they often fail to consider gains for quality of life, inclusion and participation in social and working life, psychological well-being, and human dignity and self-esteem, thereby violating the United

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Footnotes:

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Nations’ Convention on the Rights of Persons with Disabilities (UN CRPD).5

The objective of the present study was to investigate the reimbursement process from the perspective of users and key stakeholders. Based on this empirical study, we aim to reflect on the ethical and regulatory issues that need to be considered in responsible and sustainable prosthetic care provision and technological development.

Methods

The study follows an empirical, qualitative approach. In total, 26 semistructured interviews with an average duration of 30–90 min were conducted in person or by telephone between July 2019 and August 2020. They were all recorded, and those parts related to experiences with access to prosthetics were transcribed verbatim for subsequent qualitative content analysis6 using MAXQDA software (v. 21).

The expert and stakeholder interviewees (n = 10) (4 insurance representatives, 2 prosthetic technicians, 2 representatives of the medical service of the health insurance funds (abbr. MD, formerly MDK), 1 lawyer, and 1 social/medical aid law expert) were purposely selected by the researchers for their relevant expertise and potential contribution to the study. They were asked a set of questions about prostheses reimbursement (Table 1). The prosthetic users (n = 16) were recruited through self-help groups (organizers of local groups were contacted by email) and a pool of prosthetic users from a local clinic who were willing to participate in studies and gave their consent to be contacted. They were diverse in age, sex, amputation level, and affected limb as well as reason for amputation (or no amputation as they were born with a limb deficiency), as shown in Table 2. The only exclusion criterion was younger than 18 years.

The prosthetic users were asked about their experiences of reimbursement (Table 3). In this publication, only the interview material relating to experiences of the prosthesis choice (in relation to reimbursement) and the reimbursement process itself is presented. The interview questions were approved by the ethics committee of the authors’ home institution.

Because the study is based on a nonprobability sample, the results should not be generalized to the entire population of prosthetic users. The aim was to explore issues related to reimbursement, not to obtain a representative or quantitative picture of reimbursement experiences.

All interviews were coded (P1, P2, etc. for user/patient, M1/2 for MD, I1/2/3/4 for health insurer, L for lawyer, O1/2 for prosthetic technician, and S for social law expert) to ensure anonymity. None of the participants received any incentives.

Results

The reimbursement process from the users’ perspective

In general, interviewees showed an understanding of the need for a regulatory assessment (consisting of a check of the suitability of the prosthesis for the user based on his/her mobility and physical capabilities, which may be tested by the MD through medical file records, video material, or an in-person examination of the user with the requested prosthesis) and, in justified cases, of why only limited reimbursement was possible. They mentioned their awareness of the cost pressure facing health insurance funds and had heard of cases of overprovision where costly prostheses were not used by their recipients.

Half of the interviewees reported negative experiences with the reimbursement process. A relatively minor negative experience related to the nonreimbursement of special purpose prostheses or related accessories, such as gloves.

Several interviewees also reported more severe negative experiences, as follows:

- Concerns about the competence of the prosthetic technicians working at MD, based on a perceived lack of knowledge about the variety of prostheses available on the market.
- A lack of technical and regulatory knowledge of the insurance company (about certification of prosthetic parts).
- The unnecessary and exhausting need to prove the added value of the prosthesis, despite confirmation having been provided by several caregivers and the user’s subjective experience: “I have received clear information from several caregivers (…) that this improves my gait pattern, I myself notice (…) the relief of the hip, I notice the relief of the knee, and then I find it a bit difficult to get back into an argumentation (…)” (P3).
- Delays in the reimbursement process, which in some cases led to negative health-related side effects and a loss of quality of life: “(…) for me 2 years no swimming, sauna, showers is difficult (…) because if I cannot move physically at my age, that means a real physical degradation” (P3); “(…) this drags on until the MDK appointment, and then half a year or a year, and then a year and a half are lost. I have to say quite honestly that for me this is quality of life (P3).
- Regarding the way the insured persons were treated, the lack of empathy in the communication process was a key aspect mentioned in several interviews. Insurance workers were described as “(…) simply people sitting in front of a piece of paper” (P1), failing to understand the needs of each individual user and making decisions according to abstract legal requirements: “He does not know me! Does not know my conditions!” (P12). Interviewees saw themselves as victims of arbitrariness in a bureaucratic process, especially due to the discrepancy between available technology and access to it: “(…) you see the greatest things at rehabilitation

Table 1. Interview questions for experts and stakeholders.

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is a good prosthesis from your point of view?</td>
</tr>
<tr>
<td>What criteria do you use to choose/reimburse a prosthesis?</td>
</tr>
<tr>
<td>What stakeholders or experts do you interact with (directly or by using their expertise) during prosthetic reimbursement, and how do you do that?</td>
</tr>
<tr>
<td>What problems, if any, do you encounter in the process of prosthetic reimbursement?</td>
</tr>
<tr>
<td>What measures could improve the efficiency, correctness, and fairness of the reimbursement process?</td>
</tr>
</tbody>
</table>
fairs, but no one can afford them. They are not accessible. (...) people who have no idea! They decide what I can do, what I cannot do, what I do not need” (P8), and as being at the mercy of the desire of insurance companies to save money.
- To assure that the outcome of the reimbursement process is reasonably positive, patients need to be proactive in their view: “(...) you cannot think as an accident or health insurance patient that you get the best only by waiting (...) you actually always have to come across as the nasty disabled person who demands, demands, demands (...)” (P10). However, interviewees mentioned that not all patients can take this position and end up fighting for what should be their right.
- Interviewees felt discriminated against on 2 levels: based on the type of insurance they held and on their age. Regarding the first, it was mentioned that accident insurers provide much better support than health insurers. Taken together, such negative experiences lead to anxiety about the future and the feeling of being treated unfairly. One interviewee mentioned that fear of the future is multiplied by the prospect of mental decline or loss of energy in older age: “(...) if I could no longer walk, the quality of life would suddenly be gone and it would be really bad for me (...). Confidence is not there that I will get what I need. I do not know if I will be able to fight when I am older. I can verbally articulate well, but what happens if that changes, if I get Alzheimer. I am afraid of growing old with a prosthesis” (P11).

A summary of users’ perspectives is shown in Figure 1.

The following section presents the problems from the perspectives of stakeholders by the stakeholder group.

According to one insurance representative, prosthetic technicians often lack experience with prosthetics (with the exception of those working in large amputation centers). Furthermore, (some of the federally organized) MDs provide inadequate assessments, e.g., solely based on photograph or video material. In addition, the orientation provided by court decisions is insufficiently differentiated, according to one representative, who is too much engaged with “extreme” (I2) cases. According to I2, a decision of the Federal Social Court concerning a double amputee mother, for instance, should not be used as a legal example with wide-reaching implications for reimbursement practice because it is not representative of the average prosthesis user.

Another insurance representative pointed out that one difficulty faced by insurance companies is that they have a considerable responsibility, including in legal terms, to spend money only for legitimate purposes. The interviewee saw court decisions as an

### Table 2. Characterization of the interviewed users.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age range (y)</th>
<th>Age at amputation (y)</th>
<th>Amputation type</th>
<th>Prosthesis type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>56-60</td>
<td>52</td>
<td>Above knee</td>
<td>Microprocessor knee (endo-exo shaft)</td>
</tr>
<tr>
<td>Male</td>
<td>66-70</td>
<td>61</td>
<td>Above knee</td>
<td>Microprocessor knee</td>
</tr>
<tr>
<td>Male</td>
<td>66-70</td>
<td>63</td>
<td>Above knee</td>
<td>Microprocessor knee</td>
</tr>
<tr>
<td>Female</td>
<td>46-50</td>
<td>8</td>
<td>Above knee</td>
<td>Microprocessor knee (+ height adjustable foot)</td>
</tr>
<tr>
<td>Male</td>
<td>26-30</td>
<td>15</td>
<td>Below knee</td>
<td>Carbon fiber prosthesis (+ bathing and sports feet)</td>
</tr>
<tr>
<td>Female</td>
<td>66-70</td>
<td>59</td>
<td>Below knee</td>
<td>Electronic foot</td>
</tr>
<tr>
<td>Male</td>
<td>56-60</td>
<td>27</td>
<td>Below knee</td>
<td>Carbon fiber prosthesis</td>
</tr>
<tr>
<td>Male</td>
<td>71-75</td>
<td>56</td>
<td>Hip disarticulation</td>
<td>Wheelchair</td>
</tr>
<tr>
<td>Female</td>
<td>56-60</td>
<td>43</td>
<td>Knee disarticulation</td>
<td>Microprocessor knee (+ bathing prosthesis)</td>
</tr>
<tr>
<td>Male</td>
<td>41-45</td>
<td>32</td>
<td>Knee disarticulation</td>
<td>Microprocessor knee (+ bathing prosthesis)</td>
</tr>
<tr>
<td>Female</td>
<td>46-50</td>
<td>43</td>
<td>Forearm</td>
<td>Myoelectric</td>
</tr>
<tr>
<td>Female</td>
<td>61-65</td>
<td>4</td>
<td>Forearm</td>
<td>Myoelectric</td>
</tr>
<tr>
<td>Male</td>
<td>61-65</td>
<td>52</td>
<td>Forearm</td>
<td>Nonelectric hook</td>
</tr>
<tr>
<td>Male</td>
<td>36-40</td>
<td>From birth</td>
<td>Forearm</td>
<td>Myoelectric</td>
</tr>
<tr>
<td>Female</td>
<td>18-25</td>
<td>From birth</td>
<td>Forearm</td>
<td>Cosmetic</td>
</tr>
<tr>
<td>Male</td>
<td>46-50</td>
<td>From birth</td>
<td>Forearm</td>
<td>Myoelectric</td>
</tr>
</tbody>
</table>

The reimbursemnt process from the stakeholder’s perspective

In the second part of the study, the views of stakeholders and experts were collected to document and understand the reasons for the experiences of users in the reimbursement process.

The following section presents the problems from the perspectives of stakeholders by the stakeholder group.

According to one insurance representative, prosthetic technicians often lack experience with prosthetics (with the exception of those working in large amputation centers). Furthermore, (some of the federally organized) MDs provide inadequate assessments, e.g., solely based on photograph or video material. In addition, the orientation provided by court decisions is insufficiently differentiated, according to one representative, who is too much engaged with “extreme” (I2) cases. According to I2, a decision of the Federal Social Court concerning a double amputee mother, for instance, should not be used as a legal example with wide-reaching implications for reimbursement practice because it is not representative of the average prosthesis user.

Another insurance representative pointed out that one difficulty faced by insurance companies is that they have a considerable responsibility, including in legal terms, to spend money only for legitimate purposes. The interviewee saw court decisions as an

### Table 3. Interview questions for prosthetic users.

<table>
<thead>
<tr>
<th>Question</th>
</tr>
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<tbody>
<tr>
<td>How satisfied are you with the choice of your current prosthesis?</td>
</tr>
<tr>
<td>How did the selection process work, can you describe it?</td>
</tr>
<tr>
<td>What where the reasons for choosing the prosthesis you have now?</td>
</tr>
<tr>
<td>How satisfied are you with the reimbursement process for your prosthesis?</td>
</tr>
<tr>
<td>What would you wish for the next time you apply for reimbursement for a prosthesis?</td>
</tr>
<tr>
<td>What would you change or improve about the reimbursement process if you could?</td>
</tr>
</tbody>
</table>
important and relevant guideline in this respect. Regarding the ever-increasing prices of electronic prosthetic components and a potential mechanism for price regulation, one insurance representative expressed the opinion that manufacturers of prosthetics should not be “so protected by lawmakers,” but that they “do not want a state economy, we certainly do not want that, but we do want guardrails” (I4). Some insured people were criticized as having too great a sense of entitlement, based on the misconception that anything is possible with the right prosthesis.

A similar point of view was expressed by MD representatives. Advertisements and the way prosthetic users are portrayed in the media may be problematic as they raise unrealistically high expectations about the benefits users may derive from a high-tech prosthesis. Furthermore, the way assessments are organized is deemed to be inadequate. In some cases, the insured person is not able to wear the prosthesis at the time of the assessment (because a trial fitting was not performed in time) or the video material provided to the MD by the prosthetic technicians is not useful because it does not show or clearly demonstrate the benefit for the user.

According to one prosthetic technician, the reimbursement process is a “bureaucratic monster” (O1) because it is a laborious process to check and calculate prices for each insurance separately and calculate the hours needed for the provision of care in advance. The technicians mention that this lack of uniformity of pricing contracts with insurance companies also has a negative side effect on users because it does not show or clearly demonstrate the benefit for the user.

According to one prosthetic technician, the reimbursement process is a “bureaucratic monster” (O1) because it is a laborious process to check and calculate prices for each insurance separately and calculate the hours needed for the provision of care in advance. The technicians mention that this lack of uniformity of pricing contracts with insurance companies also has a negative side effect on users because it wastes time that could otherwise be spent working on the prostheses: “I could spend more time in the workshop than in front of the personal computer” (O1). One prosthetic technician also criticized the fact that insurance companies refuse in some cases to provide prostheses for purely financial reasons, insurance companies typically using statements and slogans such as: “Forget it, it is too expensive!” or “If you do not fight, you do not get anything!,” mentions O1.

According to the legal expert, quality of life is not a concept in social law (which only uses the term “functional advantage” in everyday life or occupation), but it is possible to use the quality-of-life argument indirectly through (the right to) participation and inclusion, which is laid down in the UN CRPD and the German Federal Participation Act (BTHG). Besides this potential for change with the newly implemented BTHG, the expert saw market monopolies as posing a problem in the area of high-priced prostheses, which could provoke defensive reactions on the part of health insurance funds. One critical political-legal aspect concerns the division of responsibilities between the Federal Ministry of Labour and Social Affairs and the Federal Ministry of Health (BMG) and their different views of disability. The Federal Ministry of Labour and Social Affairs represents the social model of disability and the goal of inclusion, but the BMG is more attached to the medical model of disability and a narrower concept of health. The delay in implementing disability rights about access to aids is related to the fact that the BMG is responsible for the law on aids.

From a legal perspective, improvements in the reimbursement process depend on how willing users are to engage in negotiations and lawsuits: “Between application and decision, 5 years pass (…) must be somebody who is ready to lead the conflict from beginning to end; must not lose courage along the way” (S), as major changes in jurisdiction or in the approval processes of health insurance funds can be brought about by successful lawsuits. With their specialized case management, the accident insurance funds play a pacemaker role by setting high standards for the reimbursement of arm and leg prostheses. Overall, medical aid law is complex and would benefit from simplification and clarification.8

The lawyer, who specializes in reimbursement issues, believes that the main problem when it comes to the reimbursement of arm and leg prostheses is that both insurers and service users lack clarity concerning liability and claims. According to the expert, “You can usually see in the administrative files what the problem was”. In her opinion, the MD sometimes makes misjudgments, such as incorrectly interpreting the case law of the courts or incorrectly
assessing the medical need. Often, the examination is based only on the files rather than on video documentation or examination of the patient. Up-to-date scientific evidence needs to be used in MD reports so that they can be used in turn by the social courts; this makes the task challenging for MDs and may lead to social court decisions which do not recognize the newest evidence (e.g., on the benefit of specialized sports prosthetics to prevent back pain). Another problem is posed by the processing deadlines for health insurance companies, which have been shortened and lead to pressure. “There are always cases that fall through the cracks, presumably there is no logic behind it, as in any system, mistakes happen” (L).

When asked about the future prospects for prosthesis reimbursement, the expert stated that high-priced medical aids are increasingly being rejected. The courts, however, are very “disability friendly” (L) and are becoming more so (also because of the Disability Rights Convention), although it takes 3–4 years until there is a precedent decision for a product and for an individual to file a lawsuit: “It takes a lot of effort, often 2–3 years, but it is worth it, because quality of life increases considerably, you can tell by the reactions of clients, they (...) fling their arms around your neck when the case is won” (L).

Common problems identified by several stakeholders are the unrealistic expectations of insured persons and organizational problems with the case-by-case assessment process. Another major issue that was raised was financial pressure and conflicting interests. Prosthetic technicians saw insurance companies as stakeholders concerned only with maximizing their profits, whereas insurers pointed out their legal obligation to spend money responsibly and the lack of any “guard rail” for prosthetics manufacturers’ prices. The issue of market monopolies for prosthetic technologies was also acknowledged by the legal expert. The expert also made reference to the underlying legal ambiguities and lack of implementation of the social disability model by the state ministry responsible. The problems identified by the stakeholders in the study are summarized in Figure 2.

Discussion

The reimbursement issue from combined perspectives

Organizational issues were acknowledged by stakeholders as one explanation of the negative experiences reported by insured persons. A more general issue raised by stakeholders is that ambiguities about legitimate claims persist because court decisions are often not specific enough or are interpreted or implemented differently by different insurers. Insurers, under pressure due to rising and unregulated prices of prosthetics and their mandate to spend resources responsibly, pass some of this uncertainty and responsibility on to the insured, who consequently feel pressured to justify their needs, feel discriminated against, and feel fear due to the uncertainty of future provisions. It is currently still unclear whether this situation will change significantly or quickly after implementation of the German Federal Participation Act because decisions about new prosthetic technology may take years and there is always the burden on the individual insured person to take action. We intend to discuss the ethical and societal dimension of this situation in the following section.

Anticipation of and reflection on ethical and societal issues

In the future, more costly prostheses may lead to even greater pressure on health care budgets, with potentially negative effects on users. Besides the risk of (randomly) causing unnecessary harm to some users by denying them proper access to the prosthetic technology they need, unfairness or injustice may occur on different levels: first, discrimination in the quality of care based on preferences. For instance, sports and aesthetics are not acknowledged as important factors influencing inclusion and quality of life, the argument being that insurance companies are not allowed to spend money on nonmedical purposes. Second, certain groups may experience discrimination in the sense that a bureaucratic process requires energy and knowledge from users that they may lack due to their age, education, or mental state after

Figure 2. Summary of problems identified by stakeholders and experts. BMG, Federal Ministry of Health.
Involvement of stakeholders and a 4-pillar framework to improve prosthetic care

A straightforward initial approach to address the ethical issue of equitable access might be to work on organizational and communication aspects of the reimbursement process by organizing round tables with all involved stakeholders. Even changes to the regulatory framework may be necessary to ensure more transparency in the decision processes of insurers, to reduce the bureaucratic work for OTs, or to enable reuse of prosthetics (as is also proposed by the World Health Organization [WHO], standard 20).

The legal framework is already set to change in one respect. The BTHG, which is expected to be fully implemented by 2023, contains a new definition of “disability” that is closer to the definition of the UN CRPD. The BTHG may be used as the legal basis to justify more comprehensive reimbursement, either by health insurers or by rehabilitation services, as prosthetic limbs are considered to play an important role in the social inclusion of people with disabilities in areas such as education, employment, and everyday life. Even social court decisions supporting, for example, the reimbursement of sports prostheses that go beyond directly proven medical needs will be more likely under this law, although the National Paralympic Committee Germany has criticized the BTHG for being deficient with respect to sports as one aspect of inclusion.

However, improving the reimbursement regulation and process might still not fully solve the problem when the limited budgets of insurers are the root cause of implicit rationing of prosthetics. We wish to outline a more comprehensive approach based on 4 key pillars as a way of making prosthetic care both better and more efficient. The elements of this approach are not our invention but are well known. However, they may not be as self-evident to all involved stakeholders and policy makers and, as far as we know, have not been described in the form of a condensed overview, which is why we will describe them in the following section (Figure 3).

The first pillar is a user-centered development and design approach in prosthetics and its implementation in manufacturers’ research and development processes, which is still hindered by perceived financial and regulatory barriers. User-centered development takes into account a diversity of user needs and preferences to a greater extent than is usually the case in medical product development and is commonly seen as a means to improve products with regard to functionality and user acceptance. All user groups should be included in this process, as preferences, for example, may be sex-, age-, and cultural background-specific. User-centered development could also aim to explicitly improve the cost-benefit ratio and affordability of prosthetic technology, which would be necessary to reach broader user groups, especially in low-income and middle-income countries.

The second pillar is a health technology assessment (HTA) of innovative prosthetic technologies that considers the quality-of-life gains for the target user group as claimed by the manufacturer. Health technology assessment as a standardized procedure and toolbox for evaluating the benefits and costs of medical technologies has been suggested as a potential response to economic pressures in prosthetic care. According to WHO Standards 9/10, planning and budgeting should be based on a comprehensive analysis of costs and benefits. An inclusive co-development of research designs by target groups, HTA, manufacturers, and insurers would be highly beneficial in this step. The assessment of medical technologies is generally difficult in methodological terms, and this is also true of prosthetics, e.g., when it comes to meeting HTA standards of study design (randomized clinical trials). This is because there are numerous contextual factors that influence the effect of a technology such as a prosthesis, including personal environment and motivation, media exposure and information, and the rehabilitation process. A related approach at the individual case level, evidence-based practice (WHO Standards 50 and following) can help improve and document the actual benefits of prosthetics for different users in real-life care settings after market approval. Reimbursement schemes could be based on HTA evidence, and for individual cases, evidence from practice could show the benefits (and thus prove that insurance budgets were being sensibly invested) in an objective way (and render additional assessments by MD unnecessary).

Even if a prosthesis has proven to be highly beneficial and efficient in clinical trials and HTAs, this finding does not necessarily apply to the entire health care system and all home settings. Deficits in the prosthetic care process, e.g., regarding information for patients, and a lack of capacities, e.g., for gait training, were identified many years ago in Germany, yet there has been no systematic follow-up to these findings. As a third pillar, continuous and holistic research on the prosthetic care process and evidence-based guidelines also including social and psychological aspects, could thus help increase the efficiency and quality of prosthetic care.
through nationwide registries which are in the process of being built up in Germany,\textsuperscript{30} is thus a good long-term investment.

Finally, in the fourth pillar, a societal discussion of and the political will to address the issue of rationing due to scarce resources in health care are necessary. Otherwise, there is a risk of nontransparent, implicit rationing in more and more fields of health care, starting with those where the regulatory framework allows rationing in a relatively simple way, such as prosthetics. The societal and political debate about the willingness to pay for health care in general (relative for example to education, which has a comparatively strong influence on health) and prosthetic care in particular (relative to other illnesses) is not easy, but inevitable in the long run. Examples from Switzerland and England show that engaging the public in dialogs about rationing principles is feasible,\textsuperscript{31} but that they are still rare and need to be upscaled. Although contested,\textsuperscript{32} concepts and methodologies such as quality-adjusted life years, willingness to pay,\textsuperscript{33} or a combination thereof\textsuperscript{34} can help measure health benefits and their value to the public and patients. Ethical principles for the process and criteria of rationing\textsuperscript{35} need to be implemented, and there is a need for a broader societal discussion on this topic.\textsuperscript{20}

**Conclusion**

The qualitative interviews presented in the study suggest that organizational and regulatory problems in the reimbursement system in Germany constitute a barrier to accessing prosthetics and can have considerable negative effects on satisfaction, acceptance, and quality of life of the service users concerned. Failed and/or unsatisfactory prosthetic care provisions not only have potentially negative consequences for health care efficiency but are also highly problematic from an ethical point of view. Current and future implicit rationing entails the risk of systematic discrimination against (subgroups of) users of prosthetics, e.g., persons from lower socioeconomic backgrounds who may have less time and money to engage in negotiations with insurers.

Although some measures are aimed at better organizing and regulating the reimbursement process, a more holistic approach is highly recommended. Four elements of such an approach, namely, user-centered development, HTA, health care organizational research, and a societal discourse on equity in health care, are necessary to promote access to limb prosthetics and improve the quality of prosthetic care in a sustainable manner. We are aware of the limited scope of our empirical study but hope that our contribution makes clear that there is a need to take regulatory action and make investments, and also in funding research on these topics. Extensive evidence collection on user satisfaction and provision pathways is urgently needed, as is user-centered and inclusive prosthetic design.

Although this study is based on empirical results from Germany, which are not generalizable, the problem of resource allocation in health care is universal and the 4-pillar solution framework can (in principle) be applied to all health care systems. Although a discussion of prosthetic service delivery in other health care systems extends beyond the scope of this article, sharing experience internationally can be as important as it is between stakeholders within one health care system.\textsuperscript{21}

Overall, it should be the goal, especially for high-income countries, to meet the WHO standards for prosthetic care, which state that a “guiding framework, consisting of legal acts, policies, strategic plans, standards, rules, and regulations, should be in place to guide the design of affordable, accessible, effective, efficient, safe services of high quality, and that governments should assume a leading role in or delegate responsibility for the governance of nationwide prosthetics and orthotics services.”\textsuperscript{23} The national health and social services should thus consider a review of service provision based on this explorative research. The O&T community could also play a leading role in calling for governments to respond to deficiencies in the organization and regulation of prosthetic services to improve care for service users and the conditions under which practitioners work for their patients.

**Limitations of the study**

The present study is explorative because it is based on a small number of interviewees. We encountered difficulties in recruiting interviewees from insurance companies and the MD, probably because of the sensitive topic and problems with availability due to time constraints. The amputee sample was recruited through self-help groups. It may therefore include users who are more engaged and better informed than the average user population. The topic of reimbursement was mentioned in the study description, so it cannot be excluded that there is some bias toward users who have negative experiences with this topic. A national survey of the hurdles to accessing prosthetic care is needed to guide concrete measures for improvement.

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**Supplemental material**

No supplemental digital content is available in this article.

**References**


