User Innovation of Medical Technologies in a Developing Country Setting – the Case of Lower Limb Prostheses in Malawi

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I hereby declare that this thesis has not been and will not be, submitted in whole or in part to another University for the award of any other degree.

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Summary

As is well known, users can make significant contributions to innovations, including innovating themselves. However, much work on user innovation has focussed on developed countries. The question remains whether and how users innovate in a developing country setting. Bodies of literature that explicitly consider innovations in such settings emphasise the influence of limitations. This thesis therefore investigates how limitations shape the creation and sharing of innovations by users. This issue is analysed for medical technologies, because these can have different user groups, including patients, who have been little focussed on, even in developed countries.

In this setting, a focus on innovation as defined relatively inclusively is most suitable, and therefore the term 'changes' is often used rather than 'innovations' to express this inclusiveness. By comparing the changes made to the same kind of technology by different groups of users in different settings with different limitations, the influence of these limitations can be analysed. Therefore, data were collected on changes made by patients as well as orthopaedic technicians to lower limb prostheses in two orthopaedic centres in Malawi. First, observations were conducted of the production process for prostheses, followed by semi-structured interviews with orthopaedic technicians and patients, and with additional experts to understand the broader context.

It was found that patients and orthopaedic technicians did make many changes. Three kinds of limitations were identified, that influence these changes by users. Like users in developed countries, patients and orthopaedic technicians make these changes to fulfil their needs because available products and services are not satisfactory. Limitations both restrict what products and services are available to users, and also influence the characteristics of the creation and sharing of changes by users. Many users reported on efforts to share their changes with others despite the limitations, often due to a sense of professional collegiality and solidarity.

In summary, limitations help to explain how changes by users occur in developing countries, but also how any accumulation of such changes users make is restricted. Improving this situation could help less developed countries in making better use of any user innovations that do occur, and thus contribute to their development more generally.

Table of contents

List of figures

List of tables

List of Abbreviations

AT	Appropriate Technology
BMVSS	Bhagwan Mahaveer Viklang Sahayata Samiti (Organisation in India which produced parts and materials for the Jaipur technology used to produce lower limb prostheses)
CCAP	Church of Central Africa Presbyterian
CHAM	Christian Health Association of Malawi
FEDOMA	Federation for Disability Organisations in Malawi
HIV/AIDS	Human Immunodeficiency Virus Infection / Acquired Immunodeficiency Syndrome
ICRC	International Committee of the Red Cross
ISPO	International Society for Prosthetics and Orthotics
MACOHA	Malawi Council for the Handicapped
MAP	Malawi Against Physical Disabilities
MOA	Malawi Orthopaedic Association
NGO	Non-governmental Organisation
OECD	Organisation for Economic Co-operation and Development
QECH	Queen Elizabeth Central Hospital (central public hospital in Blantyre, Malawi)
TATCOT	Tanzania Training Centre for Orthopaedic Technologists
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

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1 Introduction

This thesis investigates how user innovation of medical technologies occurs in developing country settings, by analysing the creation and sharing of changes by users to lower limb prostheses in two orthopaedic centres in Malawi. While there are many medical innovations in use in developed countries, some developing countries have few medical innovations to support their healthcare. They may also suffer from a lack of local manufacturing and sufficient finance, which can mean being dependent on external donors to obtain such innovations. An alternative source of innovations could potentially be local user innovation. While the literature includes much work on user innovation to technologies in developed countries, few studies focus on developing country settings. This thesis tries to redress this balance by investigating the concept of user innovation in the context of medical technologies in developing country settings. As it is discussed to what extent innovations are created in developing country settings, the focus of this thesis is on changes users create to lower limb prostheses, instead of innovations by users, in order to include all innovative activity that occurs. On this basis, it is analysed whether and how this innovative activity manifests itself also in more major innovations. Conclusions can then be drawn on factors that shape user innovation of medical technologies in developing countries more generally. The results of this doctoral research should be interesting for scholars of user innovation; they reveal how user innovation occurs in settings little considered in the literature so far. For policy makers and other stakeholders, this work might contribute to the formulation of strategies to identify and encourage local development of technologies. This would help to improve existing medical technologies and could also lead to the creation of more major innovations.

This introduction discusses the situation related to the provision of medical innovations in different developing countries. It introduces the research questions and outlines the structure of the remaining chapters in the thesis.

1.1 The challenge of providing adequate medical innovations in developing countries

Most medical innovations are exploited in developed countries with good healthcare provision. In countries where this provision is at best basic, which applies to many developing countries, even what might be considered essential medical innovations may not be available. Many developed countries have good supplies of medical innovations due to a number of domestic manufacturers. These countries represent large enough markets for manufacturers to invest in the development of such innovations. The costs of this development can be high; development of medical technologies for example is expensive, not least because of the extensive clinical testing required by regulation (Blume, 1985: 175; Faulkner, 2009: 22; Roberts, 1989: 39–40). These innovations contribute to the high level of healthcare in these countries.

If medical innovations are used in developing countries[1], they can have a significant positive effect, such as in the case of imagining technologies like ultrasound which can help to diagnose symptoms quicker and thus make their treatment more targeted and effective (Steinmetz and Berger, 1999; Tshibwabwa et al., 2000).

However, there are major differences in the possibilities for developing countries to acquire medical innovations. Some developing countries are considered as emerging, for example India and China, and have local manufacturing capabilities and capacities (Kaplinsky et al., 2009). They represent large enough markets for domestic manufacturers who are well aware of the domestic conditions and therefore create adequate medical innovations (Howitt et al., 2012). There are also some developing countries that represent large enough markets for foreign manufacturers to create innovations. This applies to the case of countries where individuals have few resources to spend

[1] Countries categorised as developing are, based on the United Nations system, all the nations in Africa, Latin America, Asia except Japan, and Oceania except Australia and New Zealand (United Nations Statistics Division, 2010).

on medical innovations, but their high number makes it attractive for manufacturers to serve these markets (Kaplinsky et al., 2009; Prahalad and Hammond, 2002). These users constitute the so-called ‘bottom of the pyramid’ (ibid.).

Other developing countries may have little or no local manufacturing of medical innovations and represent markets that are too small to attract foreign manufacturers to innovate for them. These include low-income countries, which are largely overlooked by the innovation literature. The small body of work on developing countries mostly focusses on emerging countries such as India and China (Lorentzen and Mohamed, 2010).

These low-income countries are dependent on imported medical innovations not designed for their specific situation. Innovations from other emerging developing countries are likely to be best suited to these conditions (Kaplinsky, 2011). In addition, there are some non-profit programmes in place to develop medical innovations for developing countries, for example the Programme for Appropriate Technology in Health (Howitt et al., 2012). However, the number and financial means of these programmes are very limited.

For developing countries with no domestic manufacturing of medical innovations there are in consequence alternatives available from developed countries and emerging developing countries. However, their cost is often prohibitive and they may not be suitable for the local conditions. Some developing countries are depending on external funders for their healthcare provision, which makes long-term planning difficult and constrains their choices regarding their health system (Crichton, 2008; Walt et al., 2008). It can also restrict the choice of innovations to acquire and use, such as medical technologies (Free, 2004). Up to 80% of all medical equipment in some developing countries comes from donations (Howitt et al., 2012).

The alternative for developing countries is to create local innovations that are not dependent on the presence of manufacturers and research and

development structures. One source of such innovations is users (von Hippel, 1988). Users have needs which they try to satisfy in the first instance with available products and services. If these products and services do not satisfy users, some may then opt to innovate themselves in order to fulfil their needs. Some users then share these innovations with others. User innovation has been investigated in various fields, including medical technologies where the main focus is on medical professionals who have created innovations in the field of surgical equipment, for example (Lettl et al., 2006; Roberts, 1989). It is only recently that innovations by patients have been considered (Habicht et al. 2012).

Most work on user innovation focusses on developed countries. There is a gap in relating the insights from this work to settings in developing countries (Chataway et al., 2013). The presence of infrastructures, such as widely available electronic communication and local manufacturers and firms, plays a prominent role in this work, which suggests there might be differences in how user innovation occurs in developed and in developing countries (Cozzens and Sutz, 2012; von Hippel, 2005).

The focus on conditions present in developed countries applies to studies of both user innovation and innovation more generally. Innovation studies hardly consider the most low-income countries, although they would likely benefit most from the insights provided by such studies (Lorentzen and Mohamed, 2010). This bias might be due to the fact that most work on innovation focusses on the firm as a central unit of analysis and, in many developing countries, firms are not as central (Lorentzen and Mohamed, 2010). Innovation is often measured by numbers of patents, research and development, sales and trade; innovations created in developing countries may not be captured by these measures and therefore are often overlooked (Chataway et al., 2013).

The definition of innovation is also crucial. While it is worth investigating user innovation and innovation in general, in relation to developing countries, there is discussion as to whether innovation actually exists in such countries. It has been argued that innovation does occur in developing countries, but tends

to be overlooked. Thus, it is important to define innovation carefully. The main aspect of innovation is newness, but in relation to what? Different definitions of innovation give different answers – ranging from new to the world to new to the individual (Fagerberg, 2006: 4; Rogers, 2003: 12). If more exclusive definitions are used, this might result in some innovations being overlooked and occurring "below the radar" (Kaplinsky et al., 2009). Such innovations are often neither high-tech nor developed in the context of firms and manufacturers – which are central to most of the innovation studies literature, which in turn focusses on developed countries (Kaplinsky, 2011; Lorentzen and Mohamed, 2010; Pavitt, 2006). However, the cumulative effect of small improvements can result in major innovations (Fagerberg, 2006: 8; Kaplinsky, 2011: 197; Kline and Rosenberg, 1986: 282–283).

In order to include all creations by users when investigating user innovation in a developing country setting, a more inclusive definition of innovation is suitable. There is evidence of changes created by users to medical technologies, but this evidence is treated more as a set of anecdotes and not considered in a systematic way (Malkin, 2007b). In this thesis, the focus is on changes by users in order to include all relevant creations by users. This argument is elaborated further in Chapter 2.

While it is important to identify changes made by users, if they are not shared, their impact tends to be small. Therefore, in addition to identifying those changes, it is important to investigate how users share them. This is an important step in the accumulation of changes that might lead to more major innovations. This analysis allows conclusions about how to foster user innovation that helps poor users, which are not the focus of manufacturers. User innovation can in addition contribute to a country's development more generally. Therefore I identify changes and analyse how they are shared and if and how they cumulate and become more major innovations.

In order to investigate user innovation in developing country settings, I focus on the changes created by users to one particular medical technology. Due to this focus I can assess the accumulation of these changes by users. In addition,

this allows the identification of factors influencing those changes by allowing comparisons between changes created by different users in different settings. Investigating one particular technology also allowed me to familiarise myself with the technical details of the technology and to identify changes. This enhances the data reliability. The selected technology is investigated in the context of one particular developing country. This is appropriate because the circumstances of the use of a technology are paramount; no technology exists in isolation and the context of use needs to be taken into account when discussing it (Bonair et al., 1989; Kline and Rosenberg, 1986: 278). A focus on a single country enables adequate breadth and depth of the context analysis. This is important because certain conditions, such as the support available from donors, can have a direct influence on the provision of medical technologies in developing countries (Free, 2004; Walt et al., 2008).

Section 1.2 discusses how these aspects are investigated and introduces the research questions.

1.2 Research questions

The overall research questions driving this research are:

> Does user innovation of medical technologies occur
> in developing country settings?
> If so, what are some of the factors that shape it?

In order to address this overall research question, a number of supporting research questions have been formulated. These are:

1. What changes do users create to a medical technology in a developing country setting and why do they create these changes?
2. How and why do users share these changes?
3. Against what background and conditions do users create and share their changes?

4. Based on the above three supporting questions, what conclusions can be drawn about the factors that influence user innovation of medical technologies occurring in developing country settings?

In order to explore the factors that influence users' creation and sharing of changes and the accumulation of these changes, it is important to investigate these changes in detail. Then the changes identified can be analysed in order to understand the reasons for their creation. In order to assess the impact of these changes in the context analysed, I then examine how users share their changes. I assess the conditions that influence the medical technology and possible channels for sharing changes to it and their effect on the accumulation of changes. Following this, more general factors that shape user innovation of medical technologies in developing country settings can be identified.

1.3 Structure of the thesis

As discussed above, this thesis examines a medical technology in the setting of one developing country. The findings in the literature on medical technologies generally, and in developing countries in particular, are introduced in Chapter 2, which sets out the literature review and analytical framework. The implications of how innovation is defined are discussed. The literature on user innovation is reviewed and, in order to take account of the conditions related to innovation in developing countries, the concepts of appropriate technology, frugal innovation and grassroots innovation are discussed. All of these bodies of literature provide important insights. The enabling innovation framework is introduced to bring together those aspects to inform the data collection. The framework, with some minor adaptations, is shown to be suitable for the research.

Chapter 3 describes the research methods and discusses the rationale for employing a case study approach, the choice of a medical technology and a developing country setting, the data collection methods and data analysis, and

elaborates on how the enabling innovation framework informs the choice of technology and setting and the instruments for data collection.

As already mentioned, no technology exists in isolation, and to fully understand the changes users create to lower limb prostheses, it is necessary to consider the context of the technology in detail. Chapter 4 provides in-depth information on the conditions surrounding lower limb prostheses in Malawi, including the national context, specific information on the two orthopaedic centres, and the technologies used there to produce lower limb prostheses.

Chapter 5 describes the changes created by orthopaedic technicians and patients and why they were created. Chapter 6 focusses on how these users share the changes they have created and in addition considers the connections between users and other important actors that generally enable the sharing of changes.

Chapter 7 discusses the insights from the data analysis described in Chapter 3. Limitations are identified as factors that influence changes by users. They are classified into three different categories, and how they influence the creation and sharing of changes by users is then examined. Insights from work on user innovation are related to these findings by demonstrating the way limitations influence the process of user innovation. Specific attention is paid to the sharing and accumulation of changes in light of the existing limitations.

Chapter 8 concludes this thesis by summarising its contributions. It provides some policy recommendations, discusses the limitations of the research and suggests avenues for future research.

2 Literature review and analytical framework

User innovation of medical technologies in developing country settings and the factors that shape it are the focus of this thesis. This chapter begins by introducing important characteristics of medical technologies and, more specifically, of medical technologies in developing countries. I discuss different concepts of innovation, including user innovation, appropriate technology, frugal innovation and grassroots innovation. While the concept of user innovation relates directly to the changes users make to a technology, it does not refer specifically to a developing country context. Other concepts of innovation are considered in order to include additional aspects relevant to innovations in developing countries. Following this review of the relevant literature, I propose to employ the enabling innovation framework to inform the data collection and analysis.

2.1 Characteristics of medical technologies

To set the context for this research, I describe the main characteristics of medical technologies in general and specifically for developing countries. The context is important because the aim is not only to understand how but also why changes are created and shared by users. To understand why users decide to create and share changes, it is necessary to consider the conditions under which the users make their decisions. In addition to the considerations in the literature, Chapter 4 elaborates on the conditions surrounding the specific kind of medical technology and country chosen for this research. Here, the general conditions are considered.

Medical and other technologies are subject to the uncertainty surrounding the introduction of a new technology. This uncertainty is especially great for medical technologies and persists after their introduction (Gelijns et al., 2001: 919–920). This is in part attributable to the fact that a treatment for one disease can also have an effect on some other part of the body. Furthermore, it is not

clear how patients' different genetic characteristics influence the outcome of treatments. Finally, patients can have very different lifestyles, which can further influence treatment outcomes and add to the aforementioned uncertainty (ibid.).

Medical technologies are subject to specific conditions. There are three important points in this respect: the purchaser-user-consumer split, regulation and attitudes to medical technologies.

The purchaser-user-consumer split emerges because these three functions may be carried out by different groups, while in the case of many consumer products they are fulfilled by the same entity (Hopkins, 2004: 9). Many medical technologies are used by medical professionals (Gelijns and Rosenberg, 1994: 32). However, some technologies are also used by patients. In some cases, patients pay for their medical treatment and, therefore, for the technology; in other cases, these payments are the responsibility of a third party (ibid.). This may be the state, for example, the National Health Service in the United Kingdom, or some other government healthcare provider, or a private insurance company. The amounts of reimbursement for treatments and technologies received by the medical professionals are fixed by these entities which thus influence the healthcare market and the purchase of technologies.

Apart from provision of healthcare, government is involved in regulating the development, testing and use of some medical technologies (Blume, 1985: 175; Faulkner, 2009: 22; Roberts, 1989: 39–40). The development and testing are highly regulated and, in many cases, expensive (ibid.). Since the development costs of medical technologies are often very high, manufacturers need to be convinced of the existence of a large enough market to warrant this investment. Since some medical technologies influence life-threatening situations and have profound effects on the life quality of patients as well as being inherently uncertain, regulation is necessary to protect patients from harm. The association between medical technologies and life and death results in the attitude towards them being distinct from other technologies. Medical innovations have been described as almost hallowed technologies according to Blume (1992: 3), meaning that they are greatly respected – more so than other

technologies. Cultural perceptions and traditions therefore have a substantial influence on medical care, including medical technologies. This is demonstrated in the attitudes of patients towards medical professionals in whom they can have an inherent trust (Blume, 2010: 148–149). However, today, this trust is not as unquestioning as in the past. Patients are better informed, partly due to the internet and, therefore, as 'informed consumers', are much more critical (Blume, 2010: 12; Gelijns et al., 2001: 922–923). This can be seen in the rise of patient organisations, such as self-help groups, and their increasing influence. Patient organisations have even been described as the 'new force in contemporary politics' (Blume, 2010: 105). While the effect of these developments is greater in developed countries, they are becoming increasingly important in developing countries as well (ibid. p.109).

One example of the influence of patients is illustrated by the case of the cochlear implant (Blume, 2010). In the course of the development of new technologies, certain assumptions are made about future users, which may prove valid or not (ibid. p.12). In the case of the cochlear implant, the deaf people for whom it was designed did not identify with the users envisaged by the firms developing the device; they had different behaviours, roles and relationships (ibid. p.52). This led to an initial lack of enthusiasm for the technology and, eventually, strong opposition to it (ibid. pp. 52, 69, 73). This example shows the importance of the user and his or her cultural background for a medical technology. It also explains why medical technologies developed in and for developed countries may not be used in the same way in developing countries: both the country context and the characteristics of the users are likely to be different. Thus, including the user in the technology development process is especially important in the case of medical technologies, as will be elaborated on in Section 2.2.1 on user innovation.

To add to the complexity, the specific characteristics of medical technologies are connected to each other. For example, the development of a medical technology and the particular characteristics of the market are connected. If users participate in the development process, they will be more likely to be convinced about the innovation and may have a stake in its success.

They will thus be more likely to promote it to both patients and the third-party payers who decide about the reimbursements for technologies and treatments. The market channels through which medical technologies typically spread include consumer participation, networks of medical training and professional collegiality (Blume, 2010: 101–103). Also, the particularities of the market depend on the distinction between users, consumers and purchasers as well as the presence of regulation (Gelijns and Rosenberg, 1994: 32). Patients as the end-users seldom decide about which technology to use, partly due to their lack of knowledge (Faulkner, 2009: 22). It is the medical professionals who take such decisions and they, in turn, are often limited in the decisions they can take, for example by hospital regulations (ibid. pp.32, 34).

These special characteristics of medical technologies are also reflected in the particulars of their development processes. The involvement of users is essential for their development; indeed, it is often a medical professional who has an idea for an innovation and in many cases develops the prototype (Lettl et al., 2006: 266; Roberts, 1989: 36). Medical manufacturers are aware of the importance of users and include them in their development processes, feeding their experience back into the ongoing development (Blume, 2010: 35; Gelijns and Rosenberg, 1994: 32; Roberts, 1989: 34–37). This highlights the importance of involving users in the innovation process. While the focus traditionally has been on innovation by medical professionals, such as physicians, some recent work highlights innovations made by patients (Habicht et al., 2013). The system of innovation for medical technologies has been described as a distributed innovation system involving independent research activities that need to be linked through close collaboration (Blume, 2010: 174; Consoli and Mina, 2009: 310). Linkages and knowledge flows between organisations and clinical expertise are important for innovation (Thorsteinsdottir, 2007: 672). Learning in practice, for example through such clinical expertise, is an important part of many medical innovations (Morlacchi and Nelson, 2011: 523).

While medical technologies have much in common with other innovations, this section has shown that in some respects they differ significantly due to their

inherent uncertainty, the number of different groups of actors involved, the attitudes to health and medical care of some of these actors, and the regulations in place. These characteristics will be related later in this chapter to the suitability of the enabling innovation framework proposed for this work. This research is about medical technologies in developing countries and the important characteristics of medical technologies in this context are discussed in the next section.

2.1.1 Characteristics of medical technologies in developing countries

Just as medical technologies can differ significantly from other technologies, their use in developing countries can differ from their use in developed ones. There are several aspects of medical technologies that need to be considered in the context of developing countries, which may influence their use and the changes made to them. These include how healthcare is funded, the infrastructures that exist, and the specific cultural differences.

The first important aspect is the heavy reliance of many developing countries on outside funding for healthcare (Walt et al., 2008). In some countries, as much as 70% of the budget for healthcare is estimated to come from outside donors (Walt and Gilson, 1994). This imposes limitations on medical professionals and patients because it restricts the choices related to the type of healthcare that is administered, including the choice of medical technologies. This funding situation also makes it difficult for the recipient countries to establish long-term healthcare programmes, since funding may be withdrawn at short notice at the discretion of the donor (Crichton, 2008). Withdrawal of donor support may lead to a programme being discontinued (Mkandawire et al., 2008). Also, the influence of donors can lead to acquisitions of medical technologies that the donors consider suitable, but which are of limited or no use to the users in developing countries (Free, 2004). Since many developing countries lack purchasing power, they may also lack the influence on the types and quality of services that are eventually delivered (Walt et al.,

2008). These aspects can restrict or prevent the use of the medical technologies in developing countries.

Poor infrastructure is a characteristic of many developing countries. Lack of transport infrastructure is problematic in relation to transporting patients as well as spare parts for medical technologies (Malkin, 2007b). Insufficient supplies of electricity, clean water and trained personnel can hinder the use of a technology that has been acquired (ibid.). Lack of manufacturing and research and development infrastructures lead to the need to import medical technologies, often from developed countries (ibid.). Importing technologies from developed countries used to be the prevailing mode for promoting development and this mode is still common for medical technologies (Bonair et al., 1989: 772; Malkin, 2007b). However, imported medical technologies can lead to serious issues. When a medical technology is imported from a developed to a developing country, Western cultural perceptions of disease[2] inherent in the technology are also imported (Bonair et al., 1989). An example is the use of ultrasound for pregnant women, which encompasses the Western idea of the foetus being regarded as an independent person (Tautz et al., 2000). If the cultures of the exporting country, whether developed or not, and the importing country differ significantly, this may prevent or limit the use of medical technologies. Although these effects have long been known, it is still often assumed that imported medical technologies will be adopted and if there is any prior consideration of influencing factors, this is generally confined to infrastructural aspects (ibid.). Further research is only carried out if a technology is not adopted, as in the case of family planning programmes (ibid.). In general, there seems to be more sensitivity about and therefore more research on other aspects, such as cultural influences, than infrastructural ones, in the case of technologies related to sexuality (Meyer-Weitz et al., 1998; Mhlongo, 2001; Omo-Aghoja et al., 2009). Again, the use of such a technology may be restricted or prevented if these aspects are not taken fully into consideration. As a further result of the distance between manufacturers and users, the connections between them may be relatively weak. The influence of manufacturers is also affected by the

[2] As reflected in the medical paradigm predominant in the West, including such elements as the separation of mind and body.

regulations in place in many developing countries, which may be weaker than those in developed countries (Walt et al., 2008). On the one hand, this might make it easier for manufacturers to introduce new technologies, on the other hand, it may make it more difficult for them to enforce certain patterns of use, such as not using pre-owned equipment.

As shown above, importing medical technologies can be problematic. The use of these technologies may be hindered because they were developed for different circumstances, infrastructural as well as cultural. This is one of the reasons why this research is centred on what users do with these technologies to make them more suited to their use, that is, what changes they create and how and why, and why they share them. Investigating these issues calls for an exploration of how these changes or innovations come about more generally.

2.2 Concepts of innovation

This section begins with more general considerations on the nature and definition of innovation, and elaborates on various concepts of innovation important for this work.

It is widely known that some users create innovations to certain technologies. For users in developing countries, the question is, given their often limited education and capabilities, if they also create innovations. There are many different definitions of the term 'innovation', but in all of them newness is a key aspect (Cozzens and Sutz, 2012: 30; Fagerberg, 2006; Kline and Rosenberg, 1986: 294).

At one end of the spectrum are exclusive definitions, that only consider changes to be innovations if they are the first attempt to convert an idea or invention into practice – in other words, they are new to the world or at least new to the market (Fagerberg, 2006: 4; Lorentzen and Mohamed, 2010: 3–6). Less exclusive definitions consider a change to be an innovation if it is new to the firm or the individual (OECD, 1992). One such definition is that "an

innovation is an idea, practice or object that is perceived as new by an individual or other unit of adoption" (Rogers, 2003: 12). In this definition, a change constitutes an innovation if it is new for the person who innovates, regardless of its global novelty. These more inclusive definitions are important in order to explicitly include innovations in developing country settings and by groups often overlooked, such as women (Appleton, 1995; Lorentzen and Mohamed, 2010). Some definitions of innovation are not suited to the present research, since they consider firms to be the unit of analysis; however, firms may not be as prominent in developing countries as in developed ones. Concentrating on 'absolute' newness can also create problems with regard to such developing country settings and result in the researcher overlooking important changes or innovations (Cozzens and Sutz, 2012). The importance of an innovation in a developing country setting may not be recognised and it may thus be below the radar (Kaplinsky et al., 2009).

Definitions at the inclusive end of the spectrum cover more changes. One such inclusive definition of innovation is “any change, however small, in the skills, techniques, processes, equipment type or organization or production that enables people better to cope with or take advantage of particular circumstances” (Appleton, 1995: 5–6). This definition relates to the newness of an innovation in terms of it being a 'change', which, by definition, creates something different and therefore new, but without this newness being qualified further.

While the appropriate level of inclusiveness is debatable, it is clear that a more inclusive approach to the investigation of innovation will ensure that no important creations by users are overlooked and that creations by less considered groups, such as patients, are also included. To reflect this inclusiveness, while also being cautious about more exclusive definitions of innovation, the term 'changes' is used in this thesis to refer to creations by users. I therefore propose a working definition of a change as something that is created by users which is different from the standard, whether it relates to the process, the artefact or the use of a technology. Chapter 3 on methodology

further elaborates how this working definition is employed practically in order to gather data to address the research questions in this thesis.

In addition to the question of inclusiveness, even those innovations which initially might seem small can have a profound effect. Within the category of innovation, a distinction is often made between incremental and radical innovation, with incremental innovation being on a much smaller scale (Fagerberg, 2006: 7–8). However, incremental innovations can be cumulative and eventually have a larger effect than radical innovations, such as in the realisation of economic benefits (Fagerberg, 2006: 8; Kaplinsky, 2011: 197; Kline and Rosenberg, 1986: 282–283). Many major innovations indeed consist of an accumulation of small incremental changes (Kline and Rosenberg, 1986).

As mentioned earlier, there are several innovation concepts that help to shed light on the changes created by users. User innovation emphasises users, in addition to manufacturers, as possible sources of innovation. As developing country settings are the focus of this research, innovation concepts that take account of the conditions in such settings are of special interest. In particular, I consider the concepts of appropriate technology, frugal innovation and grassroots innovation. The concept of user innovation is introduced first and discussed in general terms as well as specifically for the case of medical technologies.

2.2.1 User innovation

The concept of user innovation is an important one for this work, as mentioned above. It is part of the broader concept of user-driven innovation, although same authors also use the two terms synonymously (Lettl, 2007). When user-driven innovation is defined as a broader concept, its focus is including the user in the innovation process, often from the point of view of the manufacturer or firm (Bisgaard and Høgenhaven, 2010; Hjalager and Nordin, 2011; Renders and Sleeckx, 2012). Bisgaard and Høgenhaven (2010) define four distinct methods to achieve use-driven innovation: user exploration, user

tests, user participation and user innovation. The inclusion of users in the innovation process can be achieved indirectly as well as directly with these methods.

User exploration and user tests are used in order to include users indirectly into the innovation process (ibid.). User exploration uses ethnographic methods, and is focussed on observing users in situations where they use an innovation to understand their actions and habits in a respective cultural context. In this way, knowledge about their needs can be gained, including needs the users themselves may not be aware of. This method can be executed in the very early stages of developing an innovation, or when an innovation prototype already exists. User tests on the other hand are usually employed only when a prototype of an innovation has already been created (ibid.). Users then test this prototype and give feedback to the manufacturers. This feedback may then be included into the innovation in the form of minor adjustments, as more major adjustments at this stage of the innovation process would most likely be too costly.

A direct involvement of users in the innovation process can be achieved with the methods of user participation and user innovation. User participation describes a cooperation of users and manufacturers, in which they include the users in their innovation development process (ibid.). This is mostly done in the form of introducing users to probes related to the innovation, so manufacturers can uncover previously unacknowledged needs. User innovation is not only focussed on identifying users' needs, but also the solutions they develop and provide themselves to satisfy these needs (ibid.). One avenue for manufacturers to exploit this potential is to conduct expert workshops with users who are especially knowledgeable about an innovation.

In summary, all four methods bring users and manufacturers together in order to tailor innovations to users' needs. As shown above, the methods of user exploration, user tests and user participation rely on input and methods which usually only manufacturers or respective research and development structures can provide. The conditions in which this work is situated, as

elaborated on in Chapter 1, however, are such that neither manufacturers nor research and development structures for medical innovations are locally present, which make it unlikely that such methods will be employed with local users. The method of user innovation, however, can also be employed solely by users. For this work, of the four methods of user-driven innovation, user innovation is therefore the most relevant one. This concept is therefore introduced in more detail below.

Firms used to be seen as the primary sources of innovation (von Hippel, 1988). The realisation that the success of an innovation was highly dependent on a correct understanding of the needs of the users of the innovation caused this focus to change (von Hippel, 1976). In certain fields and situations the sources of innovation have been found to differ from firms and to vary significantly (von Hippel, 1988: 3). As Eric von Hippel shows in his various works, such as that on scientific instruments, users are often an important source of innovation (ibid. pp.3, 5). While empirical evidence showing that users innovate was being collected as early as the 1960s, von Hippel was arguably the first to focus on the central role of users as innovators (Bogers et al., 2010: 859; Freeman, 1968). In the term 'innovation', von Hippel includes not only the first innovation which results in a prototype, but also subsequent improvements to the technology (von Hippel, 1988: 12). It is well known that the cumulative effect of small improvements can equal or surpass major innovations. When a number of small improvements are made to a product, the resulting outcome can look very different to the original. A distinction is made between manufacturers and users as two major sources of innovation. Users benefit from an innovation either directly or indirectly. In the first case, the benefit is derived by the end-user or consumer (Bogers et al., 2010: 859–860). Users who profit indirectly are called intermediary users (ibid p.859). These intermediary users profit from an innovation by using it to produce goods and services which they in turn sell (ibid.) In the case of an electric light switch, for example, users can be homeowners or electricians, the latter being intermediary users. Both use the innovation very differently and, therefore, the adaptations they make will also be quite different (von Hippel, 2005: 3). This example shows that the question of who the users of a technology are is not trivial (Oudshoorn and

Pinch, 2005b: 6). Depending on who the developers of a technology take into account when creating the technology, the result can look very different (ibid.). This is elaborated further for the specific case of medical technologies below. The reasons why users innovate are related to a desire to have their needs fulfilled, and their abilities to innovate because of their distinct knowledge (Bogers et al., 2010). This knowledge stems from the experience of users in the use of the technology, which may be greater than that of its manufacturers. In the case that the products and services being offered by manufacturers do not meet users' needs, users may try to innovate to solve their own particular issues. One reason for these needs being unmet is the heterogeneity of users' needs, which can make it difficult for manufacturers to meet them based on their standard products and services which, in turn, are based on economies of scale in production. Some users prefer customised products targeted precisely to their particular needs rather than a 'one size fits all' approach – and some innovate themselves to create such customised products (von Hippel, 2005: 33).

Building on von Hippel's work, user innovations in a large number of highly diverse fields, such as open-source software and extreme sports equipment, have been studied (Bogers et al., 2010). Since von Hippel's 1988 book, user innovation has spread: users are innovating better and faster because of the better availability of tools, such as CAD software (von Hippel, 2005). There is an emerging system of what could be called user-centred innovation – although in many instances the focus on manufacturers as the main source of innovation persists, such as in some innovation policies (ibid.). For products such as open-source software where the design is simultaneously the product, users can develop, share, maintain and consume the product without the presence of a manufacturer at any stage (ibid.). For user innovations that are manifested in physical products, to be distributed generally, manufacturers are considered to be typically necessary (ibid.). However, these need not be existing manufacturers; funding and support can enable some user innovators to build their own manufacturing capabilities and begin production of their own innovation (Habicht et al., 2013; Shah and Tripsas, 2007). The diffusion of user innovations benefits others, and they may eventually become valuable for

society as a whole. In consequence users with similar needs do not have to expend resources to develop a similar innovation, which frees these resources for investment in other innovations (von Hippel, 2005). Most users do diffuse their innovations, often without receiving any compensation for doing so. One of the reasons proposed for this so-called 'free revealing' is that it is the best way for users to benefit (ibid.). They can diffuse their innovations at relatively low cost by exploiting electronic communication means (ibid.). If a producer takes up their innovation they will benefit significantly, and it will diffuse further. In some cases, a standard may be set by the manufacturer (ibid.). This may increase the inventor's reputation among his or her peers. This aspect of diffusion was established when diffusion was shown to be a social process (Coleman et al., 1966; Rogers, 2003). It has been argued that the free diffusion of their innovations is the most rational way for users to benefit (von Hippel, 2005).

In addition to the more general considerations of user innovation elaborated above, there are several studies specifically on medical technologies and user innovation, some of which are discussed next.

Users have a very important role in the development of medical technologies, as discussed in Section 2.1. Who the user of a particular medical technology is needs to be considered since the purchaser-user-consumer split implies that there are users, i.e. medical professionals, and consumers, i.e. patients, who, depending on the technology in question, also may use it (Hopkins, 2004: 9). Users fall into two categories in much of the user innovation literature: intermediate users and consumer or end-users (Bogers et al., 2010: 859–860). The distinct characteristic of the former is that they use an innovation in order to produce a good or service which they then sell to end-users. This applies to many medical professionals, who use an innovation not for themselves, but in order to help patients and to get paid for this service. Medical professionals are the exclusive users of some medical technologies, such as surgical equipment. Other medical technologies are also used by patients, who are mostly the end-users of these technologies. Both medical professionals and patients create changes and innovations to these technologies.

Medical professionals can and often do contribute to medical innovations; in some cases they may create radical innovations (Lettl et al., 2006: 266; Roberts, 1989: 36). One of their reasons for doing so is that those innovations are very relevant for their professional day-to-day work (Lettl et al., 2006: 266). In the case of patients, their personal wellbeing may depend on the existence of an appropriate medical technology. In developed countries, this can be an issue especially for patients with rare diseases. If a disease is so rare as not to represent a large enough market for a manufacturer, then the technology will not be produced. In such situations, some patients have innovated and some have established firms to produce their innovations (Habicht et al., 2013). In the literature, attention to patients as innovators is quite recent; the focus previously was on innovations by medical professionals (ibid.). Patients have perhaps been overlooked because of their heterogeneity. This heterogeneity of patients is reflected by their needs, which can lead them to create user innovations, as described above. Also, patients have less influence than medical professionals on health systems. However, with the emergence of structures such as patient organisations, this situation is changing, as discussed in Section 2.1 on the characteristics of medical technologies.

As mentioned above, for innovations that are manifested in a physical product, such as medical technologies, in many cases manufacturers are considered necessary for the diffusion and ultimately for the success of a user innovation. The medical professionals are often in direct contact with these manufacturers, whereas the connection between manufacturers and patients is often weak or non-existent. The medical professionals can and do establish a connection between the manufacturers and the patients on behalf of the latter (Thorsteinsdottir, 2007: 661). However, they have their own agendas, which is why they should not be the only means of relating patient concerns to manufacturers (ibid.). Other channels to bridge this gap include patient organisations, religious groups, bioethicists, governmental procurement policies and regulatory systems (ibid.). There has been some dispute over the legitimacy of patient organisations to speak on behalf of users, however (van Kammen 2005, p.154). The issue here is what can be considered the user's perspective. Some patient organisations stress that it is not representativeness

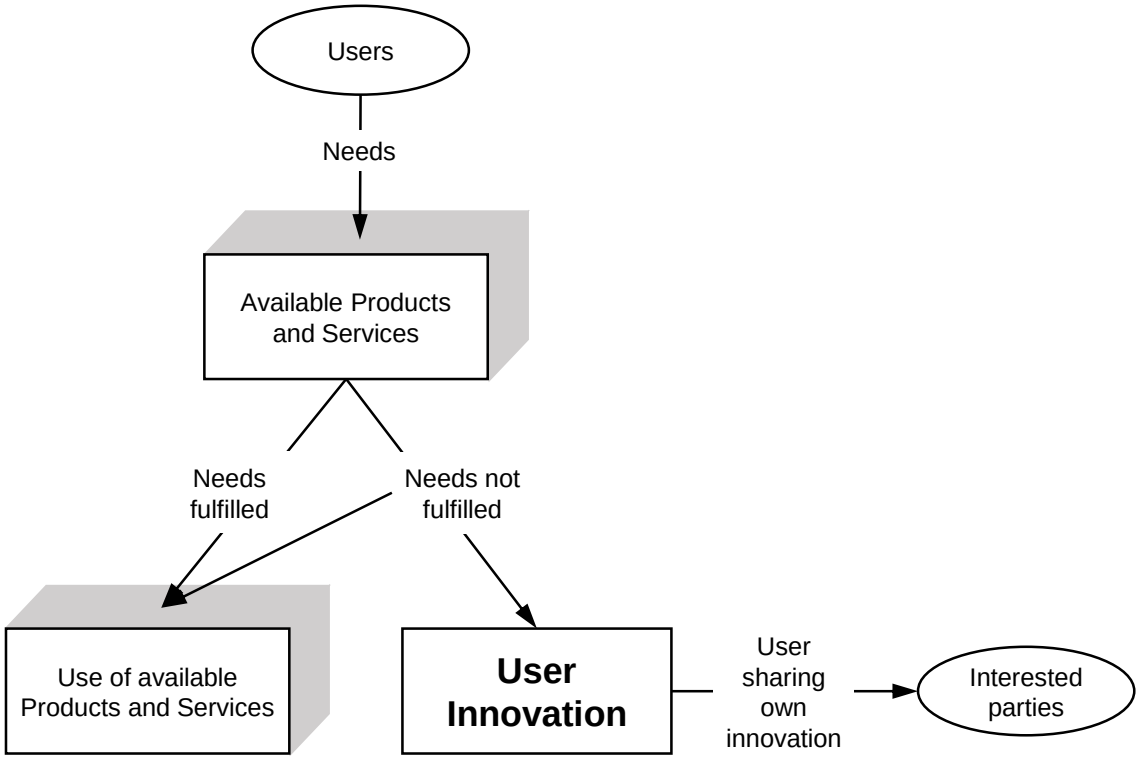
that is key, but the raising of issues that are important to users and otherwise might not have been raised (ibid. pp.155, 169).

Apart from patients and medical professionals, hospital administrators and patients' families can also be users (Oudshoorn and Pinch, 2005b: 6). How relevant each of these groups of users is depends on the specific medical technology in question. The more visible the technology to patients, the more important will be their and their families' influence. The above description shows that users are important for medical technologies, not least because there are different groups of users who may have very different views and objectives.

Following this discussion of important insights from the literature on user innovation, the basic process of user innovation is recapitulated and depicted. This will later serve as a basis to draw conclusions regarding the influencing factors on user innovation of medical technologies in developing country settings in Chapter 7 Section 7.3.

In the concept of user innovation introduced above, users are considered to have needs which they try to fulfil in the first instance using the products and services available to them. In many cases, these are satisfactory. However, in some cases users are not satisfied with the available products and services and some users then try to innovate in order to create a product or service that meets their needs. In addition to creating innovations, users often share the innovations they have created. As mentioned above, many users who reveal their innovations do so without receiving compensation, using means such as electronic communication. This free revealing might indeed be the best way for a user to benefit from his or her innovation. Further beneficiaries are other users, with similar needs. In some cases, users share physical products. In these cases they produce the innovation themselves – either because production requires minimal facilities, or because they have built their own manufacturing capacities. Interested parties might also be manufacturers or firms, to which users disclose their innovation in order for them to produce and diffuse it. Figure 2-1 provides my depiction of this fundamental process which leads users to create and share their innovations.

Figure 2-1 Model of the basic process of user innovation



Source: Constructed by the author

As shown above, the literature on user innovation is fundamental for answering the research questions in this thesis related to the creation and sharing of changes by users. There is a large body of work on user innovation and, more specifically, user innovation in relation to medical technologies, but very few studies focus on the context of developing countries (Chataway et al., 2013). This literature focusses mostly on the conditions in developed countries, as evident from the above elaborations, including the central importance of manufacturers and of electronic communication to share user innovations. There is considerable potential for more research on developing country settings. Next, I introduce concepts that take explicit account of innovation in developing countries: appropriate technology, frugal innovation and grassroots innovation.

2.2.2 Appropriate technology

Notions about appropriate technology (AT) started to emerge in the 1960s. At that time, economists were beginning to question the then dominant assumption that economic growth led automatically to economic and social development (Kaplinsky, 1990: 2). In reality, there might have been some progress in economic terms, but the living conditions of poor people were getting worse (ibid.). One of the causes of this was the use of inappropriate technology (ibid.). The idea of appropriate technology took off with the work of E.F. Schumacher, in his important publication *Small is Beautiful* (Bound and Thornton, 2012; Schumacher, 1980). In this book, he elaborated on the inappropriateness of using capital-intensive, large-scale technologies from developed countries, in developing countries (ibid.). This represented a step away from the then usual practice of transferring Western technologies without much thought to their suitability for a developing country (Ndongko and Anyang, 1981; Smith et al., 2012). However, in the case of medical technologies this practice tends still to prevail (Malkin, 2007b). The AT movement grew, with a large number of non-governmental organisations being founded to promote AT (Kaplinsky, 1990: 16). While some exist to this day – the Intermediate Technology Group, now known as Practical Action, being a case in point – the objectives of the movement have changed over time. Initially, it had a clear political focus; subsequently the institutions have focussed more on the dissemination of information (ibid. pp.16, 20). These institutions have also developed and helped to diffuse new technologies. Later on, AT returned to the political agenda (ibid. p. 20).

When considering whether a technology is appropriate or not, it is important to note that its appropriateness can only be seen in relation to its circumstances (Kaplinsky, 1990: 4, 40). The same technology can be appropriate in one situation and inappropriate in another. Technologies that can be described as 'fluid', in the sense that they are adaptable, flexible and responsive, can therefore be appropriate in many different circumstances (Laet and Mol, 2000: 225). This appropriateness of a technology for a given situation can be considered from three different perspectives: economic, social and

environmental (Kaplinsky, 1990: 30). The economic approach focusses on costs, outputs and scale of production (ibid. pp. 31-32). The social approach is based on social characteristics and tries to ensure the compatibility of the technology with the users' local cultural and social environment (ibid. p. 36). The environmental approach is concerned with minimising the negative impact of a technology on nature. This approach was especially important for the beginnings of the AT movement, helped by publications such as *Silent Spring* by Rachel Carson, which brought environmental issues to the forefront of international debate (Carson, 1960; Kaplinsky, 1990: 14, 37). In addition, the context of implementation and the distinction between private and social costs and benefits are other dimensions that play an important part in judging the appropriateness of a technology (ibid. p. 30).

Since the work described above, which was mainly done in the 1990s, recent developments, such as the dramatic rise of some countries in Asia, have had a profound impact (Kaplinsky, 2011: 194). This rise is relevant in two ways. Firstly, people at the bottom of the income scale now have surplus income to spend, whereas before they lived hand to mouth (ibid. p.199). These consumers at the bottom of the income scale, the so called 'bottom of the pyramid', have very small amounts of surplus income, but because they are so numerous they represent large potential buying power (Prahalad and Hammond, 2002: 49).

Secondly, some Asian countries have been building capacities and capabilities, and have become innovators (Kaplinsky, 2011: 198–199). The innovations stemming from other developing countries may be more appropriate for developing countries than those from developed countries (ibid. p. 193, 201, 202). Developing countries differ, but have some important characteristics in common, such as high economic constraints. Newly emerging developing countries may therefore prove to be the sources of more appropriate technologies (ibid. p. 193, 201, 202).

Innovations originating from such developing countries have been investigated drawing on the concepts of frugal innovation and grassroots

innovation. Since this research focusses on the changes made to a medical technology in a developing country setting, both concepts can provide important insights and are introduced in the next section.

2.2.3 Frugal innovation and grassroots innovation

As described above, the importance of the concept of AT has declined in recent decades and been succeeded by alternative concepts, such as frugal innovation and grassroots innovation (Bhaduri and Kumar, 2010: 30; Bound and Thornton, 2012: 18). Both these concepts explicitly consider innovations from developing countries.

Frugal innovations are innovations that are available at significantly lower cost than comparable alternatives, and which sometimes outperform those more expensive alternatives (Bound and Thornton, 2012). The limitations existing in developing countries are turned into an advantage through clever use of available resources to lower the costs of an innovation (ibid.). Frugal innovations often stem from manufacturers, or individuals who take advantage of their professional background to create such innovations. An example of this is an innovation from India. In the 1960s, an orthopaedic surgeon and local artisans developed the Jaipur technology with input from patients (Srinivasan, 2002). This is a technology to produce lower limb prostheses named after the Indian city in which it was developed. Use of local materials, such as rubber and metal sheets, made this technology at the time much cheaper than prostheses from developed countries (Sethi, 1989). The technology also provided other additional advantages including a water resistant foot which did not need a shoe, which is important in a culture where going barefoot is customary in many contexts, such as in India (ibid.). The Jaipur technology is still used today, and is discussed further in the succeeding chapters of this thesis.

Grassroots innovations also deal with limitations by turning them into advantages, and use available resources (van der Boor et al., 2012). The innovator might be an individual from a poor background, who most often is not

part of a structure that supports innovative activity (Gupta et al., 2003). The innovation might be designed to solve a local problem being experienced by the innovator. The low cost of the innovation is not the main focus; the objective is to fulfil a particular need in a given circumstance. The outcome is, however, often a low cost innovation. Some understand grassroots innovations as minor or incremental changes to existing technologies (Bhaduri and Kumar, 2010). Grassroots innovations are not limited to developing countries, and occur also in developed countries (Smith, 2013). Connected to the concept of grassroots innovation are movements whose goal is to promote and diffuse these innovations, similar to the AT movement, such as the Honey Bee Network (Gupta et al., 2003). Examples of grassroots innovations are several devices developed by rural farmers in India to scare birds to protect their crop (ibid.).

While there are some differences between these concepts, there is also a great deal of overlap – some innovations can be described as both frugal and grassroots innovations at the same time[3]. An example is a windmill made from bicycle spare parts and scrap, built by William Kamkwamba, a young Malawian man (Kamkwamba and Mealer, 2009). He educated himself after having to drop out of school, using textbooks from the local library. He constructed a windmill to supply electricity to his parents' home (ibid.). This is clearly a grassroots innovation; William Kamkwamba was an individual innovating without any outside support from manufacturers or the like. At the same time, this is a frugal innovation since the windmill is significantly cheaper to make than comparable models would be to purchase. In addition, the windmill has vast potential to bring about positive change for many people in rural Malawi with no access to electricity.

Both concepts, frugal innovation and grassroots innovation, are helpful, because they point to innovations stemming from sources other than manufacturers in developed countries. Since the focus of this thesis is a

[3] In addition to the more general concepts of frugal innovation and grassroots innovation, there are also terms which are used locally for innovations which are stimulated by existing limitations, such as Jugaad used in India and Jual Kali used in East Africa (Cozzens and Sutz, 2012; Radjou et al., 2012).

medical technology in a developing country setting and the changes created to it by users, this alternative view is important. Frugal and grassroots innovation take the locus of development of innovations to the developing countries and, at the same time, emphasise that the technology should be appropriate for the circumstances of its use.

While the work on frugal innovation and grassroots innovation offers important insights into innovation in developing country contexts, it is not specifically concerned with innovations by users. On the other hand, in the concept of user innovation, users are central while developing country settings are seldom investigated. Therefore, no single innovation concept introduced above takes into account all the aspects relevant for this research, yet all provide different insights that need to be considered to shed light on the phenomenon under study. In order to achieve this and thus create a suitable basis for the data collection, the enabling innovation framework is introduced. I demonstrate how this framework can inform the investigation of user innovation of medical technologies in developing country settings.

2.3 The enabling innovation framework

In order to identify a framework that encompasses all the aspects mentioned above, farmer-first frameworks were considered; these have a long tradition of explicitly taking farmers as end-users into consideration in all steps of the technology development process (Chambers and Ghildyal, 1985). What distinguishes those models from others is that the research and design of a technology is taken into the field to assess the conditions of use and to involve users directly in the process. The users are important throughout the whole development process, from the definition of the problem to deciding when the problem has been sufficiently solved with the developed technology. One of these frameworks is the enabling innovation framework, which is especially suitable for this research because it considers changes that users make to a technology themselves, including changes made without any contact to manufacturers (Douthwaite, 1999). Furthermore, it shows how users share

changes and how these changes accumulate to form more major changes and innovations. This framework not only provides details on the process of users creating innovations, it also considers users sharing them. By providing these details, this framework can serve as a basis for investigating how and why users create changes, and thus user innovation of medical technologies in a developing country setting more generally.

The enabling innovation framework is introduced in detail below. I consider the framework and the case studies that formed the basis for its development. The framework serves several purposes. It provides details of the process of users creating changes, which will aid data collection. It shows also how users share changes and how those changes can accumulate. The case studies on which the framework is based provide important insights for the later assessment of the specific type of medical technology and developing country setting that would be suitable for this research. Details of these aspects of data collection are elaborated in Chapter 3 Section 3.3. I show also how the framework relates to medical technologies, the focus of this work.

2.3.1 Details of the enabling innovation framework

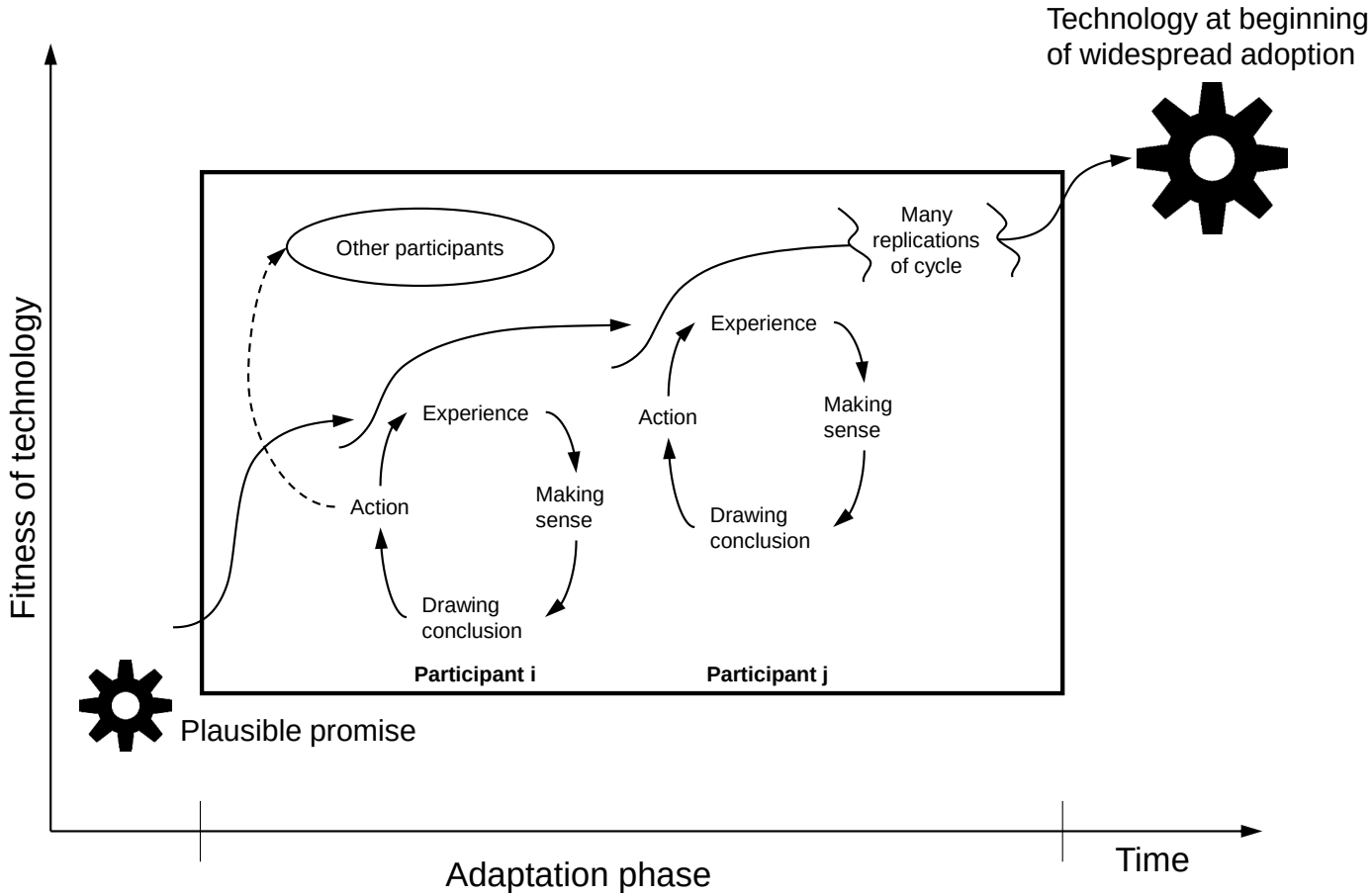
The enabling innovation framework builds on two main concepts, learning selection processes, and selection and promulgation mechanisms. Learning selection processes describe how changes come about, and how those changes can be shared and accumulated is captured by the selection and promulgation mechanisms. Both concepts are described in detail below. This framework was developed based on two major and four minor case studies of agricultural technologies in the Philippines and Vietnam (Douthwaite, 1999: 40–41, 218–219). One of the major case studies is discussed later in this section.

In the enabling innovation framework, innovation starts with a bright idea from the developers. A prototype is developed which represents a 'plausible promise' to potential users. A plausible promise means that potential users must be convinced by the prototype that they will benefit substantially from the

finished product. Only if they are convinced will they invest time and energy to contribute to the development of the technology – this joining of actors in the development process is central to the enabling innovation framework. Each user is a potential participant who can contribute to development. If the user does participate, he or she enters into a learning selection process based on the prototype. This process consists of four stages: experience of using the prototype; making sense of the experience and explaining it; drawing conclusions from the explanation; and taking appropriate action (Douthwaite, 2002: 50). This part of the enabling innovation framework is termed the learning selection process. An example of a change described in the framing of a learning selection process is that of a farmer using a device for drying rice. A farmer drying rice may experience the rice being too wet if the dryer is used in a certain way. He or she may assume that this might be because too much wet rice was put into the dryer, exceeding its capacity. The farmer may then draw the conclusion that the dryer would work better with less rice, and may take appropriate action by loading the dryer with less rice next time. Many different participants may go through these four stages and interact with one another (Douthwaite, 1999: 37). If they share their changes, they may trigger new learning selection processes. To what extent changes by different participants are possible depends on the characteristics of the technology. This is discussed in Chapter 3 Section 3.3.1 on the choice of a suitable technology for this research.

Figure 2-2 depicts several learning selection processes and how they can be connected and thus improve a technology.

Figure 2-2 How learning selection processes can improve a technology according to the enabling innovation framework



Source: Constructed by the author based on Douthwaite (2002)

The changes made in the way described above can then cumulate. The first step is participants sharing their changes. Of all the changes created and shared, the best ones are selected and incorporated into the technology. These actions are based on the selection and promulgation mechanisms available for the technology in question (Douthwaite, 1999: 318). If this selection and promulgation is successful, it can lead to the accumulation of changes by individual participants to produce more major innovations.

Two important entities which provide selection and promulgation mechanisms are the product champion and the market (ibid. pp. 286, 330-331). The product champion might be an individual who has overseen the development of a product in a company and continues to be responsible for and interested in the technology after it has entered into use. He or she will be in a position to gain an overview of the changes made to the technology, and will have the knowledge to select the most favourable ones and incorporate them into the technology. The market can also select and promulgate because 'the market' consists of people who buy and use the technology. This can provide a selection and promulgation mechanism in a situation where several variations of a technology are available simultaneously. Users will buy the variation of the technology which they consider to be of most benefit to them, and will thus select and promulgate it. After sufficient repetitions of the learning selection processes and selection and promulgation by the respective mechanisms, the technology reaches the stage where it has gained sufficient fitness and is ready for more widespread adoption. The fitness of the technology is the average measure of the characteristics that influence the rate of adoption, the comparative advantage, compatibility, trialability, observability and complexity of the technology (Douthwaite et al., 2001: 822–823; Rogers, 1995: 15–16). The technology is also more fit to be successfully operated in the existing conditions. These conditions include aspects such as the level of infrastructure available and the level of education of the users.

As mentioned above, the enabling innovation framework was developed out of two major and four minor case studies of agricultural technologies in the Philippines and Vietnam (Douthwaite, 1999: 40–41, 218–219). The two major

case studies were conducted on the stripper gatherer (SG) harvester in the Philippines and the SRR dryer in Vietnam (ibid. p. 43). The stripper gatherer harvester is used to strip the grain from rice plants and is especially suitable for small fields (ibid. p.51). The SRR dryer's name indicates its low cost (SRR means very low cost in Vietnamese) and it is used to dry rice. Rice is harvested wet so needs to be dried for storing. The development history of the SRR dryer is an example of a successful development process according to the enabling innovation framework. This case study is described in more detail in order to later identify a suitable medical technology for this investigation.

The SRR dryer was developed in 1983 by Phan Hieu Hien, a Vietnamese university lecturer (Douthwaite, 2002: 30–34). A bigger version of the initial design was built at the request of a user and, in 1985, one was installed in Pu Tam village in Soc Trang province (ibid.). It was copied and further adapted by farmers, village artisans and local builders. People living in this region in the Mekong Delta, were especially motivated to use the dryer because they did not have the possibility to dry the rice on the road which is common practice in other parts of the Philippines (ibid.). In some years, this had resulted in farmers having to throw away the whole season's crop. On learning about these adaptations eight years after the initial dryer was installed, the original innovator, Phan Hieu Hien, selected the most promising ones and incorporated them into a new design (ibid.). The resulting dryer was very successful and spread to neighbouring provinces. In 2002, there were 1,000 dryers in use in the Mekong Delta (ibid.). This case is an example of learning selection processes and selection and promulgation mechanisms. Many participants were involved all of whom made changes to the dryer. The product champion selected the best of those changes and incorporated them into the technology. This new design was taken up by the market, many people bought it and it diffused more widely. I refer back to this case study in Chapter 3 Section 3.3.1 when I discuss the type of medical technology that would be suitable for investigating the creation of changes by users. Next I show how the enabling innovation framework relates to medical technologies, which are the focus of this work.

2.3.2 Suitability of and adaptations to the framework to suit the characteristics of medical technologies

The enabling innovation framework builds on case studies of agricultural technologies. It has been used to study technologies as diverse as open source software and wind turbines (Douthwaite, 2002). In order to examine the suitability of this framework for medical technologies and to identify possible adaptations necessary, several characteristics of medical technologies need to be taken into account, which were described in Section 2.1. These aspects are technology-specific and specific to this investigation.

First, I examine several technology-specific characteristics. The importance of users, who are prominent in the framework, has been stressed in many publications on medical technologies (Free, 2004; Oudshoorn and Pinch, 2005a; Roberts, 1989). An important difference with agricultural technologies is the purchaser-user-consumer split which applies to most medical technologies (Hopkins, 2004: 9). Unlike the case of most agricultural technologies, these three functions are not necessarily fulfilled by the same person; the users are often both medical professionals as well as patients who also use and consume the technology (Gelijns and Rosenberg, 1994: 32). While this is generally true of many medical technologies, the level of patients' activity depends on the particular technology. Patients can be active in several ways including choosing a specific technology, and deciding to use it. In some cases, patients pay for their medical treatment and, therefore, indirectly pay for the technology; in other cases a third-party pays (ibid.). It follows that in the case of medical technologies, different groups of users, such as medical professionals and patients, may be involved, which differs from the case of agricultural technologies where only the farmers are users. The enabling innovation framework caters for this by incorporating multiple participants with different backgrounds.

In the enabling innovation framework, developers are responsible for the plausible promise based on their perception of users' problems (Douthwaite, 2006: 100). For medical technologies, however, in some cases an initial idea

has come from users themselves, such as for surgical equipment (Lettl et al., 2006: 266; Roberts, 1989: 36). Also, although the technical solution might have been provided by a technically knowledgeable developer, if the product is not completely relevant to the user it will likely not succeed in the market. Investing in a device to treat something that is considered not to need treatment would be unlikely. At the same time, users may perceive problems that are hidden from developers. Leaving problem definition to the technology developer could result in substantial misallocation of development resources. While some technologies will be left unused, technologies to satisfy an urgent need might fail to be developed. Therefore, to render the enabling innovation framework suitable for medical technologies, it needs some adaptation to allow for an investigation of the users' problems first, and the possibility for someone other than the developer, such as users, to develop the plausible promise.

Another aspect is the level of complexity of a technology, which is important in relation to how much users can contribute to its development by making changes to it. This aspect is also important for the enabling innovation framework; it works best if learning by using and learning by doing are important in the early adoption phase, when users are able to modify the technology. Gelijns et al. (2001: 919) state that one of the characteristics of medical technologies is the interplay between theory and practice, which emphasises this learning by using and doing approach. Morlacchi and Nelson (2011) show how medical practice can start to evolve, independently of scientific progress, based on an improved ability to develop new medical technologies. In some cases, however, neither medical professionals nor patients can make changes to the technology, either because of its complexity or because it is proprietary technology and subject to regulations or restrictions imposed by the manufacturer which is legally liable for the technology developed and produced. The enabling innovation framework stresses the importance of learning by doing and learning by using and, therefore, incorporates the important notion of interplay between theory and practice. However, as in the case of the agricultural technology for which the framework was developed, the extent to which this is possible depends on the technology in question.

Also, a medical technology representing a plausible promise can be used on patients only following a lengthy approval process after which it will be incorporated into the existing medical practice system to the extent of its remaining flexibility. The development of a medical technology needs to be more advanced than that of an agricultural technology in order to be applied in real situations as opposed to experimental settings. The framework needs to cater for this situation by allowing the development process to consist of two stages of development: in experimental and real-world settings.

Following these more general considerations, I discuss some important aspects specific to the present research.

While the enabling innovation framework mostly considers further development to a technology before more widespread adoption, this research focusses on changes made by users to technologies in regular use. It is likely that a more mature technology will be subject to fewer changes. However, technologies that are in regular use may still be changed, and the processes described in the framework will then apply. The creator of the framework stresses that learning selection needs to be encouraged to complete the development of a technology. After that, market mechanisms will ensure that the technology is further improved. Section 2.1.1 shows that, in the case of medical technologies in developing countries, a free market may not exist. Therefore, learning selection processes are likely to occur similarly to how the framework depicts them, even after a medical technology has been introduced into regular use. Thus, the theoretical considerations described above referring to the two stages of the development process, are not relevant for this research since the technologies, which are already in use, either do not need approval or have been approved.[4]

[4] Approval here refers to the processes in place in many countries to which medical devices are subject before they can be used. The approval process is a legal requirement, e.g. the United Kingdom (UK) Medical Devices Regulations (UK government, 2002).

For this research, it is important to consider outside influences on the further development of medical technologies. These include the regulations in place and the organisation of the healthcare system. The latter may be dependent on outside donations, perhaps to sponsor a particular technology directly or indirectly. In relation to the healthcare system, an important aspect is whether users have to pay for their treatment and, therefore, for the technology used. In many developed countries, neither patients nor medical professionals pay for medical technologies. However, this does not hold for all developing countries. The enabling innovation framework includes these outside influences by considering the selection and promulgation mechanisms related to the technology and by stressing the importance of those mechanisms being effective.

Table 2-1 summarises the relevant characteristics of medical technologies. It shows whether the framework in its original form considers these aspects and, if not, indicates the adaptations needed in order to include them. Table 2-1 shows that the framework considers most aspects including the importance of the user, the existence of several distinct groups of actors which are important including different groups of users, and the strong connection between theory and practice. It is also valid for the further development of technologies which are already in use, and for the special context of medical technologies in relating it to the selection and promulgation mechanisms. The only aspect not included is the fact that a plausible promise can come from users themselves.

Table 2-1 Characteristics of medical technologies in relation to the enabling innovation framework

Characteristic of medical technologies	Incorporated in enabling innovation framework	Resulting Adaptations
Theoretical considerations		
Importance of user	Yes	None
Several different groups of important actors, including different groups of users	Yes, many participants included	None
Plausible promise by others than developers	No	Plausible promise can stem from users themselves
Considerations specific to this research		
Interplay between theory and practice	Yes, learning by doing and using stressed	None
Technology already adopted widely	Yes, the same processes may still occur	None
Outside influences, e.g. regulation, liabilities	Yes, included in the selection and promulgation mechanisms	None
Considerations that are important from a theoretical point of view, but that do not apply to the research at hand		
Possible two stage process of development and testing	No	If necessary, framework can still be used for both stages

Source: Constructed by the author

As it has been demonstrated that the enabling innovation framework is generally suitable for an investigation of a medical technology, and adaptations have been suggested where necessary, it can be used to guide the later empirical work. The characteristics discussed in this section are important for adapting the framework and selecting the case studies for the empirical work. Many of the points discussed in this chapter are returned to in Chapter 3 Section 3.3.1 on a suitable medical technology for the research.

To summarise, the enabling innovation framework focusses on individual users and provides important details for this investigation by showing how users

take action to create changes by considering the four steps of the learning selection process. It includes users sharing their changes, relating this to selection and promulgation mechanisms. The sharing of changes is important for two reasons. First, it allows users with similar needs to profit from these changes and allows them to use their limited resources for other, additional changes. Second, the changes made by users can become cumulative and result in more major changes and innovations. For the present research, the level of detail this framework provides on those aspects is necessary in order to investigate the creation, sharing and accumulation of changes and thus identify influencing factors on user innovation of medical technologies in such settings.

2.4 Summary

This chapter introduced the literature on medical technologies in general, and in developing countries in particular, and work on innovation concepts. The enabling innovation framework was identified as suitable for this work.

Important aspects related to medical technologies include the high uncertainty surrounding a new medical technology, their complex surroundings including the number of actors involved and the distinct characteristics of their development process. While these factors apply to all medical technologies, in the context of a developing country it is necessary also to consider the funding of healthcare, the lack of infrastructure, and perceptions about health.

Concepts of innovation were discussed. As described in this chapter, an inclusive definition is most appropriate for the present work which focusses on 'changes' made by users. The innovation literature related to changes made by users to technologies in a developing country setting, was discussed. This included work on user innovation, appropriate technology, frugal innovation and grassroots innovation. The strand of literature on user innovation stresses that the source of innovation is not always the firm, and users can play an important role. It concludes that users create innovations in order to fulfil needs not met by existing products and services. Users innovate in many different fields and, in

many cases, freely reveal their innovations. For innovations relating to a physical product, manufacturers need to produce the product. For user innovations to medical technologies, many innovations created by medical professionals have been considered. The focus has been expanded recently to include innovations by patients. However, user innovations have mostly been researched in the context of developed countries. Since the focus of the present research is on a developing country setting, the concepts of AT and frugal and grassroots innovations are introduced since they specifically consider innovations in the context of developing countries. While AT focussed on creating appropriate technologies for developing countries, the concepts of frugal innovation and grassroots innovation consider innovations that stem from developing countries. Frugal innovations relate to innovations that are low-cost, often because they were developed in situations where resources are scarce. Grassroots innovations focus more on innovations made by individuals, often in situations of low levels of resources. The concepts of frugal innovation and grassroots innovation stress the importance of limitations in understanding innovation in the context of developing countries. However, neither concept classifies the different categories of limitations or considers the particulars of their influence on users creating and sharing changes.

While there is no one innovation concept that takes account of all the aspects relevant to this research, they all offer different insights that need to be taken into account. In order to achieve this and create a suitable basis for the data collection phase, the enabling innovation framework was identified. This framework builds on two main concepts, learning selection processes and selection and promulgation mechanisms, to explain in detail how users create and subsequently share changes. It was shown how this framework is suitable, with some minor adaptations, for investigating a medical technology since it was developed out of case studies on agricultural technologies. Therefore, the enabling innovation framework will inform the data collection and analysis to investigate how user innovation to medical technologies occurs in developing country settings, which is described in Chapter 3.

3 Methodology

This chapter describes the methodology employed to investigate changes by users to a medical technology in a developing country setting. It describes the data collection methods and the choice of the specific medical technology and country. It provides an overview of the data collected during fieldwork and how they are analysed.

The most important methodological consideration is what methods are suitable for the research problem at hand, which is defined by the research questions and their framing (Silverman, 2010: 10). The research centres on the factors that shape user innovation of medical technologies in developing country settings. It examines the changes created by users to address the research questions formulated in Chapter 1 and repeated below:

1. What changes do users create to a medical technology in a developing country setting and why do they create these changes?
2. How and why do users share these changes?
3. Against what background and conditions do users create and share their changes?
4. Based on the above three supporting questions, what conclusions can be drawn about the factors that influence user innovation of medical technologies occurring in developing country settings?

As mentioned in the third research question, when collecting and analysing the data it is necessary to consider not only the changes created to a medical technology but also the conditions under which this occurs. This involves a consideration of the organisational aspects of the technology as well as the more general national context, including the healthcare system. This approach guarantees a thorough analysis by relating the personal decisions and experience of users to the conditions under which they were made and thus allowing for generalisations.

The methods employed need to be suited to the collection of data on all these aspects. In order to achieve this, the sections in this chapter begin by presenting the methodological options and determining which is the most suitable choice in the context of this doctoral research. Section 3.1 assesses whether quantitative or qualitative research is the most appropriate for this work.

3.1 Qualitative research

The most important consideration when choosing a methodology is the nature of the research topic (Flyvbjerg, 2006: 242; Silverman, 2010: 10). Flyvbjerg states that good social science is driven by the problem under investigation, not the methodology used – methodology should be the means to an end, namely the means to answer the research questions, not the means in itself (2006: 242). The most common options for addressing research questions are quantitative or qualitative research methods, or some combination of the two. The goal of quantitative research is to isolate cause and effect, and to measure and quantify a phenomenon (Flick, 2006: 12). To achieve this, the conditions of a research project need to be controlled, in order to make an observed effect attributable to one cause and to exclude other potential causes (ibid. p.13). This includes the influence of the researcher, which has to be excluded in order to achieve objectivity (ibid.). This approach requires identification of possible causes before the data are collected, because they need to be included in the research design prior to data collection. Quantitative research relies on the data collected, for example, in experiments which allow the possibility of controlling conditions, or in formal surveys. An important aspect here is the use of statistics, which demands a certain minimum amount of data to make the outcome significant.

Qualitative research focusses on 'objects' in real life, not in controlled experimental conditions (ibid. p.15). Therefore, causal relationships cannot be established with mathematical models as in quantitative research, leading to statistics generalisations. Instead, generalisations are based on logical

deduction, which necessitates a theoretically informed choice of case studies (Flyvbjerg, 2006: 225–229; Silverman, 2010: 140–150; Yin, 2009: 38, 101). Such generalisations are termed ‘theoretical’ or ‘analytical’ by different authors (ibid.). These terms are used to distinguish between this kind of generalisations, and the statistical generalisations mentioned earlier, as the logic for the two is different. Instead of being based on mathematical models, for theoretical or analytic generalisations empirical results, for example of a case study, are systematically compared to previously developed theory.

Generally speaking, qualitative research aims at discovering causes instead of testing a priori defined ones. It considers a phenomenon in its complex, real-world context, and seeks to understand the perspectives of those who take part in it (ibid.). Thus, both quantitative and qualitative methods are important. The research problem itself and the goal of the research define the most appropriate method (Silverman, 2010: 10). Quantitative methods tend to help answer questions about quantifying a phenomenon, whereas qualitative methods are more suited to answering 'what' and 'how' questions about a phenomenon (Yin, 2009: 8). The suitability of a method depends also on the characteristics of the phenomenon being researched. In order to isolate cause and effect with quantitative methods, some element of control over the conditions surrounding the phenomenon is necessary (Flick, 2006: 12–13). This is not always possible. In addition, some phenomena are so linked to their context that trying to isolate them from it for research purposes would severely distort the resulting data.

This research is about changes by users created to a specific medical technology in a developing country setting, and how users share these changes. This also includes the conditions which the users are subject to. Central to this research is not how often such changes occur, but how and why they are created and shared. This focus on details is necessary, since one goal of this research is to uncover the factors which shape the creation and sharing of those changes. Employing quantitative methods could provide important insights into some aspects, such as the numbers of changes made by certain groups of users. They are less suitable, however, for investigating such details as the reasons for making changes to a technology when one does not want to

define possible reasons a priori, and wants to remain open to the explanations of the users. For this kind of information, qualitative studies are more suitable. In addition, it is important to investigate the explanations of users themselves in developing countries, because they have seldom been considered in previous research on user innovation.

In summary, this research looks at a phenomenon in its complex, real-world context and not in controlled conditions in an experiment, and thus needs to take the characteristics of this situation into account. From this outline of quantitative and qualitative research, it follows that a qualitative approach to data collection and analysis is best suited for the present research. The next section introduces a research strategy.

3.2 Case study approach

I have established that qualitative data are best suited to the enquiry in this thesis. There are several approaches to collecting qualitative data: case study, history and ethnography. While all of these approaches can take different forms when applied to different research topics, they have certain characteristics that distinguish them. These characteristics are listed below.

Table 3-1 Characteristics of selected approaches for qualitative research

Methodological approach	**Time of phenomenon**	**Kind of data**	**Main sources of data used**	**Minor sources of data used**
Case study	Contemporary	Quantitative, qualitative or both	Interviews, observations, documents (primary and secondary) and artefacts (cultural and physical)	
History	Mostly past	Quantitative, qualitative or both	Mostly documents (primary and secondary) and artefacts (cultural and physical ones)	
Ethnography	Contemporary	Mostly qualitative	Observations	Ethnographic interviews

Source: Constructed by the author based on Yin (2009: 5–16)

Case studies can be quantitative, qualitative or both (Eisenhardt, 1989: 534–535; Gerring, 2007: 10). They deal with contemporary phenomena in a real-world context. Sources of data for case studies include interviews, observations, documents (primary and secondary), and artefacts (cultural and physical). 'Histories', like case studies, can be quantitative, qualitative or both. The 'history' approach is often concerned with the 'dead' past, meaning that no living persons can be questioned about the topic (Yin, 2009: 11). In this case, interviews and observations are not possible, and the researcher has to rely on documents (primary and secondary) and artefacts (cultural and physical) (ibid.). Histories can also cover contemporary events, in which case they become similar to case studies (ibid.). In 'ethnography', observation is the most common method, and additional ethnographic interviews are sometimes conducted (Delamont, 2004: 218; Silverman, 2010: 202; Spradley, 1980: 122). Studies that fall into this category tend to be qualitative rather than quantitative, and are mostly concerned with contemporary phenomena (Delamont, 2004: 218–223).

In order to determine the most suitable approach the research topic needs to be considered. Diverse sources of data are necessary for this research because it considers a specific technology and the changes made to its artefacts, therefore, the artefacts also need to be considered. At the same time, the reasons for users to make these changes and how they share them is integral to this work. Since this information is unlikely to have been recorded, observations and interviews are fundamental for collecting these data. While the three approaches described may be similar, the case study approach emerges as the most suitable for this research because it considers diverse sources of data while being focussed exclusively on contemporary phenomena.

In addition, work important for this research is based on a 'case study' approach. The enabling innovation framework presented in Chapter 2 as suitable for this research is based on four major and two minor case studies of agricultural technologies in developing countries (Douthwaite, 1999: ii, 40–41). Also, case studies are widely used in the literature on medical technologies, such as the studies by Blume (1992), Faulkner (2009), Tautz (2000) and Morlacchi and Nelson (2011). These studies refer to different technologies,

such as the cochlear implant, artificial hips, ultrasound and an implant for treating heart failure, but all are aimed at presenting a real-world detailed case of the technology in its context. Therefore, case studies are a suitable method for this research, from both a theoretical point of view and in relation to important previous work.

Researching a phenomenon in a comprehensive way is emphasised in the 'case study' approach, as it aims to achieve an understanding of real-life events in their context (Yin, 2009: 4). The unit of analysis in a case study describes the core of the case study and therefore what it is about (ibid. p.31). The unit of analysis often reflects the level of enquiry of the research questions (ibid.). The research questions in this thesis focus on the factors that influence user innovation of medical technologies in developing country settings and, in order to identify these factors, changes by users to one specific medical technology in a developing country setting are studied in detail. The unit of analysis, therefore, is the changes created by users to a medical technology.

While a case study approach has been shown to be suitable for this work, this approach has some shortcomings. The most important of these are addressed here. Critiques of the case study method focus mainly on the lack of rigour in conducting case studies and on finding possible generalisations including testing hypotheses (Flyvbjerg, 2006: 219; Yin, 2009: 14–16). In relation to the first, lack of rigour can also occur in other methodologies and should be overcome by a robust research design which helps to avoid biases as far as possible (Yin, 2009: 14–16). In this research, among other things this will be achieved by using observations, interviews, documents, archival records and the artefact of the medical technology as multiple data sources, and triangulating them (ibid. p.101). In relation to possible generalisations, these will differ from results of quantitative research. However, this does not make them less valuable. While in quantitative research, sample results are extrapolated to a larger population using mathematical models, the results of case studies can be generalised to theoretical propositions. Case studies are thus useful for both generating and testing hypotheses (Flyvbjerg, 2006: 229). The choice of cases needs to be informed by the kind of generalisations the work aims for. As this

work has a qualitative focus, as discussed earlier, theoretical or analytical generalisations are the objective. These are generalisations which are not based on mathematical models, but on a systematic comparison of empirical results to previously defined theory. The choice of cases will therefore not be based on a sampling logic, as is the case for statistical generalisations, but on a theoretical basis instead. This point is further expanded on in the following Section 3.3, where the appropriate choice of cases is described to allow for such generalisations. The necessary characteristics of a medical technology and a developing country setting suitable for this research are also introduced in this section, and suitable options for both are identified.

3.3 Characteristics required of a suitable medical technology and developing country setting

First, criteria for a medical technology and a country suitable for this research are established. In order to find a medical technology that satisfies these criteria, I studied the available literature and attended workshops on medical technologies in developing countries, to familiarise myself with current discussions in the field which had perhaps yet to be published.

Qualitative case studies, in contrast to quantitative studies, are most often not sampled randomly, but on a theoretical basis (Silverman, 2010: 143). The reason for this is that the logic for doing the two types of research is different. In quantitative work, a random sample is necessary to allow inferences based on the results that apply to the whole population using mathematical models. These models can show whether the sample results are valid for the whole population, allowing statistical generalisations. Qualitative research relies on studying a specific case or cases of a general phenomenon. As the data consist of text, not numbers, mathematical models are not used. Instead of extrapolating from the results true for a sample to the wider population, one or several specific examples of a phenomenon are studied in detail (ibid. p.138). By focussing on a key part, a better understanding of the whole can be achieved (Gerring, 2007: 1). With logical reasoning and a chain of evidence, an

analytical argument is built to relate the one or several cases to more general phenomena (Yin, 2009: 101). In order to follow this procedure, the utmost care must be taken to construct one or several suitable cases (Silverman, 2010: 140–147). This then leads to theoretical, as opposed to analytic or statistical generalisations, which can be increased by the careful selection of cases (Flyvbjerg, 2006: 225–229). As already mentioned, the unit of analysis for my case study is the changes created by users to a medical technology in a developing country setting and, therefore, both a suitable technology and country to investigate these changes need to be identified.

The theoretical basis for this selection is the enabling innovation framework introduced in Chapter 2 Section 2.3. Since it was derived from a number of case studies, the details of these cases can help to determine the criteria for a suitable medical technology and country for this research (Douthwaite, 1999: 40–41). The focus is on one of the major case studies, the SRR (meaning very low cost in Vietnamese) dryer, used to dry rice (ibid. pp.51, 170). The focus is on this study because it represents an example of a successful further development of a technology according to the enabling innovation framework. There are certain characteristics of this case study that are especially important for the present research. These include the involvement of many participants, the complexity of the technology and external conditions, such as regulations, which influence the selection and promulgation mechanisms considered in the enabling innovation framework.

In general, cases sampled on theoretical grounds can be grouped into four categories: extreme or deviant, maximum variation, critical, and paradigmatic (Flyvbjerg, 2006: 230). It is important to note that these categories are not necessarily mutually exclusive; a case can, for example, be extreme, critical and paradigmatic at the same time (ibid. p.233). Extreme or deviant cases are unusual and are especially problematic or advantageous related to the relevant theory (ibid. p. 230). Maximum variation cases are different on one or several dimensions and, thus, offer the possibility to assess the influence of those dimensions (ibid.). With these kinds of cases, causal relationships can be analysed with comparisons (Gerring, 2007: 151–155). Critical cases are either

of the most likely or least likely kind (Flyvbjerg, 2006: 231). Most likely cases can be used to falsify a hypothesis: if the hypothesis is not valid for that case, where the phenomenon is most likely to occur, it is unlikely to be valid for any other (ibid.). A least likely case can in turn help to confirm a hypothesis, because if it is valid for that case, where the phenomenon is least likely to occur, it is likely to be valid for all other cases (ibid.). Paradigmatic cases are so unique that they have widespread consequences such as founding new schools of thought (ibid. p. 232). Such cases, however, are difficult to select and intuition is central to identify them (ibid. p.232-233). For this work, it was unlikely that one could identify such a paradigmatic case in advance. Identification of a deviant case requires a lot of information to judge whether it will be especially good or difficult. In the case of this research, this would have required detailed information about the changes created by users to a kind of medical technologies in a developing country setting, which was not available. Maximum variation cases could be identified in this research, such as the use of a kind of technologies at two geographically distant sites, or in different organisations. Critical cases would be those where changes by users made to a specific kind of medical technologies is either most likely or least likely. For this research, it makes most sense to choose cases which are most likely for the medical technology, and maximum variation cases in relation to the developing country setting as shown below.

The objective of this research is to identify factors which influence user innovation by investigating changes by users to a specific medical technology in a developing country setting. Therefore, the more changes by users that can be identified, the more cases exist for comparisons and, thus, the better the influence of factors can be analysed. In order to identify many changes, it is better to choose a technology where changes are more likely and, therefore, most likely cases. Also, choosing a medical technology that is used by both medical professionals and patients where both are likely to make changes provides further variation and, thus, opportunities for comparison. This notion is similar to the approach of choosing a case with a high experience level of the phenomenon to be studied (Pettigrew, 1990: 276).

In addition to identifying many changes, it would also be favourable to do so in settings which lend themselves to comparisons regarding the factors influencing user innovation. This would make it possible to identify how differences in changes relate to differences in settings. Therefore, for suitable settings for this research, maximum variation cases are beneficial, such as one country with different settings.

3.3.1 A suitable medical technology: lower limb prostheses

As set out above, a technology to which changes are likely is favourable for this research. The characteristics of the medical technologies to be considered for this research are described in this section and several suitable technologies are introduced. These are compared to one of the technologies on which the original framework is based, the SRR Flatbed rice dryer mentioned above, and the most suitable one is identified.

Chapter 2 Section 2.3.1 provides details of the enabling innovation framework, and the development of the SRR Flatbed rice dryer which is described as an example of what a successful development process according to the enabling innovation framework would look like. A suitable medical technology should be similar to this technology in as many aspects as possible, in order to present a most likely case for changes to occur as described above. The important aspects to consider are the inclusion of many users and the possibility for users to choose a specific technology and to decide whether to use this technology or not. Further important aspects include that the technology should be clearly visible to all users and there should be possibilities for changes by actors apart from the developers (Douthwaite, 2006). Such a technology, which is simpler and forgiving,[5] fosters novelty-generation, as it can be understood, repaired and changed more easily by users (Douthwaite, 2002: 103). Table 3-2 presents an overview of these aspects.

[5] Forgiving in the sense that the technology tolerates a certain amount of changes being made to it and still functions.

Table 3-2 Important characteristics of the SRR Flatbed rice dryer based on Douthwaite (1999)

Technology	**Involvement of Users**			**Complexity of technology**
	Choice	Decision to use	Visibility	Change by users possible
SRR Flatbed rice dryer	Yes	Yes, very high	Yes, high	Yes

Source: Constructed by the author

In addition to these requirements, a technology needs to have the potential to be used in the real-world circumstances in developing countries in order to make the study feasible. Since the technologies for this case should already be in use in developing countries, they should not need a lot of infrastructure, such as sterile conditions, because these cannot be assumed to be widely present in developing countries (Malkin, 2007a).

As already mentioned in Chapter 1, the focus on one medical technology is suitable because it ensures sufficient familiarity with the technical details to render identification of changes as reliable as possible. This reliability is ensured also by considering several technologies in the same family or of the same kind. This distinction is relevant, because the term 'technology' is sometimes used in different ways. 'Technology' can refer to a general category, such as a camera, or a specific make, such as digital compact camera or a digital single-lens reflex camera. Both achieve the same result, they take pictures, but they have different technical properties. Here more general kinds of technologies are considered since this makes the choice of a specific kind of technology more transparent. Otherwise, every make of a technology would need to be considered separately. Therefore, the term 'kinds of technologies' is used to make a distinction between the different levels. Technologies of different makes or from different manufacturers are treated as different technologies, which is in line with the definition of technology as a bundle of devices – that is, tools, machines and artefacts or ‘hardware’ – and procedures

– that is, techniques and methods or ‘software’ (Morlacchi and Nelson, 2011: 512). If a technology consists of a different artefact or is manufactured using different procedures, then it is distinct from another technology, even if both serve the same purpose, such as the camera technology. Different kinds of medical technologies more generally are therefore considered in what follows.

The enabling innovation framework is based on the initial development of a technology, but as shown in Chapter 2 Section 2.3.2, is equally suited to investigating a technology that is already widely used. In this work, the focus is on the latter, as the situation in developing countries is often such that medical technologies used there are often imported from outside the country or continent. They are therefore seldom in their initial stages of development.

It is thus appropriate to look at a kind of technology that is already used in an environment where it is very likely to be changed, and to look at the changes created to it by users. Technologies which need sterile conditions should not be considered, as described above. In order to find suitable technologies, I searched the literature systematically, asked practitioners for advice, and attended workshops on medical technologies in developing countries. The following kinds of technologies emerged as potentially suitable:

- Lower limb prostheses (Andrysek, 2010)
- Ultrasound devices (Bussmann et al., 2001; Dean et al., 2006; Shah et al., 2008; Steinmetz and Berger, 1999)
- X-ray machines (Malkin and Keane, 2010)
- Endoscopes (Cooke et al., 2009).

Lower limb prostheses are and have been widely used in developing countries. Ultrasound devices are increasingly used in developing countries, as are x-ray machines and endoscopes. All of those kinds of medical technologies are described below in terms of the possible involvement of all users, meaning both medical professionals and patients, and the complexity of the technology. The involvement of all users for the kinds of medical technologies is only confirmed if it is true for both medical professionals as well as patients. The

agricultural technology which served as a case for the enabling innovation framework introduced above, the SRR Flatbed rice dryer, is depicted again for comparison in order to assess the suitability of the kinds of medical technologies which are considered (Douthwaite, 2002: 30–34).

Table 3-3 Comparison of the SRR Flatbed rice dryer with different kinds of medical technologies

Technology	**Involvement of Users**			**Complexity of technology**
	Choice[6]	Decision to use	Visibility	Change by users possible
SRR Flatbed rice dryer	Yes	Yes, very high	Yes, high	Yes
Lower limb prostheses	No	Yes, high	Yes, very high	Yes
Ultrasound devices	No	No	Yes, high	Limited
X-Ray machines	No	No	Yes	Limited
Endoscopes	No	No	Yes	Limited

Source: Constructed by the author

Table 3-3 shows that lower limb prostheses are the kind of medical technology most similar to the SRR dryer and, therefore, the most suitable for this research. In addition, lower limb prostheses are an interesting case because some of the parts for producing the prostheses are pre-fabricated, while others have to be made locally as the prostheses need to be customised for each patient. Since customisation has been found to be one of the drivers for users to create changes, as mentioned in Chapter 2 Section 2.2.1, this makes changes by users even more likely.

Lower limb prostheses fit the criteria requirements described above, next a suitable developing country setting to investigate them is introduced.

[6] Choice refers here to medical professionals as well as patients being able to choose between different makes of the same kind of medical technologies, such as between a Siemens and a Philips X-ray machine.

3.3.2 A suitable developing country setting: Malawi

The focus of this research is changes created by users to lower limb prostheses in the prevailing conditions. Choosing one country rather than several countries is favourable to this focus because, as noted in Chapter 1, this ensures that the context of lower limb prostheses can be examined in sufficient detail.

User innovation is considered in this work in the setting of a developing country. In the United Nations system, developing countries include all the African, and Latin American nations, all Asian countries except Japan, and all nations in Oceania except Australia and New Zealand (United Nations Statistics Division, 2010). An important limitation for this research is language. The research questions call for a detailed assessment of users' explanations of their changes. In order to understand the users' point of view, the researcher needs substantial sensitivity in relation to the underlying issues. This is easier if the researcher is able to communicate directly with users without the help of an interpreter. This is especially important for observations, since it would be difficult for an interpreter to understand and translate quickly enough. Choosing a country where English is spoken is, therefore, an advantage. From the list of developing countries given above, this ruled out Latin America and many of the countries in Asia and Africa. Oceania consists mostly of developed countries. Consideration was also necessary in relation to the stability of the country to allow undisturbed research. This left the many African countries where English is an official language such as Botswana, Tanzania and Malawi. In Asia, the most suitable country would be India.

In addition to language considerations, it is necessary to take account of the size and complexity of a country and a single researcher assessing in detail the conditions for lower limb prostheses and their users. Large countries with large regional differences were considered less suitable for this research, which ruled out India.

This left the Sub-Saharan African countries. Information on the use of lower limb prostheses in Sub-Saharan Africa is limited and stems mostly from charities, notably the Rotary Jaipur Limb Project, Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS) and '500 miles' (500 miles, 2013c; Bhagwan Mahaveer Viklang Sahayata Samiti, 2007; The Rotary Jaipur Limb Project, 2014b). BMVSS is based in India, but has also set up Jaipur foot centres abroad with the help of other agencies such as the Rotary Club (Bhagwan Mahaveer Viklang Sahayata Samiti, 2007). In Sub-Saharan Africa, it is active in Kenya, Malawi, Nigeria, Rwanda, Senegal, Somalia, Zambia and Zimbabwe (ibid.). The Rotary Jaipur Limb Project also has helped to set up orthopaedic centres and is active in several Sub-Saharan African countries. It has established or supports centres in Ghana, Kenya, Malawi, Nigeria, Rwanda and Tanzania (The Rotary Jaipur Limb Project, 2014b). In addition, the Jaipur technology for producing lower limb prostheses is neither patented nor proprietary, which increases the likelihood of users making changes to it.

Some Sub-Saharan African countries are very large, making them less suitable for this research. One of the smallest countries in which the Rotary Jaipur Limb Project is active is Malawi where English is widely spoken, as all secondary level education is conducted in English (U.S. Department of the State, n.d.). There are four orthopaedic centres in Malawi, although the fourth was opened after conclusion of my fieldwork. Therefore, by collecting data in two of those orthopaedic centres, a substantial part of the official provision of orthopaedic centre services in Malawi could be covered in this research. This extent of coverage would not have been possible in some of the larger African countries, such as Tanzania.

The four orthopaedic centres in Malawi are:

- Orthopaedic Centre at the Queen Elizabeth Central Hospital (QECH) in Blantyre
- Orthopaedic Centre at the Ekwendeni Mission Hospital
- 500 miles Centre at the Kamuzu Central Hospital in Lilongwe

- 500 miles centre at Mzuzu Central Hospital, opened in November 2012 (500 miles, 2013b).

This research is interested in identifying factors that shape user innovation in medical technologies in developing country settings. It is useful to identify changes by users in different settings, as collecting data from two different centres allows comparison of different technologies and organisational setups. Since changes were likely to the Jaipur technology as mentioned above, the Ekwendeni centre was chosen because the centre personnel there use the Jaipur technology exclusively. Orthopaedic centre personnel are also referred to as 'orthopaedic technicians' or 'technicians' throughout the thesis, the term most commonly used to refer to people working at orthopaedic centres. It was necessary to collect data at one additional centre; including more centres would have prevented the detailed data collection and analysis necessary for this research. Of the two other centres operating at the time of the fieldwork, the centre at QECH uses the Jaipur technology, although only for a small percentage of the prostheses they make.[7] This centre was the first orthopaedic centre in Malawi, opened in 1970. Thus, its older technicians were not only able to provide information about the present situation but also how it developed, which would further my understanding of the situation of lower limb prostheses in Malawi generally. Also, the centres in Ekwendeni and at QECH differ in their organisational set up; the former is affiliated to a mission hospital and, thus, governed by the Christian Health Association of Malawi (CHAM); the other is a department of QECH, which is a public hospital and part of the Malawian Ministry of Health. This provided the opportunity to investigate the relation between the differences in the changes found in the two centres and their organisational setups. I also visited the centre at the Kamuzu Central Hospital in Lilongwe for one day, but was unfortunately not permitted to use any data collected there by the charity '500 miles', despite having received approval from the Malawian Ministry of Health for my research. More details on this situation are provided in Chapter 8 Section 8.3 on the limitations of this study.

[7] I was given this information in a personal communication with the head of the orthopaedic centre at QECH.

In summary, the most appropriate kind of technology and the developing country setting were considered which led to the focus on lower limb prostheses and the orthopaedic centre at QECH in Blantyre and the orthopaedic centre at the Ekwendeni Mission Hospital in Ekwendeni, where lower limb prostheses are currently produced and supplied to patients.

The criteria fulfilled by a case study of lower limb prostheses in Malawi are:

- Medical technology
    - Involvement of users
    - Adequate complexity of the technology
    - Usable in developing countries
- Country
    - English as official language and widely spoken
    - Adequate size and complexity of the country and the orthopaedic centre services

Next the study methods are described.

3.4 Data collection methods

The data collection methods needed to be suitable for studying changes created by users to a certain kind of medical technologies, lower limb prostheses. Qualitative data and a case study approach were identified as suitable for this study. Qualitative data consist mainly of text (Flick, 2006: 4). This may be existing text, such as documents, or original text produced for the research study. Original text includes the researcher's notes and transcriptions of audio or video recordings. In addition to available documents and archival records, interviews, direct observations, participant observations and physical artefacts make up the six principal sources of evidence for case studies (Yin, 2009: 101). The use of multiple sources of evidence is an essential data collection principle for case studies because it allows triangulation (ibid. pp.114–115). As many sources of evidence as possible should be used.

Documents and archival records are especially important for the early stages of the research. Important text is introduced in the literature review, which refers to previous work on various important aspects. During the data collection, additional important documents were collected including newsletters, production manuals, textbooks and official letters. These documents and archival records refer to general aspects of the wider context, and also provide information on regulations and characteristics of the healthcare system. They include information on the specifics of the development, and details of the technologies. Details on the creation and sharing of changes by users to lower limb prostheses are not recorded. Therefore, data on the changes as well as the individual experiences of users were gathered through observations and interviews. The physical artefacts of the different lower limb prostheses played an important role in all stages of the research. They are important for two reasons: to understand the technologies in detail, and to identify changes made to them. The data on changes collected in observations, interviews and from the artefacts was triangulated.

Prior to data collection in the field, documents, archival records and information from websites were collected, to inform the fieldwork and to get a better understanding of lower limb prostheses. Data collection in the field centred on observations, interviews and the prostheses as physical artefacts. Details of what was observed, who was interviewed and on what topics are contained in Sections 3.4.2.2 and 3.4.3.5. During the fieldwork I also collected documents and archival records such as production manuals.

The data collection methods of investigating literature and documents, conducting observations and interviews are described in more detail below.

3.4.1 Literature and documents

There is extensive literature on lower limb prostheses covering various aspects such as the development process, biomedical testing and economic implications (e.g. Andrysek, 2010; Arya et al., 1995; Cummings, 1996; Meanley,

1995; Sethi, 1989; Sharp, 1994). This literature was studied to understand the technical aspects of this kind of technology, including its development. However, there is little available information on the specific technologies used in Malawi apart from the website for the Jaipur limb campaign conducted by Rotary International (The Rotary Jaipur Limb Project, 2014b). It was necessary to contact experts[8] to get more information on the situation on the ground. With the help of these experts, I was able to assess the situation regarding lower limb prostheses. After having chosen Malawi as the country of study, I sought more specific information on the conditions there. This included information available online from the Malawian Ministry of Health, a large study on disabilities in Malawi and other documents on Malawi and its healthcare system (Government of the Republic of Malawi, 2011; Loeb and Eide, 2004; Makoka et al., 2007; National Statistical Office, 2010).

3.4.2 Observations

Observations undertaken during this research served two purposes: they provided rich contextual information on cast-taking, production, fitting and use of lower limb prostheses in Malawi, and the possibility to identify changes made to prostheses. Observations can help to better understand a technology being studied (Yin, 2009: 110). There are different methods of observation, one of the most important distinctions being between non-participant and participant observation (Flick, 2006: 216). In the former, the researcher is an independent observer who takes no part in the activity being observed and does not influence it in any way. In the latter case, the observer is actively involved (Flick, 2006: 217–220; Yin, 2009: 110–112). In non-participant observation, the influence of the observer on the situation is minimised as much as possible; in participant observation there is the possibility for the observer to influence the situation being observed (ibid.). Both are valid approaches, and their feasibility and suitability depend on the situation being observed (Yin, 2009: 112). In the

[8] These experts included, among others, the head of a charity promoting the Jaipur technology, and a prosthetist and orthotist with extensive experience on lower limb prostheses in developing countries.

case of participant observation, there is a range of levels of participation possible, from passive participation, which includes just asking a few questions, to complete participation where the observer is part of the group under study (Spradley, 1980: 59–61).

In the case of this research, it was necessary to ask questions of both orthopaedic technicians and patients involved in order to fully understand the technology and processes. Thus, participant observation was the appropriate choice, as such informal interviews are part of this approach (Flick, 2006: 217–220; Spradley, 1980: 122; Yin, 2009: 110). In the setting of the orthopaedic centres, the researcher cannot be a non-participant as drawing back so much that he or she will not be perceived is not possibly. However, the participation of the researcher was passive and consisted of occasional questions and visible presence during observations. The method of participant observations is described in detail below.

One approach to participant observation is to progressively narrow the focus of the observation, to move from descriptive, to focussed, to selective (Silverman, 2010: 234; Spradley, 1980: 73). Descriptive observations are conducted with no particular question in mind; the researcher observes what is happening (Spradley, 1980: 73). This becomes the foundation for further observations (ibid. p.128). A more narrow ethnographic focus is the basis for focussed observations (ibid. p.101). In my case, this focus was selected according to the theoretical interest (ibid. p.106). Finally, observations become selected observations with an even narrower focus (ibid. p.122). The researcher, after several observations, is now recognised by people in the social situation and is no longer a complete stranger (ibid.). This presents the opportunity to conduct informal ethnographic interviews (ibid.). Formal interviews were also conducted in the course of this research, but were not part of the observations. They are discussed in Section 3.4.3. While the general approach is an ever more narrow focus of observations over time, the different kinds of observations sometimes need to be conducted in parallel.

For this research, this meant that the observations initially were fairly unstructured, to allow me to get to know the orthopaedic technicians and to get a good understanding of the organisation of the centre. Once this orientation phase was over, the observations focussed on the production of and repairs to the prostheses, including interaction with patients. The observations also served as a starting point to contact patients who potentially could be interviewed. The observations were based in the two orthopaedic centres, at QECH and at the Ekwendeni Mission Hospital. As described above, the observations were participant observations, which gave the researcher the possibility to ask the participants in the situation questions – also described earlier as conducting informal ethnographic interviews. This not only fostered an understanding of the technology and the production and repair processes but also served to gain the trust of the orthopaedic technicians and patients. Since all the technicians responsible for prostheses spoke English, they were able to translate during an observation where necessary, and to answer my questions in English. In the course of these observations, it was important to observe different technicians doing the fittings of the lower limb prostheses. It was important also to inspect many artefacts of the lower limb prostheses in order to establish the standard make. This allowed me to identify changes created by both technicians and patients. In this way, I operationalised the working definition introduced in Chapter 2 Section 2.2, of a change as something that is created by users which is different to the standard, whether it relates to the process, the artefact or the use of a technology. In addition to these observations, I conducted interviews in order to gather information on changes to the prostheses and the context. I was able to identify changes during the observations, which interviewees had not been aware of or regarded as too insignificant to mention. I also used the interviews to gather more details on the changes, such as who made them and if they were shared. The interviews are described in Section 3.4.3. This way I obtained details on the changes which gave the opportunity to triangulate different sets of data from the observations, the interviews and the artefacts of the prostheses.

In order to prepare for the fieldwork and to learn how best to carry out the observations for this research, I conducted pilot observations in an orthopaedic

centre in Germany. Details of these observations are introduced and lessons learned from them are identified in the following section.

3.4.2.1 Pilot observations

In the orthopaedic centre in Germany, I conducted three pilot observations, each spanning a consultation with one patient. The centre employed six technicians and one administrative assistant. I observed two different patients and four different technicians. There were two technicians present during each consultation. One observation covered the fitting for a new prosthesis, and the second observation covered the fitting of the prosthesis produced since the fitting and so involved the same patient. A third observation with a different patient covered the trouble-shooting of an already produced prosthesis. I gained informed consent for these observations from all the technicians and both patients involved. During the observations, the technicians explained many details to me, and I asked questions of them and the patients. I was present in the centre during the whole time of the patients' visits, and stayed on for an additional 15 minutes to talk to the technicians further. I took extensive notes throughout the observations which I wrote up soon after.

Although the situation in the orthopaedic centre in Germany was quite different from the orthopaedic centres in Malawi, it gave me an insight into conducting observations and I learned from this pilot experience. For later observations it was important to have a focus since it was impossible to note down everything that happened or was said. This coincides with the strategy mentioned earlier of ever more narrowly focussed observations (Silverman, 2010: 234; Spradley, 1980: 73). The pilot observations also gave me the opportunity to test two strategies I had developed theoretically. These were gaining the trust of participants and complementing the observations with interviews. Both approaches were confirmed during the pilot observations. The strategy of gaining trust worked well; at successive observations I was given more detailed explanations and spoken to more openly. Openness can lead to better results and disclosure of more information. I also felt more comfortable

asking questions. The technicians were welcoming and explained a considerable amount of detail. It was important to gain their trust since they acted as facilitators and helped me to gain the trust of patients. The second strategy that was confirmed during the pilot was that interviews are a key method for gathering the information I needed related to what changes were created, as talking with technicians after the observations yielded important insights. The observations are important for understanding the context in an orthopaedic centre and gaining a certain level of technical knowledge, and are complemented by interviews. I next describe the fieldwork observations.

3.4.2.2 Observations conducted during fieldwork

During the fieldwork, data were collected first with observations. The observations were conducted in two orthopaedic centres in Malawi, in the orthopaedic centre at QECH in Blantyre and in the orthopaedic centre at the Ekwendeni Mission Hospital. The observations spanned cast-taking, production and fitting as well as repairs to the prostheses. I also observed the interactions among centre personnel, also called orthopaedic technicians, and patients during cast-taking, fitting and repair. I gained informed consent from all involved. In addition to making field-notes, I took photos of the prostheses and production steps (Spradley, 1980: 63–64). These observations took place over 25 days in each centre.

In addition, I attended the annual conference of the Malawi Orthopaedic Association (MOA), which includes many professionals working with lower limb prostheses. I was asked to present my research there, an invitation I gladly accepted. Table 3-4 summarises the observations conducted in the field.

Table 3-4 Observations conducted during fieldwork

Place	Total	Centre at QECH	Centre in Ekwendeni	Content
Orthopaedic centres	50 days	25 days	25 days	Prostheses production process, prostheses repairs, interaction between patients and centre personnel and among centre personnel; including photos
MOA conference	2 days			Presentations and interaction, own presentation of research

Source: Constructed by the author

The data collected during the observations were used to prepare the interviews and are the basis, together with the data from these interviews, of the data presented in Chapters 5 and 6.

Participant observation was chosen as suitable for this research. Pilot observations were conducted in an orthopaedic centre in Germany and the lessons learned from them were taken into account. Lastly, the observations conducted during the fieldwork were introduced. Data collected during these observations were analysed to inform the subsequent interviews. The method of collecting data with interviews is described in detail next.

3.4.3 Interviews

In addition to observations, interviews were used to collect data for this research. The interviews served to cast light on the creation and sharing of changes to lower limb prostheses. They also gave more information about the general conditions surrounding lower limb prostheses and their users. The focus of the interviews was on users directly involved with prostheses who could therefore potentially create changes to them. These included centre personnel, also called orthopaedic technicians, and patients, who made up

most of the interviewees. I also interviewed experts such as physicians and policy makers in order to understand the context in which users create and share changes to lower limb prostheses in Malawi. The information on the context of lower limb prostheses in Malawi is explored in detail in Chapter 4. In this section different forms of qualitative interviews are introduced and the most suitable form for this research is identified. I describe various aspects related to conducting interviews including interview guides, practical considerations and strategies for different groups of interviewees. Finally, the interviews carried out are described.

3.4.3.1 Different forms of qualitative interviews

Interviews can be used to collect both quantitative and qualitative data. To collect quantitative data, interviews are usually very structured. Structured refers to how much freedom the interviewee has to answer a question. Interview questionnaires for quantitative research generally take the form of closed questions with a choice of specific answers for the interviewee (Oppenheim, 1992: 113). Semi-structured or unstructured interviews employ more open questions, which the interviewee is free to answer in whatever way seems appropriate. The entire responses need to be recorded (ibid. p.112). Asking closed questions allows the collection of quantitative data. These questions are highly comparable and the approach allows a lot of questions and answers in a short space of time (ibid. p.115). However, this research is not interested in quantifying, for example, how many users of lower limb prostheses make changes to their prostheses. It is focussed on the details of the creation and sharing of these changes in order to identify the factors that influence them. This includes what changes are created to the prostheses and how they look, who made them and whether they were shared. This led to the choice of a qualitative approach – and rejection of the use of closed questions.

There are many types of qualitative interviews and their taxonomy is not uniform. Names such as unstructured, semi-structured, in-depth, semi-standardised or narrative are used to describe different types of qualitative

interviews (Flick, 2006: 149–155; Hopf, 2007; Kvale, 2007). However, they have three main characteristics (Hopf, 2007: 351). First, questions can be pre-defined and used to guide the interview in a given direction, or use of pre-defined questions might be very scarce, leaving the interview very open (ibid.). Second, the interview can centre on a particular topic or stimulus such as a film, or cover a very broad spectrum of topics (ibid.). Third, the interview can be aimed at creating a narrative, in which case active listening by the researcher is key (ibid. p.351-352). Alternatively, the researcher may need to ask probing questions and make provocative statements, to find out about specific opinions the interviewee for example (ibid.).

As already stated, the goal of the interviews in this research is to find out about the changes created by users to lower limb prostheses and to assess the general situation surrounding lower limb prostheses, such as the nature of the healthcare system and government regulations. First, it was necessary to decide how many pre-defined questions to include. Both more guided interviews and very open interviews use open-ended questions, and yield qualitative data. Since there were specific topics of interest, some guidance in the interviews was necessary, but it was necessary also to give interviewees the freedom to state their opinions. This implied that the interviews should focus on a certain number of topics and not try to cover too broad a spectrum of issues. Semi-structured interviews were chosen precisely because they provide this openness and flexibility while also ensuring a focus on the topic being researched (Flick, 2006: 149). An interview guide was used to leave enough room for the interviewee to express his or her views, and to keep the conversation on the topic of interest for this study (Helfferich, 2009: 179). An interview guide should ensure that the interviewee's narrative is maintained and to keep the conversation centred on the topic of interest (ibid.). The interview guides used for the interviews were based on the enabling innovation framework introduced in Chapter 2, and are described in the following section.

3.4.3.2 Design of the interview guides

The interview guides started with a conversational opening question to set the scene, and then used general and specific probing and ad hoc questions (Helfferich, 2009: 181–186). The researcher has to maintain a good atmosphere, which the conversational entry question helped to establish (Kvale, 2007: 60). The probing questions served two purposes: the general ones kept the narrative flowing and asked for details, while the specific ones provided feedback and confrontation (ibid.). This approach is likely to be especially valid for conducting interviews in a culture substantially different from the researcher's, as in this case. This is important because data collection requires that the researcher disregards his or her concepts and expectations in order not to wrongly interpret answers from a different perspective (Helfferich, 2009: 123–126). Probing helps to ensure a full understanding of interviewees' narratives and a good rapport is especially helpful if researcher and interviewee are from different cultures and backgrounds. A good rapport includes friendliness, warmth, trust, appreciation and neutrality in the sense that the researcher is open to what is being said (ibid. p.130). The interview is framed by a briefing before the interview and a debriefing afterwards (Kvale, 2007: 55–56). The briefing includes an explanation of the interview situation, such as duration and purpose of the interview, and answers to any questions the participant may have (ibid. p.55). It is also important to stress that the participant's privacy will be protected, and that he or she can refuse to answer questions or stop the interview at any point. The interview ends with a debriefing; the researcher sums up what he or she has learned from the interview to give the participant the opportunity to provide feedback (ibid p.56). In addition, the participant is asked if he or she wants to add anything to the interview (ibid.). This is important as it leaves the participant room to offer additional comments which may provide the researcher with further valuable insights.

Two different interview guides were used for this research, one for centre personnel, also called orthopaedic technicians, and patients, and one for experts such as physicians. Both interview guides are described below.

First, the interview guide for centre personnel and patients is introduced. This research is informed by the enabling innovation framework, which provides details such as the learning selection processes users experience when creating changes. These details are especially helpful for investigating the changes users create and share. Therefore, the interview guide for centre personnel and patients, as the users who create changes to lower limb prostheses, uses the concept of the learning selection processes. The interview guide includes questions on four general topics. The first topic is the personal learning selection processes that interviewees go through when making specific changes to lower limb prostheses. The other three topics refer to the characteristics of the wider process of changes to lower limb prostheses and their use and acceptance. The learning selection process covers the four stages identified by Douthwaite (2006: 96–98) in the enabling innovation framework introduced in Chapter 2 Section 2.3.1: experience, making sense, drawing conclusions and action. In the part of the interview that focussed on the general process of changes, interviewees were asked about who participated in this process, and what were its outcomes. This was relevant to the research questions because it gave details about the changes made to lower limb prostheses in addition to the personal level covered in the previous question. These two sections formed the major part of the interview. Additional questions were asked about the use and acceptance of lower limb prostheses. This was important for understanding the context of lower limb prostheses.

The interview guide for the other experts centred specifically on this context and external conditions. The questions were informed by topics indicated in the literature as relevant to medical technologies in developing countries. There were three parts to this interview guide: healthcare, technologies for disabilities, and disability in general. The part on healthcare included questions on topics such as the structure of healthcare, the financial situation and the role of aid. The next part on technologies for disabilities covered lower limb prostheses and alternatives, and included issues such as production and training. Finally, the part dealing with disability in general was concerned with advocacy and social security.

In both interview guides, personal data were collected on the interviewees including names, gender, age, occupation, place of residence and the reason for their disability, if known and if applicable. These questions were asked at the end of the interview in order not to disconcert interviewees (Helfferich, 2009: 187; Oppenheim, 1992: 109). Both interview guides are provided in the appendices. I next consider important aspects of conducting the interviews in practice.

3.4.3.3 Practical considerations for conducting interviews

The important aspects to be considered are setting the scene for the interviews, the role of the researcher, and power aspects.

At the beginning of the interview, the researcher needs to set the scene and mood for the interview. This includes choosing the location, seating arrangements and the roles of both researcher and participant. It is important to create an atmosphere of interest, understanding, respect, friendliness, trust and openness (Helfferich, 2009: 130; Kvale, 2007: 55). Introducing the interview is very important and sets the tone for the remaining interview; how the researcher introduces him- or herself has major implications (Kvale, 2007: 55).

In structural terms, the power related to the roles of interviewer and interviewee is important. The researcher has power because he or she is guiding the interview and knows what questions will be asked (ibid. pp.133, 134). The participant has power in that he or she is providing the narrative that the researcher seeks, and can refuse to give information or stop the interview at any time (ibid. p. 134). It is important to be aware of these issues so the researcher can keep control of the interview situation.

While these points apply to all interviews, there are some important differences that need to be taken into account. In the next section, the specific characteristics of expert interviews and differences for interviewing centre personnel, other experts and patients are introduced.

3.4.3.4 Interview strategies for different groups of participants

This research involved three different interview situations, which are all considered here. Interviews were conducted with centre personnel, other experts such as physicians and policy makers, and patients. The first two groups are professionals in the field of lower limb prostheses and related issues, the patients are laypersons. However, this does not mean that the patients are not experts in the use and practical aspects of living with a lower limb prosthesis.

Expert interviews are a special category of interviews which is discussed in the literature. The difference between expert and other interviews is that experts are interviewed because of their special status (Helfferich, 2009: 163). The interest is primarily in their expert role not their person and personal details are generally not of interest (Flick, 2006: 165; Helfferich, 2009: 162–164). Because of this characteristic, the interview guide for expert interviews is often quite directive to exclude unproductive topics (ibid.). Also, in expert interviews the focus is on facts (ibid.). The interviews with centre personnel were similar to those with experts in most aspects. Centre personnel are also experts, but they were asked about experiences as well as facts. Therefore, the interview guide was less directed than in the case of expert interviews because experiences were the focus. Apart from keeping the interview on the topic of interest, the interview guide also had the function of presenting the researcher as competent (ibid.). This was important for centre personnel and expert interviewees.

The researcher can adopt different roles when interacting with research participants. He or she can either be a superior researcher who takes it as given that participants take part, or a grateful researcher with little prior knowledge who wants to learn from the participants (Helfferich, 2009: 133). Both roles can be appropriate, depending on the interview situation. Here, there were two different situations as described above: that of interviewing experts on lower limb prostheses, including centre personnel and other experts, and patients. In the case of the patients, the role of the superior researcher could have been unfavourable and made patients unsure, such as about the use of unfamiliar

terms. This would have made the interviewees less open or prone to use terms without understanding them, which could be misleading. While it was important to establish the patients' trust and to overcome their possible hesitance to share their opinions, for the experts it was important that the researcher was taken seriously. The issues and respective strategies derived for the different participants in interviews are summarised in Table 3-5.

Table 3-5 Strategies for interviewing different groups of participants

Issue	Strategy for centre personnel, also called technicians	Strategy for other experts	Strategy for patients
Interview guide	More open, focus on experiences and facts	More directive, focus on facts	More open, focus on experiences
Role and amount of previous knowledge shown	Show familiarity with medical terms to be taken seriously	Show familiarity with medical terms to be taken seriously	Do not use too may technical terms so participants will not be reserved in interviews

Source: Constructed by the author

Semi-structured interviews were used to allow participants the freedom to express their views while keeping the interview focussed on the topic of interest. In this section the special characteristics of the expert interview were described and suitable strategies for interviewing the three different groups of participants, centre personnel, other experts and patients, were discussed. The next section provides details of the interviews conducted during the fieldwork for this research.

3.4.3.5 Interviews conducted during fieldwork

Interviews were conducted with three groups of participants: centre personnel, patients and other experts, and Table 3-6 summarises them. The data sources are indicated in the text as follows: letters denote the professional status (P is patients, C is orthopaedic centre personnel and E is experts), the

method (I is interview), and, if relevant, the location (B is Blantyre and E is Ekwendeni), and are numbered consecutively. As mentioned earlier, orthopaedic centre personnel are also referred to as 'orthopaedic technicians' or 'technicians', the term most commonly used to refer to people working at orthopaedic centres.

Table 3-6 Interviews conducted during fieldwork and indication of data

Participants	**Total**	**Centre at QECH**	**Centre in Ekwendeni**	**Content**	
Centre personnel (Technicians)	9	7 CIB01-CIB07	2 CIE08, CIE09	Details of changes including reasons, if change was shared with someone else	Networks, Training
Patients	22	11 PIB01-PIB11	11 PIE12-PIE22		Experiences with prostheses, life circumstances
Experts	14 EI01-EI14			Healthcare system, issues of disability	

Source: Constructed by the author

Semi-structured interviews were conducted with technicians and patients. Nine technicians were interviewed. In the centre at QECH, I interviewed all four technicians who produced prostheses. I also interviewed the centre head and two other technicians who had important functions in the centre. One had worked there since the centre had opened and was able to give me a history of it. Its long history of providing orthopaedic services in Malawi was one of the reasons for choosing this centre for the research. The other technician was in charge of the administration and was the first point of contact for patients coming to the centre. In the centre in Ekwendeni I interviewed both the technicians working at the centre. All the interviews were informed by the observations made earlier, and especially the changes I had seen being made

to the prostheses. Observation notes and photos were analysed prior to the interviews and questions were asked about changes observed. This order of data collection allowed me to be familiar with the standard production process and to identify changes, and to gain the trust of the technicians which provided a basis for the interviews.

I also interviewed 22 patients, 11 from each centre. All but three were interviewed at the respective centres. The three exceptions were interviewed at the offices of a disability organisation in another town which was more convenient for them. In the centre at QECH, patients were chosen from those who attended the centre for repairs or new prostheses. All except one patient had been using their prostheses for some time, they included men and women, different causes of disability, different kinds of prostheses, and different occupations and education levels. The centre at the Ekwendeni Mission Hospital had a complete database of its patients, which allowed me to contact additional patients to those who attended the centre for repairs or to acquire new prostheses. Patients were sampled for diversity of the characteristics mentioned above. Following this strategy of maximum variation elaborated in Section 3.3, I was able to investigate whether patients making changes was a general phenomenon or limited to patients with certain characteristics.

In addition to conducting interviews with patients, I inspected their prostheses in order to identify changes, and, if I found any, I included respective questions in the interview. This was possible in all cases except two where the patients had not brought their prostheses with them.

In order to collect information on the conditions surrounding lower limb prostheses in Malawi, 14 experts were interviewed. The interviews with experts were conducted at their workplaces or the two orthopaedic centres. These experts came from relevant medical professions, ministries and disability organisations. The information provided by these interviewees allows the prostheses to be seen as part of a wider context which influences the changes created to them by users, and which helps to describe how users can and do share these changes. This allowed triangulation with information from the

literature and documents in relation to the conditions of lower limb prostheses in Malawi.

These data allowed me to assess the changes to lower limb prostheses in the two orthopaedic centres in Malawi, and to draw more general conclusions and implications about the factors influencing user innovation to medical technologies in developing country settings. In order to achieve this, I analysed the collected data and the analytical strategies are described below.

3.5 Data analysis

As noted earlier, the data collected in this research are based on the case study approach and are mostly qualitative based on observations and interviews, complemented by available documents and artefacts of lower limb prostheses.

Pattern matching, explanation building, time-series analysis, logic models and cross-case synthesis are the major analytical techniques for case studies (Yin, 2009: 136–160). Pattern matching consists of comparing an empirically based pattern with a predicted one. Explanation building is an exploratory approach and involves a special type of pattern matching, where the respective pattern is not preconceived before the study, but emerges through iterations of the analysis. This approach is part of grounded theory (Glaser and Strauss, 1967). Events over time are the major focus of time-series analysis; rival trends are theoretically defined before data collection and then matched with the empirical data. Logic models consider subsequent cause-effect patterns, in sequential stages. While all of these techniques can be used for single as well as multiple case studies, for the technique of cross-case synthesis, several case studies are necessary. Here, the data from all cases are displayed according to a uniform framework and then compared.

This research is informed by the enabling innovation framework proposed in Chapter 2 Section 2.3. Of the above described approaches, neither the time-

series analysis nor the logic model approach were suitable since the focus is not on the timely unfolding of events or sequential stages. The cross-case synthesis treats each individual case as a separate study, which also is not suitable for this research since the objective is to compare cases of changes between different users and centres.

Therefore pattern matching was chosen with the model of the basic process of user innovation and the enabling innovation framework providing the predicted patterns. The factors that influence the changes by users are identified only as limitations on the basis of insights from frugal innovation and grassroots innovation concepts, but there are no details about how they can be categorised and how they affect these processes. Therefore, the data can be matched with predicted patterns in the form of the framework since they are predefined, and explanations can be built about how factors, namely limitations, influence the processes they describe.

The data analysis included a preliminary stage and a main data analysis stage. The preliminary data analysis was conducted during the fieldwork in order to prepare for the interviews with technicians. Before each interview, I revised all observation notes concerning the respective technician in order to include questions on the changes he created.

The main data analysis was conducted after the fieldwork phase. The interviews were transcribed and relevant parts of the field-notes typed up. The data were ordered using the NVivo software to help analyse the qualitative data. Relevant codes were defined in this software to code the interview and observation data. The pattern matching was based mainly on three aspects of the data: details of changes made by users and the reasons for them, how users shared their changes and connections that allowed this, and the conditions under which users create and share their changes. The data were categorised according to different users, patients and technicians, and the two orthopaedic centres. NVivo allows the data to be displayed under pre-defined categories in matrices which then are used as the basis for comparisons, the results of which are presented in Chapter 7. I compared sets of changes and

related their differences to the different circumstances of users and centres. In this way I could identify factors that influence the creation and sharing of changes and, thus, user innovation to medical technologies in such settings more generally. Chapters 4, 5 and 6 present the data on the background, creation and sharing of changes by users.

3.6 Summary

This chapter provided details of the research and data collection methods, the data collected during the fieldwork and their analysis.

Qualitative research was chosen as suitable to address the research questions on changes created by users to medical technologies in a real-life setting in a developing country in order to stay open to the experiences of users and seeking their perspective. There are several different approaches to qualitative research, and the case study method was found to be the most suitable one for this research. This was due to its focus on multiple data sources and contemporary phenomena. A suitable medical technology and country were chosen, based on criteria derived from the enabling innovation framework proposed for the research. An investigation of lower limb prostheses in two orthopaedic centres in Malawi was found to be suitable.

The main data collection methods were introduced and the semi-structured interviews and observations described. An overview of the data collected in the field and details of interviews and observations was provided. Finally, the analytical strategy was described.

As mentioned at the beginning of this chapter, in order to investigate the topic of this research it is crucial to consider the conditions and the background to lower limb prostheses in Malawi. Chapter 4 introduces these based on available documents and the data collected during fieldwork.

4 Background to lower limb prostheses in Malawi

This chapter discusses the background conditions to lower limb prostheses in Malawi. As already mentioned, it is important to understand the circumstances in order to draw more general conclusions based on specific changes made by users to factors that influence user innovations in medical technologies in developing country settings. It is important to take account of the environment in which users create and share these changes. In relation to identifying influencing factors with the aid of the enabling innovation framework, as mentioned earlier in Chapter 3 Section 3.5, a detailed description of the conditions is important for two reasons. First, these conditions influence the learning selection processes the users go through, with the four stages experience, making sense, drawing conclusions and action, as detailed in Chapter 2 Section 2.3.1. Furthermore, the conditions a technology is subject to considerably influence the mechanisms of selection and promulgation of the changes created to this technology. Both concepts, in addition to the model of the basic process of user innovation, are important to identify factors which influence user innovation of medical technologies in developing country settings.

In order to describe the background, this chapter draws on both, secondary data from the literature and information available on websites, and primary data collected during the fieldwork, thus allowing data triangulation. What kind of data is mostly referred to is different for the different sections. Therefore, at the beginning of each section it is indicated what kind of data the specific section and its subsections mostly refer to.

Secondary data are indicated with the names of the authors and the year of publication, as it is done throughout the thesis. Primary data are indicated as has been listed in Chapter 3 Sections 3.4.2.2 and 3.4.3.5. Letters signify the professional status (P is patients, C is orthopaedic centre personnel, also called technicians, E is experts), the method (I is interview, O is observation) and, where relevant, the location (B is Blantyre, E is Ekwendeni), and are further

distinguished by consecutive numbering. Observation data are labelled 'observation' followed by the date (in the form year, month, day). This chapter provides background information on Malawi and its healthcare system, the country's orthopaedic centres and how they were established. For the two centres which are the focus of this research, the Queen Elizabeth Central Hospital (QECH) centre and the Ekwendeni Mission Hospital centre, previous and current technologies used to produce lower limb prostheses are described and compared. This chapter concludes with a discussion of disability in Malawi, including statistics, important organisations, beliefs and customs.

4.1 Geographical and population data

Malawi is part of Sub-Saharan Africa and is located in the East of the continent. This section gives details on its geography and population, based solely on secondary data. Malawi has borders with Zambia, Tanzania and Mozambique (Central Intelligence Agency, 2013). Its surface area is 118,000 square km, 20% of which is water (National Statistical Office, 2010: 1). It has a population of 13 million (ibid. p.6), 80% of whom live in rural areas (Central Intelligence Agency, 2013). The percentage of people below the poverty line was 52% in 2005 (National Statistical Office, 2010: 87). The situation for the rural population is worse, with 56% below the poverty line compared to 25% of the urban population (ibid.). Thus, many patients have little disposable income to spend on health services. Malawi's economy is mainly based on agriculture; 83% of employment in 2009 was in the agricultural, forestry or fishing sectors (ibid. p.34). This highlights the importance of personal mobility to secure a livelihood and the immensely positive effect of lower limb prostheses for disabled persons. In 2007, agriculture accounted for 29% of the gross domestic product. A large proportion of agricultural activity is subsistence agriculture, that is, what is harvested is enough to satisfy the family's food demands, with little surplus available to sell. However, the remaining proportion supplies the major part of Malawi's exports. The most important export crops – tobacco, tea and sugar – comprised 69% of total exports from Malawi in 2010 (ibid. pp. 39, 77-79, 83). Malawi is a recipient of aid from the International Monetary Fund, the

World Bank and individual donor nations. The aid received has a profound effect on healthcare, which will be elaborated on in Section 4.2 (Central Intelligence Agency, 2013).

4.2 Healthcare in Malawi

This section provides detail on healthcare in Malawi, including Western as well as traditional medicine, which are an important part of the conditions of lower limb prostheses in Malawi. All subsections mostly refer to secondary data as well as primary data in the form of expert interviews. Section 4.2.3 additionally refers to interviews with technicians.

4.2.1 Western medicine

There are three levels of Western healthcare provision in Malawi: health centres, rural or district hospitals and central hospitals (Mkandawire et al., 2008; EI07). For the many Malawians who live in rural areas the 300 health centres are the first point of contact. Most villages are within a 10 km distance from a health centre (ibid.). If health centre personnel, usually a nurse and a medical assistant, are unable to treat a patient, he or she is referred to the nearest rural or district hospital, 26 such district hospitals exist in Malawi (ibid.). More complex cases may be referred to a central hospital, which provide the most specialised level of public medical care. There are five central hospitals in Malawi, one each in Blantyre, Lilongwe and Mzuzu, and two in Zomba, one of which is a mental health hospital (EI07). In addition to these facilities which are run by the Malawian Ministry of Health and are not-for-profit, there are some not-for-profit private facilities. Church missions provide 45 mission hospitals, 26 of which serve as additional government district hospitals (Mkandawire et al., 2008). They are organised under the Christian Health Association of Malawi (CHAM) (Loeb and Eide, 2004: 32–33). In addition to the Ministry of Health and CHAM facilities, in 1998, 40% of all health facilities were operated by the Ministry of Health, and 20% by CHAM, a further 17% are provided by firms to

provide better healthcare for their employees, also on a not-for-profit basis (Ministry of Health and Population[9], 2001). Private for-profit healthcare accounts for 13% of all health care facilities (ibid. p.33), and includes a private institution for orthopaedics - the Beit CURE hospital in Blantyre, which provides private orthopaedic care for adult patients, but treats children for free (Cure Malawi, n.d.). Finally, 10% of health facilities are provided by other government structures than the Ministry of Health (ibid.). Most of the services provided by government are free for patients, with the exception of “paying wards” in selected government health facilities (Loeb and Eide, 2004: 32–33). CHAM charges user fees for all its patients at subsidised rates, on a not-for-profit basis (Mkandawire et al., 2008). Some CHAM hospitals have memoranda of understanding with their respective district government and provide certain services for free, especially for mothers and children (Mkandawire et al., 2008; EI10). Health insurance is available in Malawi, but is not compulsory and only a very small proportion of the population has health insurance (Makoka et al., 2007: 3–4).

In addition to the health facilities described above, the Ministry of Health manages various medical rehabilitation services including the orthopaedic centres. The head of medical rehabilitation services in the Ministry of Health oversees, coordinates and lobbies for all rehabilitation activities (EI11). In general, applications to do research on health in Malawi, including this research, require approval from the Ministry of Health in the form of the National Health Sciences Research Committee (NCRM, 2003). An exception is research conducted by the Malawi College of Medicine, which is approved by the college's own approving body, as long as the research is not of national importance (COMREC, n.d.). Donors are important for the provision of healthcare. In the fiscal year 2010/2011, donors accounted for 23% of the national budget in the form of grants, of which the Ministry of Health received 27.6 billion Malawian Kwacha, representing just under 10% of the total healthcare budget (Ministry of Finance, 2012). Donors put special emphasis on HIV/AIDS, malaria and tuberculosis, and additional donations go to such

[9] The Ministry of Health and Population was renamed the Ministry of Health after publication of this 2001 report.

programmes directly (Ministry of Finance, 2012; Ministry of Health and Population, 2001: 41; EI01; The Global Fund to Fight AIDS, Tuberculosis and Malaria, 2013).

There are several health professions crucial for orthopaedic care in Malawi. Orthopaedic surgeons provide services in Malawi, but their number is small: a total of nine of whom two are Malawians (Mkandawire et al., 2008; EI01). One of the reasons for this shortage is that a local orthopaedic postgraduate programme at the Malawi College of Medicine was not offered until 2002 (ibid.). Since intake for this programme has been one or two candidates a year, it will take some time to increase student numbers and to train more orthopaedic surgeons (ibid.). In addition, there is an 'internal brain drain' effect, which means that some medical doctors choose positions in public health programmes and with donors and aid agencies, which offer better pay and added benefits, rather than going into clinical services (EI01). The shortage of medical doctors, in orthopaedics and also in other medical specialties, has resulted in the creation of a paramedical professional, the clinical officer, who is somewhere between a nurse and a doctor (Mkandawire et al., 2008). Individuals trained as clinical officers can perform basic medical procedures (ibid.). This relieves some of the workload on the few medical doctors and means that at smaller clinics that do not have a medical doctor, patients receive better treatment. In orthopaedics, there are orthopaedic clinical officers, trained at the Malawi College of Health Sciences, who can perform basic procedures such as non-operative fracture treatment, treatment for burn injuries and amputations (ibid.).

Especially important for providing lower limb prostheses are the orthopaedic technicians. Currently, there is no formal training available in Malawi for orthopaedic technicians (EI01; EI03). Most orthopaedic technicians working in Malawi have been trained in the orthopaedic centres or at the Tanzania Training Centre for Orthopaedic Technologists (TATCOT) in Moshi. A few received their training abroad, for example, in the United Kingdom or in Norway

through an exchange programme with Sophies Minde[10] (CIB02; CIB03). Also important for orthopaedic services are rehabilitation technicians and physiotherapists. In relation to prostheses, their main work is related to postoperative care: they train patients and bandage stumps to achieve a well-rounded shape that will give as little problems as possible when the patient uses a prosthesis (EI04, EI06). In theory, they can do gait training[11] after the patient is fitted with a prosthesis. However, I found that, in practice, in the two orthopaedic centres at QECH and the Ekwendeni Mission Hospital gait training is the responsibility of the orthopaedic technicians (EI06; observations 120530, 120606, 120613, 120824, 120913).

4.2.2 Traditional medicine

In addition to Western medicine, traditional medicine is supplied in Malawi, with many people using both (Ministry of Health and Population, 2001: 11). Traditional medicine is provided mainly by two groups, traditional healers and traditional birth attendants (ibid.). The focus in this section is on traditional healers, as these were referred to in interviews in relation to disability issues.

For some people, traditional healers play an important role in the healthcare sought and received. The traditional healer may be the first point of contact for someone requiring medical treatment, and is likely to be more easily accessible, often residing in the same village, than the nearest health centre (EI03; EI12). Traditional healers often work with roots and herbs (EI03). Cooperation between traditional healers and the Ministry of Health is increasing and is aimed at encouraging the former to refer patients with more serious illnesses to a health centre instead of trying to treat them themselves and possibly exacerbating the condition (EI07; EI12). Witchcraft is sometimes tied in with traditional medicine, but not in all cases: “There are two types of these healers. Traditional medicine, natural medicine whereby you do not seek the intervention

[10] Sophies Minde Ortopedi AS is Norway’s largest physical rehabilitation centre, and is owned by the Oslo University Hospital (Sophies Minde Ortopedi AS, n.d.).
[11] Gait training is exercises for patients to optimise their balance and motion when using their prostheses (ICRC, 2008).

of the spirits and the like, and the other traditional medicine whereby you seek the intervention of the spirits. (…) So I believe there are two categories." (EI12). The relation between witchcraft and disability is discussed further in Section 4.4.3 on beliefs and customs related to disability.

4.2.3 System and history of main orthopaedic centres in Malawi

As noted earlier in Section 3.3.2, at the time of writing, there were four main orthopaedic centres in Malawi. A short history of their establishment and subsequent development is presented below, as this represents conditions for the production of lower limb prostheses which can subsequently influence the users' learning selection processes and thus the changes they create.

QECH in Blantyre is one of the largest hospitals in the country and was opened by Queen Elizabeth the Queen Mother of the United Kingdom, in July 1957, while Malawi was still under British colonial rule (Idana, 2006). The orthopaedic centre at QECH, which was the first such centre to be opened in Malawi, was officially opened in 1970 (CIB01; CIB05). The orthopaedic centre is a department of QECH and, under this structure, is run by the Malawian Ministry of Health (EI07). It is also supported by the Rotary Club, which funded an extension to the building and materials required for the Jaipur technology (CIB05). It previously received support from the International Committee of the Red Cross (ICRC) in the form of supplies of materials, but this support was discontinued at the end of 2012 with the expiry and non-renewal of the memorandum of understanding (ICRC, 2013a; CIB02). At the time of writing, the orthopaedic centre in Blantyre was offering the most diverse services in the country; in addition to prostheses, it also supplies orthoses[12], surgical boots and wheelchairs (CIB02).

The Ekwendeni Mission Hospital in Ekwedeni, in the North of Malawi was the second centre providing prostheses in Malawi, being established in 2006

[12] Orthoses do not replace a missing limb, but provide support for an existing limb that is too weak to function on its own.

(Presbyterian Church (U.S.A.), n.d.). The Ekwendeni Mission Hospital was founded by the Free Church of Scotland and currently is operated by the Synod of Livingstonia of the Church of Central Africa Presbyterian (CCAP) (Church of Central Africa Presbyterian Synod of Livingstonia, 2010; Presbyterian Church (U.S.A.), n.d.). As referred to in Section 4.2.1, the mission hospital, like other mission hospitals, is organised under CHAM (Loeb and Eide, 2004: 32–33). The then head of the orthopaedic centre at QECH initiated the establishment of this orthopaedic centre in Ekwendeni (CIE08). He tried to establish an orthopaedic centre close by at the Mzuzu Central Hospital under the Ministry of Health, but was not successful (ibid.). He had contacts with the Rotary Club's Jaipur Limb Campaign project through earlier limb camps organised at the QECH centre (CIE02). The Ekwendeni Mission Hospital was proposed as an alternative site to the Mzuzu Central Hospital for an orthopaedic centre, and the proposal was accepted (CIE08). The Rotary Club funded the building of the orthopaedic centre, which still includes some structures from an old building which used to serve as the maternity ward (ibid.). The building was renovated and extended, equipped with machines and then handed over to the Mission Hospital. The head of the QECH centre, together with a technician from the QECH centre, prepared the centre, and trained the two technicians the hospital had employed (CIE08; CIE09). The technician with previous experience of working at the centre in Blantyre who was employed by the Ministry of Health, was seconded by the government and has continued to work at the centre in Ekwendeni (CIE08; EI11).

The orthopaedic centre at the Kamuzu Central Hospital in Lilongwe opened in March 2009 (500 miles, 2013a; E11). Previously, there was a small unit at Kamuzu, but the technicians there only did small repairs, and did not produce prostheses (EI11). A Scottish charity, '500 miles', approached the Malawian government with a plan to open a third orthopaedic centre in Malawi at this hospital. The charity signed a memorandum of understanding with the Ministry of Health, stating that it would run the centre for the first seven to ten years and then hand it over to the Ministry (500 miles, 2013a; E11). It provided the building, made from containers, and funded training for some of the staff, at TATCOT (ibid.). The staff are Ministry of Health employees. This centre is also

supported by Sophies Minde Ortopedi AS. Sophies Minde supports an exchange programme for orthopaedic technicians and, under this programme, at the time of the fieldwork was funding a Scottish prosthetist to work at the centre for one year (Sophies Minde Ortopedi AS, n.d.). Sophies Minde supported the orthopaedic centre at QECH under the same programme until 2009 (CIB02; personal communication with a prosthetist and orthotist from Sophies Minde Ortopedi AS). An orthopaedic centre was built in Mzuzu under similar conditions by '500 miles' and opened in November 2012 (500 miles, 2013b; E11).

In summary, the orthopaedic centre in Blantyre is run by the Ministry of Health, while the centre in Ekwendeni is run by the Synod of Livingstonia of the CCAP, under CHAM. Both centres in Lilongwe and Mzuzu are run by the charity, 500 miles.

In addition to these four official centres, there are other possibilities for acquiring lower limb prostheses. There is a private orthopaedic centre in Blantyre run by an orthopaedic technician trained at TATCOT, employing materials imported from developed countries, namely the manufacturer Otto Bock (EI13). Also, the Malawi Against Physical Disabilities (MAP) office in Rumphi in the North of Malawi supplies prostheses which have leather sockets and wood instead of a foot, similar to the prostheses made in the orthopaedic centre at QECH in the 1970s and 1980s, see Section 4.3.2.1 (EI09; CIB01; Observation 120905). I next discuss the technologies used for lower limb prostheses in developing countries generally and in the orthopaedic centres at QECH and at the Ekwendeni Mission Hospital.

4.3 Lower limb prostheses

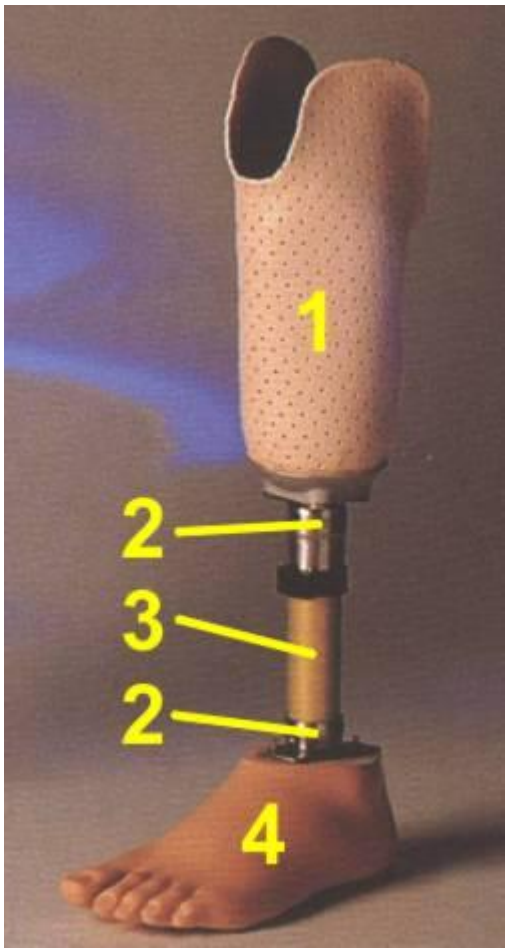
For investigating lower limb prostheses in developing countries, the technologies used are important since they have a major influence on the changes users can make to their prostheses and thus their learning selection processes. The characteristics of a technology are for example important for the experiences the users will have with it, as the first step of their learning

selection processes, as well as for the options they have for the action steps in these processes. In this section, particular aspects of lower limb prostheses in developing countries are therefore introduced, and the technologies used at the two orthopaedic centres visited are described and compared. Section 4.3.1 refers solely to secondary data, whereas the remaining sections refer to secondary data as well as primary data, the latter mostly in the form of interviews with technicians.

4.3.1 Particular aspects of lower limb prostheses in developing countries

A lower limb prosthesis generally consists of several different elements, as shown in Figure 4-1. Two elements common to all the technologies are the prosthetic foot and ankle (4) and the prosthetic socket (1). The prosthetic foot is either connected to a knee joint and then a prosthetic socket, or a prosthetic socket alone, depending on whether or not a replacement for the knee is required. For some technologies, this connection is achieved by using pyramid joints (2) on the foot and socket, which then are connected with a tube or pipe (3).

Figure 4-1 Photo of a lower limb prosthesis with main components indicated



Source: http://www.weilinger.at/unfall_neu/prothese.htm

Pyramid joints are also used to adjust the prosthesis to achieve proper alignment. Such joints are part of the ICRC polypropylene technology used in the orthopaedic centre at QECH. It comprises two concave disks which fulfil this task. In the case of other technologies, such as the technology used in the orthopaedic centre at the Ekwendeni Mission Hospital, the Jaipur technology, the prosthetic foot and socket are connected with alternative materials such as a plastic cover as a shank, or metal rods. The details of these technologies are important in discussing how and why users change them. This chapter provides details on the history of their use in the two orthopaedic centres in Section 4.3.2 and their similarities and differences in Section 4.3.3.

Lower limb prostheses can have a considerable positive effect on patients' lives, as they can be the key to escape poverty and earn one's livelihood (Harkins et al., 2013). This has resulted in a large body of work on such prostheses, especially in relation to developing countries. In the 1990s, there was an increase in publications about lower limb prostheses in developing countries (Cummings, 1996; Sharp, 1994). Since then, there have been many developments, including standards for testing the different components of a prosthesis (Andrysek, 2010: 392). However, some issues remain, the most prominent being problems related to the durability of the prosthetic foot, better prosthetic knee joints and improved socket fit and alignment (ibid p.378). Therefore, it is crucial that development of lower limb prostheses continues.

The technologies presently used in developing countries consist of prosthetic feet and ankles constructed mostly from polyurethane or rubber (Andrysek, 2010: 383). The prosthetic socket has to be custom-made for each patient to ensure a proper fit. The current technology is to produce a plaster wrap cast of the stump, from which a plaster model is made (ibid. p.388). This model is then covered with thermoplastics such as polypropylene and heated to achieve the prosthetic socket (ibid.). Sand casting and computer assisted systems, which are still being tested, are potential future alternatives (ibid. p. 389).

Some of the above mentioned problems with lower limb prostheses are difficult to solve without formal research and development structures, which are often not present in developing countries. These include durability of the foot. However, other issues, for example, correct alignment of the prosthesis, depend on what is being achieved in developing world orthopaedic centres. Next, details of the technologies used in the specific context of this research are elaborated on.

As described in Section 3.3.2, I conducted my research in two orthopaedic centres in Malawi: the QECH Orthopaedic Centre in Blantyre and the Orthopaedic Centre at the Ekwendeni Mission Hospital. Below, I discuss the two main technologies used in these orthopaedic centres, the ICRC

polypropylene and the Jaipur technology, and compare their similarities and differences.

4.3.2 Technologies used at the orthopaedic centres at QECH and the Ekwendeni Mission Hospital

4.3.2.1 Past and present technologies used to produce prostheses in the orthopaedic centre at QECH in Blantyre

Since the orthopaedic centre at QECH was established in 1970, several different technologies for making prostheses have been employed. Four distinct technologies can be differentiated: peg legs, Otto Bock, ICRC polypropylene and Jaipur. With the exception of Otto Bock, all were used to produce the prostheses of the patients who participated in this doctoral research. However, the emphasis is on those technologies currently used to produce prostheses at the centre, the ICRC polypropylene technology and the Jaipur technology.

The first prostheses produced at the QECH centre were so-called 'peg legs'. They consisted of a socket made out of leather from a cast of the stump and an iron sheet joint with rivets; for above knee prostheses there were also metal joints on both sides (CIB01; CIE08). In place of the foot there was a wooden block with a piece of used tyre nailed to the bottom (CIB01). This technology subsequently evolved, with the iron sheets being replaced with already joined aluminium, and the wooden block replaced by a wooden foot that was prefabricated (CIB01).

In the 1980s, peg legs were replaced by prostheses produced with a technology developed by the German company Otto Bock. The socket and the remaining leg were carved out of pre-made wood parts and the outside was laminated with liquid plastic mixed with hardener (CIB01; CIB05). The foot was ready-made and then attached to the prosthesis (CIB01).

At the beginning of the 1990s, the ICRC began to support the centre in order to increase the number of prostheses supplied (CIE05). This support was prompted by the influx of war amputees from Mozambique, many victims of landmines, as Blantyre is only about 50 km from the border to Mozambique (CIB05). Initially, the ICRC provided the raw materials and training for technicians, and the whole prosthesis, all its parts including the knee and the foot, were produced at the centre from these materials (CIB02; CIB04; CIB05). Local production was the dominant ICRC policy at the time. However, problems with differences in quality prompted the ICRC to move production of prosthesis parts for the whole of Africa to its centre in Addis Ababa, Ethiopia (CIE02). Again, problems emerged and, on the advice of hired consultants, in 2000 the ICRC began a gradual switch from producing the parts in Ethiopia to procuring them from C.R. Équipements, a Swiss company (ICRC, 2001). Various parts including the foot, knee, metal rods and other plastic parts, are delivered ready-made from this company to orthopaedic centres all over the world. The socket is produced in the centres with polypropylene sheets, hence the name ICRC polypropylene technology, and the prosthesis is assembled and finished so it closely resembles a natural leg.

In parallel with the ICRC support, the orthopaedic centre was contacted by Rotary International which offered to hold a limb camp producing prostheses using the Jaipur technology (CIB02). The components for this technology are manufactured centrally in India by the Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS) (CIB02; Bhagwan Mahaveer Viklang Sahayata Samiti, 2013; The Rotary Jaipur Limb Project, 2014a). It was agreed that a limb camp should be held at the centre (CIB02). The foot and knee joint, and the material for producing the socket and peg, were provided pre-made. Technicians came from India for the duration of the camp to produce the prostheses (CIB01). During this two-week camp, 150 limbs were fitted at no charge (CIB02; CIB05). However, patients returning for repairs to their prostheses were disappointed because the centre had not been provided with any spare parts or materials (CIB02). The head of the centre then contacted the local Rotary Club and five years later, in 1997, there was another limb camp, held this time for four weeks during which 300 prostheses were fitted (CIB02). The success of the limb camp

resulted in the establishment of the QECH centre as a permanent limb centre the following year in 1998 (ibid.). This allowed the centre to request supplies of materials (ibid.). Since then, it has received several consignments of materials paid for by the Rotary Jaipur Limb Campaign (ibid.).

Since 1998, both the ICRC and the Jaipur technology have been used at the orthopaedic centre. However, the Jaipur technology was rather sidelined, because an ICRC official did not favour it as he believed it to be inferior to the ICRC polypropylene technology[13] (CIB02). In addition, not all the centre's technicians were willing to learn how to make prostheses using the Jaipur technology (CIB02). At the time of writing, most prostheses made at the centre are produced with the ICRC polypropylene technology. During my two months at this centre, I did not observe any prostheses being produced using the Jaipur technology.

In addition to the supply with these technologies, the centre receives donations from developed countries of pre-used prostheses and prostheses parts (Observation 120613). Prostheses and prostheses parts are generally not re-used in developed countries, but programmes have been set up for patients there to donate their old prostheses (Amputee Coalition, 2012). Some of those programmes then bring the prostheses to developing countries (ibid.).

This history of the technologies shows the influence of manufacturers, donors and funding bodies on the changes users can create to technologies – whether through provision of certain technologies or support for certain activities, and thus their influence on users' learning selection processes. The connections between users, technicians and patients, and manufacturers and funding bodies is further discussed in Chapter 6, Sections 6.2.2 and 6.2.3 in the context of users sharing their changes and in consequence connecting their learning selection processes.

[13] Although there is no agreement about how the two technologies compare, subsequent delegates from the ICRC to the orthopaedic centre did not suggest abandoning the Jaipur technology (CB02).

4.3.2.2 Technologies used to produce prostheses in the orthopaedic centre at the Ekwendeni Mission Hospital

In the orthopaedic centre in Ekwendeni the Jaipur technology is used exclusively to produce prostheses. The centre was established with substantial help from the Rotary Jaipur Limb Project, which provided the centre with the Jaipur technology (CIE08; CIE09). As for the orthopaedic centre at QECH in Blantyre, the components are manufactured in India by BMVSS (CIE09; Bhagwan Mahaveer Viklang Sahayata Samiti, 2013; The Rotary Jaipur Limb Project, 2014a).

At the time of the fieldwork, the centre has received no further consignments of materials from the Rotary Jaipur Limb Project and no later developments of parts and materials. The centre received some materials from two small orthopaedic centres which had used the Jaipur technology, and which upon closure donated their remaining materials (CIE09). The technicians said they noticed a difference in some of the materials, but since it is unclear when the materials were originally supplied, it cannot be specified whether these materials are a further development or older than the original consignment received by the centre (ibid.). The centre also receives donated pre-used prostheses and parts from developed countries (CIE09).

Since the exact nature of the technologies is important to understand the learning selection processes that can and do occur, I discuss in detail and compare the two technologies primarily used in these two orthopaedic centres: the ICRC polypropylene technology and the Jaipur technology.

4.3.3 Comparison of the ICRC polypropylene technology and the Jaipur technology

The ICRC polypropylene technology and the Jaipur technology are similar in certain aspects. Both technologies were developed explicitly for developing countries, and are much simpler and cheaper than the technologies used to

produce lower limb prostheses in developed countries. Both technologies are also manufactured centrally far away from Malawi, in Switzerland and India, respectively, and distributed to developing countries all over the world (Bhagwan Mahaveer Viklang Sahayata Samiti, 2013; C.R. Équipements SA, n.d.). Both the ICRC and BMVSS are not-for-profit organisations and, therefore, the prostheses are supplied through non-market structures (Bhagwan Mahaveer Viklang Sahayata Samiti, 2013; ICRC, 2010a). This is important to note for identifying existing selection and promulgation mechanisms, as the enabling innovation framework refers to the market as an important entity for such mechanisms. In addition, all of these aspects influence the changes created to the technologies. As discussed in Section 3.3.1, prostheses were chosen for this research on the basis that they are sufficiently simple to allow changes to be made by many of their users – which is confirmed in the data collected on the creation of changes, in Chapter 5. How the properties of the technologies represent limitations and how these limitations in turn influence the changes created to them is discussed in detail in the results Chapter 7.

While the technologies are similar in some respects, they differ in others. Both technologies are produced centrally outside of Africa, although the ICRC has regional centres in Africa. The regional centre closest to Malawi is in Ethiopia, and many technicians from the orthopaedic centre at QECH in Blantyre have been there for short training periods (ICRC, 2013b). In addition, delegations from the ICRC have visited the centre (CIB02; CIB04). These connections between manufacturer and funding bodies of the technology and the orthopaedic technicians using it are important, to identify the sharing of changes and their subsequent selection and promulgation, as described in Chapter 6, Section 6.2.2. The ICRC training provides a connection through which changes can and have been shared. In the case of the Jaipur technology, there is contact between technicians and the funding body, but not the manufacturer BMVSS.

The two technologies differ also with regard to their development histories. The ICRC polypropylene technology was developed by the ICRC and manufactured locally. In 2000, production moved to C.R. Équipements in

Switzerland where all components are now manufactured centrally (ICRC, 2001, 2011). The Jaipur technology was initially developed not by the manufacturer, but by an orthopaedic surgeon and artisans in India with input from patients. This makes it an example of a technology jointly developed by various participants, as described in the enabling innovation framework. The orthopaedic surgeon involved, Dr Sethi, saw patients that he had previously fitted with prostheses who were not using them (Srinivasan, 2002: 335). He talked to them and discovered the disadvantages of these prostheses – all models from developed countries and, therefore, suited to the predominant lifestyle in those countries. They did not allow the wearer to squat and could not be used in water. They also needed the patient to wear shoes. In India shoes are not worn in certain circumstances, such as when entering a temple (Sethi, 1989: 119). In 1966, Dr Sethi set out to develop an alternative prosthesis which allowed the patient to squat, could be worn without a shoe and was water-resistant (Srinivasan, 2002: 328). Production of this technology then was taken up by BMVSS in Jaipur (Bhagwan Mahaveer Viklang Sahayata Samiti, 2013).

Lastly, there are differences between the make of the technologies which influence the changes created to them. Two main differences are the number of components in one prosthesis and the possibilities for alignment allowed by a particular technology. A prosthesis produced with the ICRC polypropylene technology has more components than one produced with the Jaipur technology, making it easier to create changes to the former - single small components can be changed more easily than larger ones. In addition, in the case of the ICRC polypropylene technology the alignment can be changed after the patient tries the prosthesis, which allows more options for changes. In contrast, once the Jaipur prosthesis has been produced and is ready for the patient to try, the alignment is fixed and cannot be changed.

In summary, the similarities and differences between the two technologies are of an organisational, historical and technological nature. It is important to investigate these in detail since they affect the scope for users to create changes, and thus influence their learning selection processes, and share their changes, this sharing being a first step to an eventual selection and

promulgation. This will be further discussed in Chapter 7. In addition to the technological details of lower limb prostheses, the prostheses are influenced also by issues of disability, as the patients who use them are themselves disabled. The next section discusses aspects of disabilities relevant to lower limb prostheses in Malawi.

4.4 Relevant aspects of disability

Above, the system of orthopaedic centres in Malawi and the corresponding technologies have been discussed. The context of disability in Malawi is important, because it influences the changes created to prostheses by both technicians and patients, as will be shown in Chapter 7. I first present some statistics to enable an overview of disability and assistive devices in Malawi, referring to secondary data only. There are several organisations introduced, which are committed to disability and have an important impact. I also discuss various disability related beliefs and customs which may influence prostheses users and the changes they create, as these among other things shape the experiences they make with prostheses and thus their learning selection processes. The sections giving this information refer to secondary data as well as primary data in the form of interviews with experts and patients.

4.4.1 Statistics on disability and assistive devices in Malawi

Most disability statistics for Malawi come from a study on the living conditions of people with activity limitations (Loeb and Eide, 2004). The report considers disabilities in terms of activity limitations rather than impairment (ibid. p.12). This is testament to the complex nature of disability: the same disability can have very different effects on different people depending on their circumstances, and even the healthiest person will, at some point, experience limitations to their activity or their social participation (ibid. pp.74, 144–154). Also, people born without a disability can become disabled later in life – for

example, through a road accident whose incidence is very high in developing countries (Nantulya and Reich, 2002).

The study by Loeb and Eide covers many aspects of the lives of disabled people. Especially noteworthy for this research are the data on people with physical disabilities. The study shows that this group makes up 43% of all disabled persons in Malawi (Loeb and Eide, 2004: 16). The remaining disabled have sensory impairments such as issues with seeing, hearing and communication, or intellectual and emotional disabilities, or learning disorders.

Loeb and Eide's study also includes findings on assistive devices, which are of particular interest to the present research since they include lower limb prostheses. Among all disabled people, 17% use assistive devices and of these, 70% use devices to aid personal mobility, which includes prostheses, wheelchairs and crutches (Loeb and Eide, 2004: 120–121). The study shows clearly that there is enormous unmet demand for assistive devices: 75% of physically disabled persons do not receive assistive devices, although they state that they need this service (ibid. p.112). Most assistive devices are claimed to function well by their users, 64% in total. There are several providers of assistive devices. Government health services provide 19% of these devices, while non-governmental organisations (NGOs) provide 9%, 30% are supplied privately and the rest are acquired through other sources (ibid. p.122). Of those receiving assistive devices, between 35% and 65% of recipients, depending on the type of device used, have been instructed in the proper use of the device (ibid. p.17). After a certain length of use, the devices need to be maintained and repaired. For 7% of assistive devices, this is done by government services; 40% are maintained by the users or their families (ibid. pp.17-18). Many of the patients interviewed for this research cited the need for repairs as the reason for creating changes to their prostheses, as described in Chapter 5 Section 5.2.3. 40% of devices are not maintained or repaired, among other reasons because of lack of money (ibid. pp.18, 122). This is clearly unsatisfactory since lower limb prostheses can become unusable from wear and tear if not maintained. This reverts the patient to the same difficult situation as before receiving a

prosthesis. The capacities of patients and technicians alike to repair lower limb prostheses are thus crucial, including the creation of changes when necessary.

Also important is what people believe caused their disability. In the study reported above, the most common cause was a physical illness, which accounts for 48% of all disabilities (Loeb and Eide, 2004: 108). Other important causes include being born with a disability, which accounts for 17% of disabilities, and accidents, identified as the cause of 11% of disabilities (ibid.). These reasons are common across the world. However, in Malawi another reason that was given was witchcraft – believed to be responsible for 4% of disabilities (ibid.). This points to the importance of beliefs and customs about disabilities, which are discussed in Section 4.4.3. 14% of disabilities were attributed to various other causes, including hard labour and environmental factors.

As already noted, help for disabled people in Malawi is available in different forms. Some patients with disabilities have been proactive and founded organisations to represent them. Other organisations concerned with disability have been founded by government. Those organisations, which are important for understanding the context of lower limb prostheses in Malawi, are discussed in the next section.

4.4.2 Disability organisations in Malawi

The three main organisations relevant for investigating lower limb prostheses in Malawi are the Malawi Council for the Handicapped (MACOHA), the Federation for Disability Organisations in Malawi (FEDOMA) and Malawi Against Physical Disabilities (MAP). These organisations may influence the creation of changes to prostheses in the orthopaedic centres I visited, as will be shown in Chapter 7 Section 7.2.1. Here, I introduce the organisations and their activities.

The MACOHA is an implementing agent for the government (Loeb and Eide, 2004: 167; EI05). It was established by the 1971 Handicapped Persons

Act in order to promote the welfare of persons with disabilities and to provide vocational and special training (Ministry of Persons with Disabilities and the Elderly, 2006: 10). It provides services directly and monitors the disability sector and disability services provided by other entities (EI05). MACOHA's aim is to identify disabled persons, to refer them for the services needed, and eventually to transfer skills to the disabled persons because “we would like persons with disabilities themselves to be on the forefront advocating their rights” (ibid.). One strategy to achieve this is rehabilitation volunteers – some of whom are disabled themselves, although most are not. These volunteers go into the villages, register disabled persons and give them information on the services available to them (PIE22). In addition to this practical help, they offer encouragement: “We even explain that to our fellow disabled people. (...) As a disabled person we can do things as well to help ourselves. So it's not the end of everything. Because if God allowed us to be disabled, we know that he has a purpose for us” (ibid.). There are also disability support clubs which offer an opportunity for disabled people to support each other and to make their voices heard (EI05). A further service that MACOHA provides is vocational training centres for disabled people, one in Lilongwe and one in Zomba, which offer various courses including tailoring (EI09; PIB05; PIE21). These structures could potentially lead to connections between patients and thus to sharing and eventual selection and promulgation of changes. They are therefore further discussed in Chapter 6 Section 6.1.2.

Another organisation is FEDOMA (FEDOMA, 2012). FEDOMA is an umbrella body for disability organisations in Malawi and has seven affiliated members: the Association of the Physically Disabled in Malawi, the Malawi Union of the Blind, the Malawi National Association of the Deaf, Disabled Women in Development, the Malawi Disability Sports Association, the Albino Association of Malawi and the Parents of Disabled Children Association in Malawi (Lang, 2008: 74). FEDOMA's role is to help its member organisations to build capacities and to coordinate their activities (EI14). The member associations bring their concerns to FEDOMA, which then communicates with government and other related parties about the issues raised (ibid.). A similar structure exists at regional and international levels; FEDOMA and other

organisations comprise the Southern Africa Federation of the Disabled, which is part of Disabled Peoples' International, which unites disabled people's organisations from every continent (Disabled Peoples' International, 2010; Southern Africa Federation of the Disabled, 2014). In addition to promoting specific issues, FEDOMA aims to raise awareness about disability in general, for example, by turning disabled people who are working and have families into role models (ibid.). It also engages in lobbying activities, for example, for the Disability Bill passed in 2012, and meetings with parliamentarians (Disabled Peoples' International, 2010; Ministry of Persons with Disabilities and the Elderly, 2006; EI14).[14] FEDOMA has been relatively successful in working with the Malawian government to develop disability policies (Lang, 2008: 75).

The third important organisation is the NGO MAP, which supports disabled people in several ways. MAP has a big rehabilitation centre in Blantyre called Kachere, which provides various services to patients, such as physiotherapy, and training for a diploma in medical rehabilitation (Malawi Against Physical Disabilities, 2013). There are also four workshops in the country in Blantyre, Zomba, Lilongwe and Rumphi (EI02; Malawi Against Physical Disabilities, 2013). These workshops provide services such as physiotherapy and assistive devices and run outreach clinics (Malawi Against Physical Disabilities, 2013; EI02; EI09). During these outreach clinics, health professionals visit health facilities and treat patients or refer them back to their own workshop or to some other service (EI09). I visited the Kachere rehabilitation centre and the MAP workshop in Rumphi. When a patient comes to MAP in Blantyre for a prosthesis, he or she is referred to the orthopaedic centre at QECH, or the MAP technician who has been trained to make prostheses, visits the QECH centre to produce the required prosthesis, based on the cooperation between the centre and MAP (EI02). At the MAP workshop in Rumphi, patients are referred to the orthopaedic centre at the Ekwendeni Mission Hospital for prostheses (EI09). If they cannot afford the transportation and prosthesis costs, the technicians at the MAP workshop make them a prosthesis for free (ibid.). These prostheses

[14] Although the Bill was passed only in 2012, the policy document has existed since 2006.

are made from a leather socket, a U-shaped metal bar and a piece of wood, similar to the peg legs described in Section 4.3.2.1 (EI09; Observation 120905).

All three organisations are interlinked to varying degrees. Since MACOHA has the mandate to monitor disability service providers, it is in touch with both FEDOMA and MAP. It has supported FEDOMA with training and acquiring donors, and the two organisations hold regular joint meetings (EI05). MAP and MACOHA refer patients to each other, as they provide different services: “So our clients whom after assessing them we see that they can benefit from vocational training and then we refer them to MACOHA. And the MACOHA when they find clients, patients, who can benefit from our services like physiotherapy then we refer. So we work hand in hand” (EI09). No evidence was found of FEDOMA and MAP directly working together, but they may maintain contact through meetings and other formal and informal channels (EI09).

In addition, customs and beliefs have varying degrees of influence on the lives of disabled people and, thus, on the changes patients create to prostheses. Important customs and beliefs about disabilities in Malawi are presented in the next section.

4.4.3 Beliefs and customs about disability

Several studies have shed light on beliefs and customs in Malawi in relation to disabilities, thus providing secondary data. In addition, primary data on these beliefs and customs was collected in interviews, mostly those conducted with patients and experts. Therefore, data from previous studies could be triangulated with the individual experiences which local experts and patients reported on and this section draws on both sources to describe the situation. Beliefs and customs about disability are important as they among other things shape the experiences users make with prostheses and thus their learning selection processes.

The literature describes the situation of disabled persons in their families in Malawi as good. In the family circle, disabled people have very similar standing to non-disabled family members (Loeb and Eide, 2004). They are well respected and looked after by their families (Braathen and Kvam, 2008: 465). Even parents who were shocked, saddened or ashamed to discover their child was disabled, later accept the situation and care for their disabled child with the same attention as to their other children (ibid. p.465-466). One difference between families with and without disabled members is that those with disabled members tend to have more children (Loeb and Eide, 2004: 148). Since there is little help available to families with a disabled child, having more children can be seen perhaps as a coping mechanism (ibid.). In interviews, the descriptions of the situations of disabled people in their families were more differentiated. The situation has improved for disabled people; for instance, the practice of killing disabled infants at birth has been stopped (EI14). However, it is still the case that in some families with many children, disabled children are less likely to attend school than their siblings (EI03; EI14; PIE22). The study on disability in Malawi referred to in Section 4.4.1 confirms this and shows that for children aged five years and over, of those who are not disabled 18% had never attended school, while the percentage for those with disabilities was 35 (Loeb and Eide, 2004: 13). No doubt there are many reasons for this, but the family can be expected to be a major influence. The literature describes developments that include a changed attitude, towards more respect for and less discrimination against disabled persons, which were confirmed in the interviews (EI03; EI05; EI14). However, discrimination still occurs, including within families. The organisations mentioned in Section 4.4.2 are actively involved in bringing about further positive changes for disabled people (EI05; EI14; PIE22).

As already mentioned, some Malawians believe disability can be caused by witchcraft or contagion – assumptions that can have a major influence on the lives of disabled persons (Braathen and Ingstad, 2006: 605; Loeb and Eide, 2004: 108). If there is a belief that their condition is contagious, disabled people will more likely be shunned and excluded from many social activities. The witchcraft issue is two-sided. The disabled person may be blamed for practising witchcraft; in one instance, a patient was believed to be a witch because she

was wearing prostheses (PIB05). However, her demonstration and explanation of the prostheses resulted in her being cleared (ibid.). Nonetheless, this incident almost led to her dropping out of school (ibid.). On the other hand, someone can be blamed for inflicting a disability through witchcraft. If witchcraft is seen as the cause of the disability, the disabled person has to be treated by a witchdoctor rather than a health professional in a hospital or orthopaedic centre, because the witchdoctor is the person who can invoke the intervention of the spirits, as described in Section 4.2.2 (EI03). These patients may end up with no prostheses, which would render them less self-sufficient and more vulnerable than if they had prostheses. Disability is sometimes also considered a curse, especially in the case of children born with a disability, where the parents are seen as responsible through some wrongdoing of their own (EI14; PIE22). While perceptions are changing, they are still sufficiently pervasive to influence at least some disabled persons.

Another noteworthy aspect is the importance of religion in Malawi. The population mainly follows the Christian faith, with 83% identifying themselves as Christians (Central Intelligence Agency, 2013). Muslims make up 13% of the population, while only 2% describe themselves as being non-religious (ibid.). This situation has a major impact on the perception of disability: in a study of disabled women, God was central to their explanation of their disability and how they dealt with it (Braathen and Kvam, 2008: 465). Again, the picture described in the interviews was slightly more differentiated. Some patients interviewed regarded their disability as God's will (PIE14; PIE18; PIE22). This meant that they accepted their disability and had high self-worth (ibid.). As one patient put it: “Because if God allowed us to be disabled, we know that he has a purpose for us” (PIE22). While religion was mostly seen as a positive influence, attributing self-worth to disabled people, there were some cases where religion worsened the situation. This applied to disability regarded as divine punishment or to the case of religious groups that forbade all medical assistance, including prostheses (EI08).

In summary, most disabled people are still discriminated against, but not as severely as in the past. Witchcraft can have a negative influence, either

because disabled people are thought to be witches, or because they are not supplied with prostheses because the disability is seen as caused by spiritual, not biomedical issues. Religion has a negative influence in a few cases, but is mostly positive for disabled people as it gives them a sense of self-worth.

4.5 Summary

This chapter provided background information on lower limb prostheses in Malawi. This is important in order to explain what changes are created and thus show details of the occurring learning selection processes, as well as what selection and promulgation mechanisms may exist for created changes. First, data on Malawi in general were introduced, such as the geographical situation and population statistics. Next, the structure of the healthcare system was described. Lower limb prostheses as the focus of this research were elaborated in general terms for all developing countries, and for the specific orthopaedic centres where I collected data. In addition, the two technologies used in these orthopaedic centres to produce prostheses, the ICRC polypropylene technology and the Jaipur technology, were compared and their similarities and differences described. Finally, details on disability were examined, including statistics on disability and assistive devices, Malawian disability organisations, and beliefs and customs about disability. In Chapter 5 the focus is on the changes created by users to lower limb prostheses.

5 Creation of and reasons for changes by users

This research investigates user innovation of medical technologies in developing country settings by analysing changes which were created by users to lower limb prostheses in two orthopaedic centres in Malawi. Chapter 5 describes these changes which orthopaedic technicians and patients created in detail. It refers solely to primary data collected in observations and interviews with patients and technicians. These data sources of observations and interviews are indicated as introduced in the beginning of Chapter 4.

The working definition of a change created by a user, introduced in Chapter 2 Section 2.2, is an aspect of the technology, created by the user, that differs from the standard, whether related to the process, the artefact or the use of a technology. Changes to the production process, in many but not every case, lead also to physical changes to the artefact. In line with the above definition, repairs to broken prostheses are considered changes only if they change the physical appearance of the prosthesis from the original. Repairs that involve replacement of broken parts with original spare parts are not considered changes since the prosthesis is returned to its original state.

This chapter describes the production processes in the two orthopaedic centres and the changes technicians have made to these processes and the resulting prostheses. The reasons why they created these changes are also considered. The chapter also examines the changes to prostheses made by patients and their reasons for doing so. Changes by users are considered, in relation to the enabling innovation framework, as the outcome of the learning selection processes these users go through. These processes, including what experiences the users make and the resources they have available to execute actions, determine the details of the resulting changes. An important part of these details are the reasons of users to create changes, which are explicitly mentioned in the following, as noted above.

5.1 Production processes and changes by technicians

The data collection included numerous observations of prostheses production, and interviews with the technicians involved to discuss the changes observed. The assessment of the patient and the production processes in both orthopaedic centres are discussed first and then the changes created by technicians to these processes and to the prostheses are examined. The chapter concludes with a summary of the reasons given by technicians for the changes made.

5.1.1 Assessment of the patient

Before a prosthesis is produced, the patient needs to be examined in detail. The following description is based on observations 120528, 120726, 120727, 120813, 120816, 120823. They are identified here rather than in the text because in most cases the observations were of the whole assessment, not only individual steps. Identifying the observations here keeps the text simpler.

When a patient comes to either of the orthopaedic centres, he or she is first assessed by a technician. If the patient has not previously attended the centre, personal data are collected. In the case of an existing prosthesis being brought in for repair, it is examined to assess what is needed. In some cases, the prosthesis can be repaired using original materials and spare parts. If it is deemed beyond repair, a new one is produced. If the damaged prosthesis has been produced using a technology for which the centre has no original materials it may be possible to still repair it, such as by combining different technologies. The cases observed of combining technologies are described in Sections 5.1.3 and 5.1.4. Alternatively, a new prosthesis is made or the patient is sent to a different centre. These different possibilities to solve an issue all represent different options for technicians to take action steps in their learning selection processes, which in consequence lead to different changes or repairs being created.

The next step is to determine what type of prosthesis the patient needs. The options are below, through or above knee prostheses, an extension prosthesis or a hip disarticulation prosthesis. The names of the prostheses correspond to the length of the remaining stump. If the foot is missing, but the rest of the leg is intact, the patient needs an extension prosthesis. If the foot and part of the lower leg are missing, but the knee joint is intact, he or she needs a below knee prosthesis. If the foot and lower leg are missing and the amputation was through the knee joint, a through knee prosthesis is needed. If the foot, lower leg, knee joint and part of the thigh are missing, but the hip joint is intact, the patient receives an above knee prosthesis, which includes an artificial knee joint. The most extreme form is where the whole leg is missing, including the hip joint, which requires a hip disarticulation prosthesis which also includes an artificial knee joint. In the orthopaedic centre in Ekwendeni, extension and hip disarticulation prostheses cannot be fitted and relevant patients have to be sent elsewhere. The most common prostheses are the below, through and above knee prostheses; in what follows I focus on these types.

The final step in the assessment is evaluating the condition of the stump; certain conditions, such as a bent stump or one with a prominent bone structure, need to be catered for by making changes. These changes, which are made by the technicians, are described in Sections 5.1.3 and 5.1.4.

5.1.2 Production processes

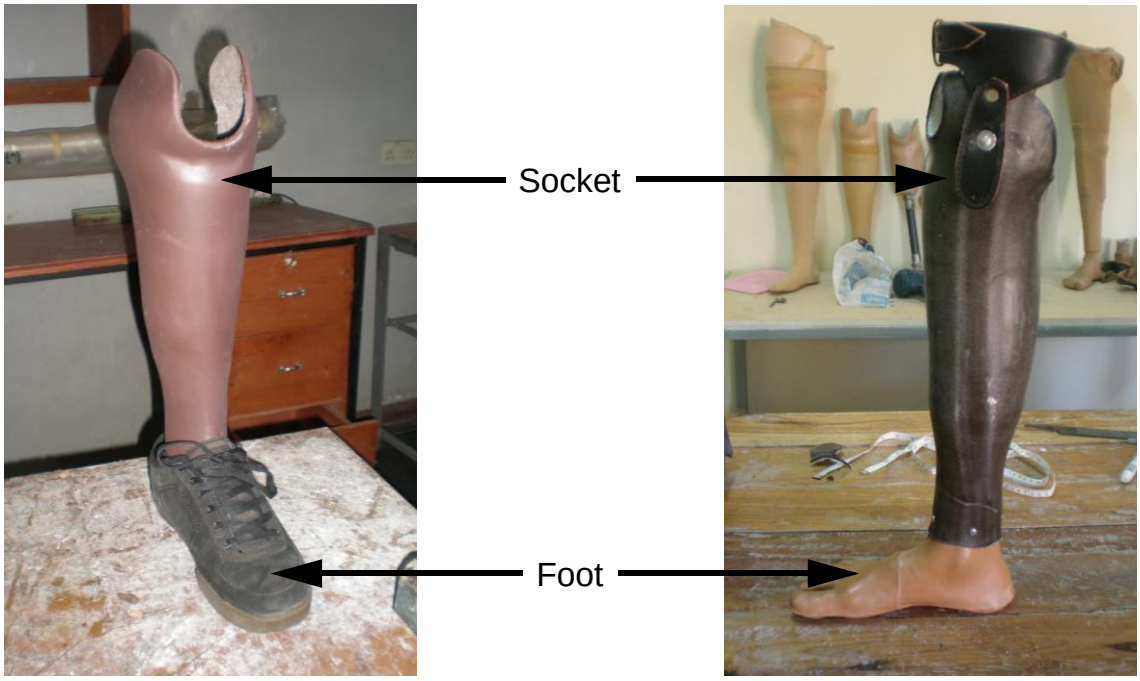
If after the assessment, it is decided the patient needs a new prosthesis, this is produced for him or her. I describe the production processes in both centres here because some of the changes created by the technicians are changes to the production processes and can only be distinguished as changes by comparing them to the standard production process. As described in Chapter 4 Section 4.3.2, the two orthopaedic centres use different technologies. Prostheses are mainly produced with the ICRC polypropylene technology in the orthopaedic centre at the Queen Elizabeth Central Hospital (QECH). While the centre stocks the components and materials for the Jaipur technology, and has

made Jaipur prostheses in the past, during my observation I did not see this technology being used there. In the orthopaedic centre at the Ekwendeni Mission Hospital, prostheses are produced exclusively with the Jaipur technology. The following description of the production processes is based on the observations 120528, 120529, 120530, 120531, 120601, 120604, 120605, 120606, 120607, 120611, 120613, 120615, 120627, 120702, 120703, 120704, 120705, 120712, 120713, 120726, 120727, 120730, 120731, 120802, 120809, 120813 – 120817; 120821 – 120824; 120817; 120829 – 120831; 120904, 120906, 120913, 120914. Again, listing them here rather than in the text is to keep the text simple. Also, in most cases, the observations covered the whole assessment, not just particular steps.

The production process for prostheses in both orthopaedic centres consists of the production of parts, and their assembly in combination with prefabricated parts. The parts produced at the two centres are the sockets for all prostheses and the soft inserts for below knee prostheses, which provide additional cushioning in the socket for the stump. In the orthopaedic centre at the Ekwendeni mission hospital, the peg and, for above knee prostheses, the lower leg, are produced. In the orthopaedic centre at QECH, also the cosmetic cover for the prosthesis is produced. To produce the socket, in both centres, the patient’s stump is enveloped in wet plaster of Paris bandages in order to form a negative cast. The cast is then filled with liquid plaster of Paris to achieve a positive cast, which is used to produce a custom-made socket and, if necessary, a soft insert. The prosthesis is assembled from the different parts; the ICRC polypropylene technology uses more prefabricated parts than the Jaipur technology. For the latter the peg is produced as a hard plastic empty cover; for the ICRC polypropylene technology several parts are assembled, two concave disks for the alignment, a metal rod and various other plastic parts. At this point, the prosthesis is ready for fitting. The patient tries it on and the alignment and height are checked. During this stage, technicians can create certain changes, as shown in Sections 5.1.3 and 5.1.4. When the prosthesis has been adjusted and deemed satisfactory, all parts are joined permanently. In the case of the ICRC polypropylene technology, a cosmetic cover is added so the prosthesis looks more similar to a sound limb.

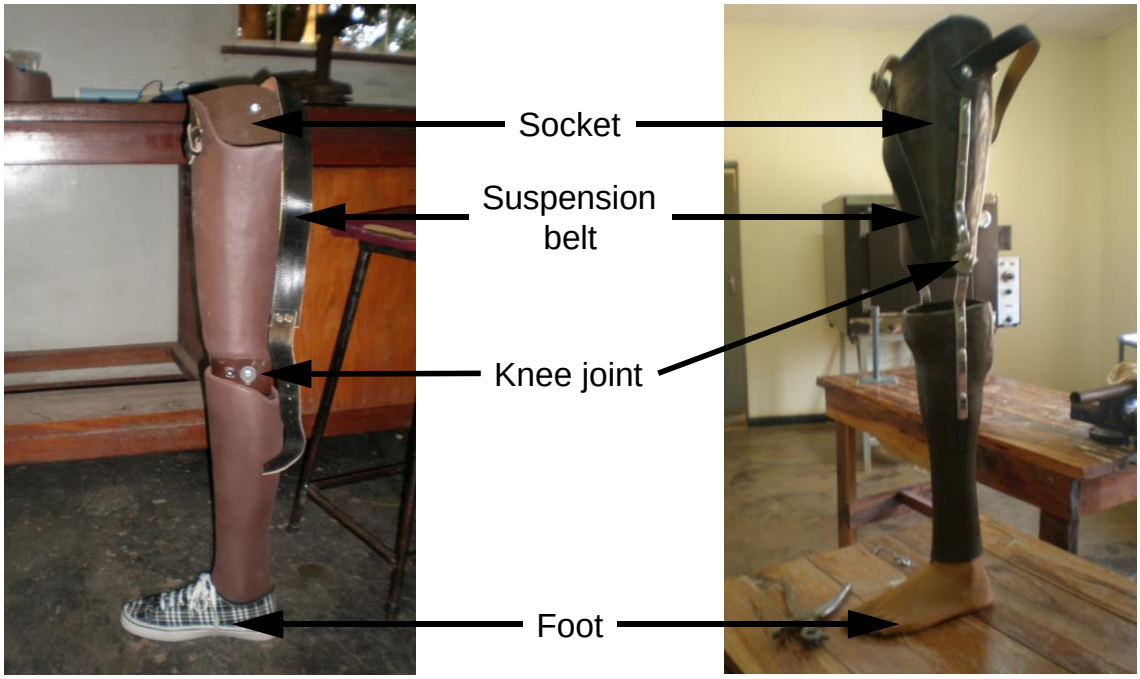
Figure 5-1 and Figure 5-2 show finished below and above knee prostheses. The left side of the figures depict the ICRC polypropylene technology and the right side the Jaipur technology.

Figure 5-1 Photos of below knee prostheses produced with the ICRC polypropylene technology (left) and the Jaipur technology (right)



Source: Photos by the author

Figure 5-2 Photos of above knee prostheses produced with the ICRC polypropylene technology (left) and the Jaipur technology (right)



Source: Photos by the author

5.1.3 Changes created by the technicians from the orthopaedic centre at QECH in Blantyre

This section describes the changes created to prostheses by technicians in the orthopaedic centre at QECH. The descriptions of the changes are arranged according to why technicians made them.

First, there are changes made for individual patients because of their particular characteristics. As explained above, the stump is assessed in detail because certain conditions require particular changes. In the case of undercuts in the stump, the cast is taken apart in two pieces and later joined again using a wet plaster of Paris bandage (Observation 120601). This allows the negative cast to be removed from the stump after the plaster bandages have dried and hardened. If the stump is bent, the prosthesis has to be constructed to balance out any curvature to ensure that the force runs in a straight line (CIB06; observation 120627). If this is not done, the prosthesis is more likely to break. If

the stump is very long, then different parts are used, such as a long stump foot, so the prosthesis is of an appropriate height and not too long (CIB04; CIB06; observation 120611). If the stump is shaped in such a way that putting the prosthesis on and removing it will be difficult for the patient, a hole is made in the socket and sometimes a cover is attached to allow it to be closed once the patient has put on the prosthesis (CIB02; observation 120612). A patient who is very overweight will also require changes to the prosthesis. In the case of very heavy patients, additional pieces of material are included in the socket to make it stronger to withstand the greater body weight (CIB04; EI02). In one case, the patient receiving a prosthesis was young, strong and had a good understanding of what he was being asked to do by the technicians, and thus was given an extension assist (CIB03; CIB04; observations 120608, 120615). An extension assist is a piece of elastic fabric which is attached above and below the knee joint on the front of the prosthesis (ibid.). This knee joint can be locked, with the result that the prosthesis is stiff. It can also be used unlocked which requires more understanding and concentration on the part of the patient, but has the advantage of enabling a more natural gait. The elastic fabric causes the unlocked knee to straighten again by itself, but allows it to bend when pressure is put on it, making it easier to walk with an unlocked knee. It also allows the patient to drive a car, which was very important for this specific patient (Observation 120606).

In addition to the changes made for individual patients because of their characteristics, there are also a number of changes which were made for numerous patients. These are routinely made during the fitting phase of the production process in order to resolve recurring issues. A common problem is the patient feeling the prosthesis is not the right length. He or she is then asked to stand with the shorter side on boards of varying thickness, which allows the technician to determine how much to lengthen or shorten the prosthesis (CIB03; observation 120606). The alignment is also checked and often adjusted (CIB03; CIB04; observations 120529, 120530). Sometimes the patients find wearing the prosthesis painful. In some cases, this can be due to muscle degeneration as a

result of not using the leg,[15] making changes to the prosthesis can relieve some pain. Realignment can get rid of some pain, as can extra padding at the distal end of the socket or the soft insert (CIB04; observation 120530). The socket can also be adjusted at this point; the rim can be made lower and the form can be changed slightly by grinding off material (CIB03; observations 120606, 120621). If the pain persists, pain medication may be an option, which was the advice given to one patient who had returned to the centre because of experiencing pain when using her prosthesis (PIB03).

In addition to changes to suit individual patients, technicians also create changes to prostheses to suit the circumstances at the centre. This applies to the combining of different technologies. Two reasons were given for this. The changes were made either for convenience or because not all original parts and materials were available and the technicians needed to combine different technologies to produce a complete prosthesis. In one case a different component was used to provide a more durable prosthesis.

It is common practice at this centre to use parts from the Jaipur technology for the prostheses made with the ICRC polypropylene technology since there are currently no prostheses being made using the Jaipur technology. The most common parts used are the waist belts and foam material. The waist belts would otherwise have to be made from scratch, so it is more convenient to use pre-made ones (CIB01). The foam material, together with the foam material originally supplied for the ICRC polypropylene technology, is used to build up the shape of the prostheses (Observation 120618). In the case of the extension assist mentioned above, an elastic fabric from the Jaipur technology was used for a prosthesis which otherwise was made using the ICRC polypropylene technology (CIB03; observation 120615).

In addition to parts from the Jaipur technology, donated, pre-used parts from developed countries are also combined with the ICRC polypropylene

[15] This is more of an issue in settings where there are no temporary prostheses fitted, as in the case of Malawi. Patients have to wait to receive a prosthesis until the stump is not swollen, which can take several weeks and lead to muscle loss.

technology. The orthopaedic centre at QECH at one point lost many materials due to the building burning down. To still be able to supply a patient with a prosthesis, a polypropylene socket was combined with a carbon fibre setup and a foot, both of which were donated parts from developed countries (CIB02). The particular patient liked this foot so much; she did not want any other type. When she received a prosthesis produced with the ICRC polypropylene technology paid for by an individual donor, she used it only for one or two days (CB02; PIB03). She liked the other foot because it allowed her to wear shoes with different heel heights; the technician's view was that she liked it because of how the heel feels when stepping on it (ibid.). Another patient was given a foot donated from a developed country because an ICRC polypropylene technology foot was not available at the time. The patient was asked to bring the prosthesis back at a later point to have it exchanged (Observation 120607). One patient received a suspension for his above knee prosthesis which was donated from a developed country and made out of fabric and velcro. He was given this different suspension because he had broken his previous suspension twice, and the particular materials were available at the time (Observation 120621).

Thus, technicians in the orthopaedic centre at QECH created numerous changes because of patients' characteristics and the prevailing conditions at the orthopaedic centre. These points are discussed again in Chapter 7 Section 7.2.1 which describes the factors that influence the creation of changes. Section 5.1.4 describes the changes made by technicians in the orthopaedic centre at the Ekwendeni Mission Hospital. Section 5.1.5 discusses the reasons why technicians at both centres create changes.

5.1.4 Changes created by the technicians from the orthopaedic centre at the Mission Hospital in Ekwendeni

In the orthopaedic centre at the Ekwendeni Mission Hospital, just like in the centre at QECH, the technicians created changes because of patients and the circumstances of the centre. The changes made for individual patients due to their characteristics are described first. Several of these changes were related

to the condition of their stumps. In the case of undercuts in the stump, a strip of leather is placed under the plaster of Paris bandages when producing the negative cast of the patient's stump (CIE09; observation 120816). The bandages are then cut along this strip to allow the cast to be removed (ibid.). It is then resealed with wet plaster of Paris bandages. In the case of a stump that is curved not straight, the prosthesis has to be straight so that the patient can use it properly (CIE09). This is achieved by adjusting the shape of the socket by adding plaster of Paris to the positive cast (ibid.). If the area around the kneecap fits the stump properly, the suspension is secured and the rest of the socket can be modified (ibid.).

Some stumps have a protruding bone. To accommodate this condition, the socket can be changed slightly by grinding some material off it. This applied to one patient with a through knee prosthesis, who was experiencing pain. An addition was made to the positive cast to provide additional space for the patient's protruding bone. However, since the socket had shrunk during production, the stump did not fit in the socket as intended and the protruding bone hit the socket. To remedy this, the rim of the socket was cut down and a hole was made in the socket which allowed the technicians to check for a correct fit of the stump in the socket (CIE09; observation 120824).

Technicians also made changes to the knee joints used for heavy and old aged patients, and in response to complaints. For the through knee prostheses, steel joints are used, while for the above knee prostheses there are two options – the same steel joints or plastic joints. Originally, the steel joints were meant to be used only for through knee prostheses, but they are used at the centre for most above knee prostheses as well (CIE09). Two reasons were given for this change. One was the complaints from patients about the plastic joints because they cannot be locked and require greater strength and balance to use them (CIE08). The second reason was a heavy body weight which applied to a specific patient with an above knee prosthesis who was too heavy for the plastic joints that were held in place by screws (CIE09). The rivets that hold the steel joints in place are stronger (ibid.). Thus, the technicians created an additional option: according to the weight and age of the patient, they now decide which

joint to use (CIE09). Plastic joints are used much less and only for patients who are relatively light and are not over 30 years of age (CIE08; CIE09). In the time I spent at the centre, I saw only steel joints being used to produce above knee prostheses.

In addition, changes are made during the fitting to adjust the prosthesis. In the case of the Jaipur technology, there are fewer options for changes compared to the ICRC polypropylene technology since the former has a smaller number of components including those related to alignment. In consequence, this leads to different options for the action steps in the learning selection processes for the technicians in the centre in Ekwendeni compared to the technicians in the centre at QECH, and this in turn can lead to different changes being created by the two groups. During the fitting, the height of the prosthesis is checked. Patients experiencing issues are asked to stand with the shorter leg on boards with a predefined thickness to assess the correct length, and the height of the prosthesis is changed accordingly (Observation 120802). In case of the patient experiencing pain, a soft material is added as padding inside the distal end of the socket or the soft insert and the rim are cut down depending on the seat of the pain (CIE08; CIE09; observation 120824, 120904).

As in the orthopaedic centre at QECH, due to general circumstances technicians at the centre in Ekwendeni sometimes combine technologies. They do so for instance, if patients come to have prostheses repaired that were produced using a different technology from that available at the centre. The orthopaedic centre in Ekwendeni has had several patients coming for repairs to their ICRC polypropylene technology prostheses. In one case, the foot was tightened and the waist belt was repaired (CIE08; CIE09). In another case the foot was so degenerated that it needed to be replaced, but there was no matching foot available. The option of a new prosthesis was not given since the patient was not present. The prosthesis had been brought in for repair by Malawi against Polio (MAP) employees (CIE09). The technicians disassembled the prosthesis, kept the polypropylene socket, manufactured a new peg with the Jaipur technology over this socket and fitted it with a Jaipur foot (ibid.).

The technicians from both centres create changes because of patients' characteristics and the prevailing conditions at the orthopaedic centres. The next section elaborates on the reasons why technicians at both centres create changes.

5.1.5 Reasons why technicians create changes

As described above, changes are made mostly for two reasons: to accommodate patients, and to deal with general conditions at the orthopaedic centres. These reasons relate to the learning selection processes of the technicians, especially to the options they have to execute the action steps, such as the general circumstances of the centres, as will be detailed below.

Some of the changes made during the production process were to suit the characteristics of the patient, such as heavy weight (CIB03; CIB04; CIE08; CIE09; observations 120529, 120606). The condition of the stump also prompted changes, such as being bent or having a protruding bone (CIB02; CIB04; CIB06; CIE08; CIE09; observations 120611, 120727, 120824). Other changes were made to relieve pain when using the prosthesis (CIB03; CIB04; CIE09; observations 120530, 120606, 120612, 120614, 120824). It was explained that this sometimes meant deviating from conventional principles to accommodate a particular patient (Observation 120620). Some changes were made during the production process before the patients were discharged, other changes were made when patients returned to the centre with their used prostheses.

Some changes were made as the result of the general conditions at the orthopaedic centres, such as lack of parts or suggestions from an ICRC employee (CIB02; CIE09; observation 120607). Changes to the production process were considered based on the accumulated experience of the technicians (CIB04; CIE09).

While the reasons for making changes are similar in both orthopaedic centres, the technicians in each centre have different means to execute them. These means represent different options for actions which the technicians have, and can thus lead to different changes or repairs as the outcome of their learning selection processes, as the second example below shows. At both centres, soft material, such as plastic foam, is added to make sockets more comfortable and reduce pain at the distal end of the stump. Other changes are unique to one centre, for example the changes created in the case of a patient with a prosthesis made with the ICRC polypropylene technology going to the orthopaedic centre at the Ekwendeni Mission Hospital for repairs. The technicians there do not have the components for this technology since they only produce prostheses using the Jaipur technology; therefore, they combined different technologies in order to repair the prosthesis. The technicians in the centre at QECH have original spare parts and materials for both the ICRC polypropylene technology and the Jaipur technology and can repair prostheses of either type without having to create changes to them.

It can be seen that individual patients and circumstances influence changes by the technicians. Since patients have different conditions, the technicians create changes suitable for a specific condition and its requirements. The changed prosthesis is therefore better for this specific patient. Due to the fact that the technology needs to be customised in this way, changes made to a prosthesis become options for the future, should a patient with a similar condition need a prosthesis. The changes do not displace how the prostheses were made previously, but rather add options, for example to the production process. Similarly, the changes created to suit circumstances do not displace 'older' options, but add new ones. This is important since the circumstances may change and call for different changes at different times.

To summarise, both the requirements of patients and the circumstances influence whether and how technicians create changes to lower limb prostheses and their production processes. Some of the changes made are similar at the two centres, but some are different. The differences between the centres and the technologies used there are discussed further in Chapter 7 Section 7.1.2

and how those differences relate to the differences in the changes created in the two centres is analysed in Section 7.2.1. I next describe the changes created by patients to their prostheses.

5.2 Changes by patients

I chose lower limb prostheses as a technology to which I expected users to create changes, as discussed in Chapter 3 Section 3.3.1. Among the 22 patients interviewed, 15 had indeed created one or more changes to their prostheses. In the case of reported physical changes to prostheses, I could observe most of them for myself, allowing triangulation of different data as described in Chapter 3 Sections 3.2 and 3.4. In a small number of cases this was not possible, as the changes described applied to different prostheses than the ones the patients had brought to the centres. In what follows I describe the changes created to prostheses by patients in the orthopaedic centres at QECH and at the Ekwendeni Mission Hospital, involving mostly prostheses produced with the ICRC polypropylene technology and the Jaipur technology. Changes were also reported to other types of technologies, such as those supplied by MAP. These prostheses consist of a leather socket, metal bars and a wooden block with rubber on the bottom as a foot. Changes were also described as being created to an old prosthesis from the orthopaedic centre at QECH that comprised a leather socket and an aluminium shank. Although these changes were to technologies not currently used to produce prostheses in the orthopaedic centres, they are illustrative of the factors that influence the creation and sharing of changes by users and, therefore, are included here.

5.2.1 Changes by patients from the orthopaedic centre at QECH in Blantyre

I interviewed a total of 11 QECH patients at the centre of which five had created changes to their prostheses. Three of these had polypropylene prostheses (PIB02; PIB08; PIB09). One patient had a polypropylene socket with

a carbon fibre setup and a foot donated from a developed country, and one patient had an old prosthesis from the orthopaedic centre at QECH made with a leather socket and an aluminium shank (CIB02; PIB03; PIB10). In addition, two patients who were observed but not interviewed had made changes which are included here (POB02; POB04). Physical changes to prostheses are described first, and they are arranged according to which part of the prosthesis they were made to, starting with the feet. The changes to the old prosthesis from the QECH centre are described separately. Next, I describe changes to the use of prostheses.

Changes were created to repair a broken foot, tying it together with bandages or crepe (PIB08; PIB09). One patient had melted plastic containers and carved a new foot and part of the leg with a hot knife because the foot was worn out and he had difficulty walking because the prosthesis was too short (POB04; observation 120611). One patient tied a cloth around the knee joint because he described how the knee would unlock and the leg tremble when he walked (PIB02). Another patient was very concerned over the appearance of her prosthesis and wore several stockings of different colours to make the prosthesis look more like her sound limb[16] (PIB03).

The most common change by patients to the ICRC polypropylene prostheses was the addition of soft material as padding inside the distal end of the socket or soft insert (PIB02; PIB09). One patient had attempted this change, but abandoned it because it made the prosthesis too long (PIB10). One patient had made slits in the soft insert to allow the air to circulate (PIB02). Another change – not to the prosthesis directly, but which affected its use – was to wear several socks on the stump (PIB09).

The patient who had the old prosthesis with the leather socket had made many changes to his prosthesis – some he made himself, some were made by others (PIB10). A new belt had been made by a shoe repairer, and was sewn again by the patient. He tied the foot to the shank with rubber, and also used

[16] This patient succeeded in this; although I knew one of the limbs was a prosthesis, I could not tell which when the patient was seated.

rubber to close the holes in the leather socket. He had replaced a nut and welded some metal parts together. In addition, he told me that he had advised other patients with prostheses about repairs. One patient had lost a nut, and when she replaced it, he recommended that salt mixed with water should be put on the nut so it would rust and then would not become loose again. The patient said he had this idea because of the technical knowledge he gained in his training as a welder (ibid.).

In addition to these physical changes to prostheses, patients also changed the use of their prostheses. The most common change was the decision not to use the prosthesis. Both patients who reported this decision said it was because they preferred their old prostheses – for pain reasons, or because the prosthesis had a foot donated from a developed country (PIB03; PIB10). In the case of prostheses causing pain, some patients had opted to take pain medication to allow them to continue to use their prostheses (PIB02). Another change was the decision to use different prostheses for different purposes. One patient used an old prosthesis for work, including building work, and his new prosthesis for special occasions such as going to church (PIB02). A technician told me that some patients wanted to keep their old prostheses and to use the new one only for particular occasions (CB02). They did this against the technicians' advice and the risk that the old one was not good for their posture (ibid.). A patient and his mother gave another reason for keeping the old prosthesis (Observation 120605; POB02). Since the new one had been paid for by donations from people in their village, it was not meant to be used until an official handover ceremony in the village had been conducted (ibid.). The old prosthesis had been a pre-used prosthesis given to the patient as a gift but which was not fitted for him (ibid.). A technician advised against its continued use, but the patient and his mother insisted (ibid.).

As this section showed, changes created by patients can be simple alterations such as tying together a broken foot. However, some were more profound and improved the prosthesis significantly for the user. Examples are slits in the soft insert and the system of stockings worn on the prosthesis. I next

describe changes created by patients from the orthopaedic centre at the Ekwendeni Mission Hospital.

5.2.2 Changes by patients from the orthopaedic centre at the Mission Hospital in Ekwendeni

I interviewed a total of 11 patients from the centre at the Ekwendeni Mission Hospital, eight at the centre and three at the MAP office in Rumphi. Ten of them had made changes to their prostheses (PIE13; PIE14; PIE15; PIE16; PIE17; PIE18; PIE19; PIE20; PIE21; PIE22). All had prostheses using the Jaipur technology. Some had previously had prostheses from MAP which consisted of a leather socket, metal bars and a wooden block with rubber on the bottom as a foot, and some reported making changes to those (PIE15; PIE18; PIE22). While those changes are included in the data, I did not ask the patients for details as I could not observe these changes because all were old prostheses that the patients were no longer using and had not brought to the interview. In addition, to the ten interviewed patients who created changes, two of the observed patients, also created changes which are included in this section (POE07; POE09).

I describe the physical changes starting with those made to the foot, then changes to the use of prostheses.

The most common changes related to reattaching the foot to the shank, achieved by nailing the foot to the shank or tying them together with a belt, cloth or rubber (PIE13; PIE15; PIE21). Sometimes these alternatives were combined. One patient hammered a wire flat to use as a screwdriver to tighten the screws (PIE15). Sometimes tightening the screws was sufficient (PIE14; PIE15). One patient used adhesive bandage to cover cracks in the ankle of the prosthesis (PIE21). The artificial feet of one patient’s prostheses for both lower legs had disintegrated to the point that only the plastic core remained. The patient had inserted wire triangles to hold his shoes (Observation 120813; POE07). Many repairs involved the belt; it was sewn back together or wire was tied around it

(PIE14; PIE15; PIE16; PIE17; PIE22). In one instance, the belt had been stitched by technicians from MAP Rumphi (PIE21). If the belt was beyond repair, a new belt was made, or shoelaces were used as a replacement (Observation 120726; PIE13; PIE21). Some of the steel joints had been repaired by loosening broken screws and replacing them with nails (PIE14). An additional repair on the joints involved nuts and bolts (ibid.). Two patients added soft material to the distal end of the socket or the soft insert as padding (PIE16; PIE19). The changes to the prostheses from MAP differed in that a patient reported shortening the belt (PIE18). The other changes were similar to those mentioned above.

Physical changes that affected the use of the prosthesis included patients bandaging their stumps or wearing several sock layers on their stumps (PIE15; PIE16; PIE17; PIE18; PIE21). One patient, who was a tailor, had made socks himself from leftover fabric, in addition to those provided from the technicians (PIE21).

In addition to these physical changes, patients from the Ekwendeni orthopaedic centre also reported changes to their lower limb prostheses use: some did not use their prostheses at all, some only for short periods or for specific tasks. One patient reported that he only used his prosthesis in the house (PIE20). He said that where he lives, it is hilly, which puts him at a high risk of falling, and the prosthesis therefore “doesn’t help at all” when walking outside (ibid.). He also reported pain when wearing the prosthesis (ibid.). One patient came to the interview using crutches, and reported that he currently was not using his prosthesis because the shoes he was supposed to wear with it had worn out (PIE19). In the case of an old patient, according the date of birth he gave he was over 90 years old, who came to the centre to have a prosthesis fitted, a technician commented that he doubted whether the patient would actually use it because of his advanced age (CIE08; observations 120913). In addition, several patients reported changes to the use of prostheses not made at the centre at Ekwendeni (PIE13; PIE14; PIE19; POE09). These were prostheses made by MAP or MACOHA, and the patients reported either not

being able to use them or using them only for short periods (ibid.). One patient reported the prosthesis had been too heavy for him to use (POE09).

Thus, interviewed patients from the orthopaedic centre at Ekwendeni, like those from the centre at QECH, created numerous changes. Most of these were relatively minor, such as adding padding to the socket, but some patients were more creative, such as the patient who sewed his own socks and wore layers of them on his stump. I also investigated the reasons for these changes as described below.

5.2.3 Reasons why patients create changes

Most of the reasons why patients create changes fall into three categories: repair, comfort and aesthetics. Patients' reasons to create changes relate to their learning selection processes, especially to the experiences they make and to the options they have to execute the action steps. The most common reason was repair because parts had become loose or had broken (PIB02; PIB08; PIB09; PIB10; PIE13; PIE14; PIE15; PIE16; PIE17; PIE21; PIE22; POB04; POE07). In a few cases, the prosthesis had a fault, such as being too short or the socket being too large (PIE13; PIE14; PIE16; PIE18; PIE19; PIE21; POB04). This was perhaps due to a fault in the production or because the patient had grown in height or had a reduced stump circumference. Another common reason for changes by patients was pain when wearing the prostheses (PIB02; PIB09; PIB10; PIE15; PIE16; PIE17; PIE19; PIE20; PIE21; PIE22). An additional change was made to reduce excessive sweating in the prosthesis (PIB02). One patient sewed additional stump socks himself because the centre had not provided him with enough (PIE21). Another patient placed a high priority on the look of her prosthesis and wore several stockings of different shades to achieve a natural colour (PIB03). She also decided not to use a new prosthesis because she could only wear flat shoes with it (ibid.). She did this in order to avoid discrimination: "That's all my own idea. As I already said that I don't want people to know that I'm artificial" (PIB03).

When patients were prompted as to why they chose to make changes themselves instead of going to one of the centres to get assistance, most cited distance to the centre and the cost of transport as reasons (PIB10; PIE16; PIE21; PIE22). One patient regarded the changes as too small to warrant a long trip to an orthopaedic centre: “Because I knew it's simple things, I can't go to Lilongwe or Blantyre. I do it myself” (PIB10). Another patient saw the change she had made as a temporary fix until she could get to the orthopaedic centre to get a repair (PIE22). Another did not mean his changes to be temporary, but they eventually failed and he returned to the centre for a repair (PIB09). Other reasons included urgent need for a repair because of the need to attend school to sit for an exam or to travel home from work: “What can I do to go to school and write exams.” (PIE13; PIE16; PIE17). One patient created changes himself because he was told not to come to the orthopaedic centre, which turned out to be wrong information (PIE21). Some patients did go to an orthopaedic centre, but received no assistance (PIB08; PIB10). The patients reported that this was due either to a lack of funds to pay for a new foot, or the prosthesis being deemed by the technicians as beyond repair (ibid.). The patients who created changes had different attitudes to this; some saw them as a temporary solution or even undesirable (PIE16; PIE 22). However, one patient stated that he knew best what needed to be done to the prosthesis, as he was the one wearing it (PIB02).

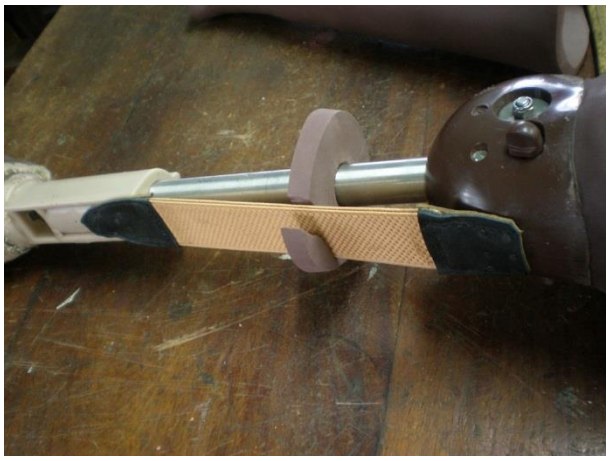
5.3 Summary

This chapter elaborated on the data collected on the creation of changes to lower limb prostheses by technicians and patients in the two orthopaedic centres that are the focus of this research, the orthopaedic centre at QECH in Blantyre and the orthopaedic centre at the Ekwendeni Mission Hospital. In relation to the enabling innovation framework, changes by users are considered to be the outcome of their learning selection processes. These processes, including the experiences users make and the resources they have available to execute actions, can influence the details of the changes, as shown in this chapter. During my observations in the two orthopaedic centres, the ICRC

polypropylene technology was used to produce prostheses at the QECH centre, and the Jaipur technology was used at the Ekwendeni centre. First, the assessment of the patient and production processes carried out in those two centres were described. The changes created by technicians were described next. The reasons why technicians created changes were examined and found to be individual patient characteristics and conditions at the orthopaedic centres. The changes made by patients were considered and the reasons for them discussed. They were related to problems with the prostheses and conditions that made it difficult or undesirable to consult an orthopaedic centre instead of making changes themselves.

The data presented in this chapter show that all technicians producing prostheses in these two orthopaedic centres in Malawi also created changes to the prostheses. This means that they do not produce every prosthesis in the same way, but introduce different options which result in some of the artefacts being physically changed. In addition to technicians, patients created changes to their prostheses. They created physical changes to the artefacts and changes to the use. This was relatively common: of 22 interviewed patients, 15 had created changes to their prostheses. In addition to making simple repairs, patients also created changes which improved their prosthesis for them. In order to illustrate the breadth of changes created by both technicians and patients in both orthopaedic centres, the photos below show four different changes.

Figure 5-3 Photo of a change created by two technicians at the orthopaedic centre at QECH, called extension assist



Source: Photo by the author

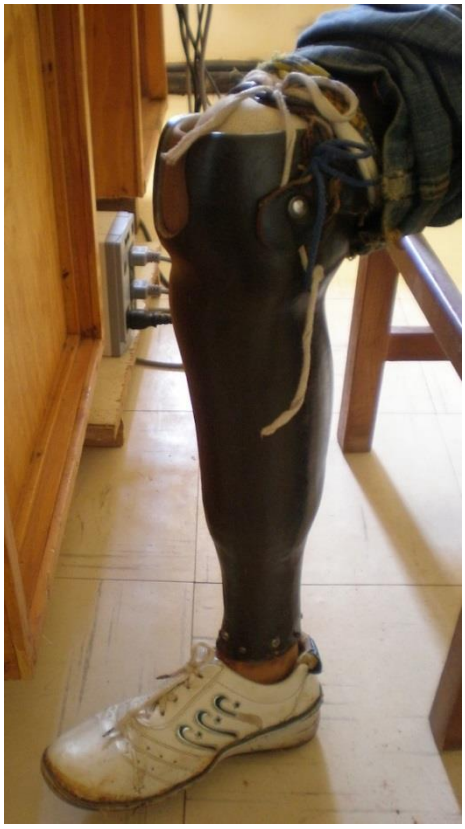
Figure 5-4 Photo of a change created by two technicians at the orthopaedic centre at QECH, using a long stump foot

Source: Photo by the author

Figure 5-5 Photo of a change created by a patient at the orthopaedic centre at QECH, a system of stockings to disguise her prosthesis

Source: Photo by the author

Figure 5-6 Photo of a change created by a patient at the orthopaedic centre at the Ekwendeni Mission Hospital, repairs of the belt with shoelaces, additional nails in the shank to secure the foot



Source: Photo by the author

In addition to the details of changes by users, this research was interested also in how these changes were shared. Chapter 6 discusses how users share their changes, and the connections between technicians and patients, and manufacturers and funding bodies that allow this sharing of changes.

6 Sharing of changes and connections between users and other important actors

Chapter 5 described the changes users created. How they share their changes with other users and other interested parties is described in this chapter. With one exception of a secondary reference to confirm facts given by an interviewee, it exclusively refers to primary data, including observations and interviews with technicians, patients and experts.

The sharing of changes is important for two reasons. Users sharing changes with each other create connections between their individual learning selection processes and thus create the opportunity to build on changes by other users to increase the overall fitness of the technology, as stated in the enabling innovation framework. In addition, sharing allows users to use their resources to the fullest, by being able to build on each other's changes instead of different users having to create similar changes multiple times.

To explain the sharing of changes and how it occurs, I examine the connections between users and other interested parties. These connections exist within the groups that were the focus of this research – technicians and patients, and also between both groups and the manufacturers and funding bodies. Manufacturers and funding bodies are responsible for production and supply of the ICRC polypropylene and Jaipur technologies and can create and share changes. Considering these connections is also important because manufacturers and funding bodies are responsible for a significant amount of the selection and promulgation of changes as described in the enabling innovation framework. It is therefore necessary to investigate the connections they have to be able to show what selection and promulgation does or does not exist. I describe all connections within and between different orthopaedic centres, in order to show the connections between different users and manufacturers and funding bodies, from the same and from different centres. This distinction demonstrates the extent to which changes are shared.

6.1 Sharing and connections within groups

The sharing of changes within groups of technicians and patients is described separately, and also within and between different centres.

6.1.1 Sharing and connections of different technicians

6.1.1.1 Within centres

In the connections between technicians, there is a distinct difference between the two orthopaedic centres. At the QECH centre one technician is usually responsible for producing a prosthesis while every prosthesis I saw being produced in Ekwendeni involved the two technicians present. Usually, one technician took the lead and the other assisted, but for some steps both technicians worked on an equal basis. At the QECH centre sometimes also more than one technician works on a prosthesis. For some steps in the production process, such as the production of the socket, two technicians are needed (Observations 120528, 120530, 120604, 120613, 120627). This is routine and happens without the need for much communication between the technicians (ibid.). Technicians also work together for special, more complicated cases – either a senior technician gives instructions and another technician executes the prosthesis, or two technicians work jointly on a prosthesis (CIB02; CIB04; CIB06; observations 120611, 120615). Technicians also work together on a prosthesis if there is a particular urgency (Observation 120606). Technicians also cooperate in the final inspection of a finished prosthesis before the patient is discharged; this inspection requires at least two technicians (CIB02; observation 120605). This avoids the risk of providing a patient with a badly aligned prosthesis which would reflect on the centre (Observation 120605).

All these incidents of working together provide opportunities for technicians to share their changes. Technicians reported asking each other for advice on special cases (CIB06; observation 120627). They also suggest and share ideas: “It's a matter of sharing ideas. It's not a matter of yourself only, no” (CIB06). In Ekwendeni, where the technicians always work together, they tell

one another about any changes they create. One technician described how he “pushed an idea”, which was then “accepted by my fellow technician” (CIE09). A specific change, which was shared and jointly created by technicians in the orthopaedic centre in Ekwendeni, was the use of steel joints instead of plastic joints for above knee prostheses in (CIE08; CIE09). In the orthopaedic centre at QECH, a specific change which was shared among the technicians in the centre was the extension assist, where one technician reported that he had learned about the change at the orthopaedic centre (CB04).

6.1.1.2 Between different centres

Technicians in the two centres can be linked through both direct and indirect contact. The direct contact occurs when technicians communicate directly with one another about a specific change; indirect contacts may be based on the artefacts of the prostheses. Both are described below.

Technicians from the different orthopaedic centres in Malawi meet through membership in professional organisations and meetings or deployment at different centres. Two professional organisations were mentioned in interviews with technicians: the International Society for Prosthetics and Orthotics (ISPO) and the Malawi Orthopaedic Association (MOA). The connection of the QECH centre to ISPO is not very strong and there were no reports of attendance at ISPO meetings; only one of the technicians in the centre is a member of ISPO. However, changes to technologies could be shared through perusal of the quarterly ISPO publications (CIB05). The technicians at the orthopaedic centre in the Ekwendeni Mission Hospital have no connection to ISPO.

Many of the technicians at the QECH centre are members of MOA. They meet annually, and several members of the orthopaedic centre at QECH attend these annual meetings and present their work there (CIB03; CIB07). MOA membership includes orthopaedic technicians, orthopaedic surgeons and orthopaedic clinical officers, the latter making up the largest group (CIB07; observations 121005, 121006). Apart from the orthopaedic technicians from

Blantyre, orthopaedic technicians from the orthopaedic centre at the Kamuzu Central Hospital in Lilongwe attend these annual meetings, which are an opportunity for technicians from different centres to meet and to exchange information about changes they have made to prostheses (Observations 121005, 121006). While no specific changes were mentioned as being shared via this channel, after I attended an annual meeting of MOA, I concluded that the sharing of changes via this channel was possible. At this MOA annual meeting, several orthopaedic technicians gave presentations and I was invited to present my research (Observations 121005, 121006). There was also ample opportunity for personal discussions between orthopaedic professionals, during breaks and over meals (ibid.). These meetings also serve to advertise the services provided by orthopaedic centres to other professionals who can pass on this information to patients (CIB03; observations 121005, 121006). In contrast to the orthopaedic centre at QECH, the technicians in the orthopaedic centre in Ekwendeni did not report contacts with MOA.

Technicians also form links with other centres through being transferred there. Several technicians from the QECH centre were posted to work at the orthopaedic centres in Lilongwe and Ekwendeni (CIB02; CIB04; CIE08; observation 120702). Two technicians had worked for several years at the orthopaedic centre at QECH before being posted to the orthopaedic centres in Ekwendeni and Lilongwe. While no specific sharing of changes through these connections was identified, they make such sharing likely. Several technicians said that the technician who was transferred from the QECH centre to the Lilongwe centre would have taken with him ideas and changes (CIB02; CIB04; CIE08).

Connections between learning selection processes can also occur without direct personal contact between users, but via indirect contact. Such indirect contact between the technicians in the two centres can take place via artefacts which are transported between them and contain changes. For example, a technician might make changes to a prosthesis, which later is taken by the patient to another centre for repair. The technician in this centre may decide that the change he or she can see is useful, and will try to understand how to

reproduce it and incorporate it. This applied to two changes to prostheses made in the orthopaedic centre in Ekwendeni. Making holes in the socket of a prosthesis to allow ventilation was first seen on an ICRC polypropylene prosthesis a patient had received from the centre at QECH and brought to the Ekwendeni centre, and subsequently was included in some prostheses made with the Jaipur technology in Ekwendeni (CE09). The idea to pad the distal end of the socket with soft material was attributed to the donated prostheses from developed countries, which were constructed from soft material (ibid.).

6.1.2 Sharing and connections of different patients

6.1.2.1 Within centres

Communication between patients occurs in two ways. It can occur through direct patient to patient communication based on friendship, working together, chance encounters, or being neighbours (PIB04; PIB06; PIB11; PIE13; PIE20). In addition to these chance contacts, there are also structures that help to establish contact between patients. These could potentially lead to users sharing their changes and thus connections between their learning selection processes. One such structure is groups for disabled people living in the same area (PIE18; PIE19; PIE21). These groups apply for small loans for projects, and teach various skills such as how to manage the family and home, how to run a business and how to avoid HIV/AIDS (PIE19; PIE21). One patient described meeting with other patients without referring to a formal group (PIE14). The patient stated that in this group they discuss general things, but when asked about discussions of prostheses, she said they give one another advice on how to repair them (PIE14). The Malawi Council for the Handicapped (MACOHA) arranges workshops for disabled people and disability support clubs where patients meet (EI05; PIE18). There are also rehabilitation volunteers who register disabled people and provide them with information on the services available to them; some of those volunteers are also disabled (EI05; PIE22). However, none of these existing structures specifically bring patients who use lower limb prostheses in contact with each other. In consequence, the effect of

sharing changes and thus connections of learning selection processes through these structures is likely to be small.

Whether patients meet in formal structures or informally, they share information about their use of and changes created to prostheses and give each other encouragement. One patient reported that she explained about prostheses to a member of the group who needed one, but did not have one (PIE18). Some patients give each other advice about how to repair them (PIB10; PIE14). One patient was asked by other patients how to use prostheses because he was an experienced user (PIE13). Another patient discussed with a fellow prosthesis user the reasons why he had decided not to use his prosthesis outside of the house (PIB20). Many patients reported telling other patients about lower limb prostheses and where to get them, or said they would do so if they came in contact with anyone who needed one (PIB01; PIB11). This attitude to other patients was reflected in the statements the patients made during the interviews. One patient said that “their problem is mine. So I can't even neglect them” (PIE16). Another stated that it was “...very important to encourage my friends. I try my very best because I know we with disabilities, we face many problems” (PIB10). Encouragement was also mentioned by another patient, who said “I shall always come and I shall always encourage the people with the same problem to come here (…) I'm always free to give the information to the people who need such a treatment” (PIB11). Giving advice to other disabled persons was seen as the task of disabled persons themselves, as one patient put it: “What is supposed to be done because we who is disabled am the very person who has to advise other people who are in a very same situation” (PIE19). Another patient said “If I've known that someone is disabled, I can give him instructions or assist him with some tips like just to empower him that he shouldn't be discouraged” (PIE21). A patient who was a rehabilitation volunteer stated that they as volunteers “visit those people who are disabled. (…) We find out what their problem is. (…) If we find that the problem maybe requires that they have to come here in Ekwendeni, we have to explain to them” (PIE22). The encouragement given refers to the use of lower limb prostheses as well as to life in general, especially to encourage patients to help themselves and not be dependent on others (PIE22). Advice was also given to parents of disabled

children, especially about not hiding their children, and letting them go to school and challenging them to do tasks in the house or on the field, so they would not become a burden and would learn to be independent (PIE22). Patients not only talked about giving encouragement, but also reported how important encouragement had been for them in order to accept their situation and use a prosthesis successfully (PIB01; PIB06).

Several patients reported sharing changes they had made with other patients, such as wearing several stockings over the prosthesis to make it look more natural (PIB03). Another patient reported sharing with others changes she had created to repair her prosthesis, including using nails to reattach the steel joints, and getting in turn tips from other patients on how to repair the suspension belt of the prosthesis (PIE14). Further examples of encouragement were an interviewee who told me he had spoken to another patient: “Ah, I know a friend here in Blantyre. Because it was me who encouraged him to come here” (PIB06). They had colleagues in common in the police force, which resulted in their meeting one another (ibid.). When they talked on the phone, the experienced patient explained about the special suspension he was using, and advised the other to ask the centre for a similar suspension, which he did (PIB04, PIB06). However, he had not yet received it because the original suspension was a donated part from a developed country and these parts were not available anymore at the time (Observation 120621). Thus, details of the change were shared, but it could not be reproduced.

6.1.2.2 Between different centres

Most accounts of contacts between patients were not specific about whether they were patients from the same or different centres. Given the geographical distance between centres, in most cases it is likely that they were from the same centre. While they are attending the centres, patients meet and sometimes they may be patients supplied by prostheses from a different centre (PIB05, PIB08, PIE13, PIE21). In these rare cases, patients from different centres could come into contact with each other.

6.2 Sharing and connections between groups

This section describes the sharing and connections, and thus also potential connections between their learning selection processes, between technicians, patients and manufacturers and funding bodies, within the same centre and between different centres.

6.2.1 Sharing and connections between patients and technicians

The connections between the patients and technicians considered here occur at the orthopaedic centre; otherwise the two groups are unlikely to meet.

6.2.1.1 Within centres

First, the patients receive the prostheses which are the physical outcome of the production process executed by the technicians. The most intense interaction between patients and technicians happens during the assessment, cast-taking, fitting and training for the prostheses. During the assessment, technicians ask about the patient's life circumstances, and offer advice to patients on how to care for the prosthesis, when to return to the centre if there is a problem, and how to walk using the prosthesis (EI02; CIB02; CIB03; CIB05; CIB06; CIB07; CIE08; observation 120528, 120530, 120606, 120608, 120613; 120813, 120824, 120913; PIB01; PIB11; PIE18). In some special cases, if a patient has a good understanding and lives far from the orthopaedic centre, the patient is advised about how to do small repairs to the prosthesis (CIB03; observation 120606). Technicians also encourage patients, which was described by the patients as very important and helpful (PIB01; PIB06; PIB11). Patients ask the technicians for advice about how to put on the prosthesis by themselves and what to do if it gets wet (Observation 120606, 120608, 120824, 120913; PIB01). Patients give feedback on how the prosthesis fits and whether they experience any pain (CIB04; observation 120606, 120824; PIB01). If patients do have pain, the technicians will make some adjustments to the prostheses and ask for feedback (CIE08; observation 120824). The cycle is

repeated until both parties are satisfied[17] (CIB03; CIB06; observation 120824). In addition to this interaction with new prosthesis patients, there is some interaction with patients who bring in their prostheses for repair. If the patients have made changes to their prostheses, the technicians can see them. The reactions of the technicians to these changes differ. Patients are generally discouraged from making further changes (CIB02; observation 120611). However, if the change is not seen as damaging the prosthesis or harming the patient, the technicians do not discourage the patients (CIB02). The patients may also give the technicians feedback about the technology. This includes reasons for not using a prosthesis (CIB02; PIB03). However, feedback from patients is rare, which was seen as a disadvantage by one technician: “Unfortunately in our setting here, patients rarely rarely rarely come with an idea (…) if they came with ideas (…) that would be wonderful” (CIB02). These connections also allow technicians to share their changes with patients. This often occurs indirectly, that is, the technician may not point to specific changes created, but the patient receives the changed prosthesis. An example for this is a change created to a prosthesis by a technician at the QECH centre. The change involved the use of fabric and velcro for the suspension of an above knee prosthesis (Observation 120621). It was not available to another patient who requested it, however, because the material used had been donated from a developed country and was not available anymore (PIB04; PIB06; observation 120621).

6.2.1.2 Between different centres

Technicians and patients from different centres come into contact when patients go to a different centre from the one that supplied their prosthesis, sometimes because a new, closer centre has opened (PIE13; PIE21). This applied to patients who brought prostheses from the QECH centre to the Ekwendeni centre. In the centre at QECH I met two patients who had received a prosthesis from the orthopaedic centre at Kamuzu Central Hospital in Lilongwe

[17] Not all pain can be avoided; sometimes the muscles and tissues need time to adjust to bearing weight again, but this pain is only temporary.

(PIB05; PIB08). In the case of patients with prostheses from different centres, in some cases repair was possible, but in others they received new prostheses (CIE09; PIE13, PIE21).

The patients with prostheses from the QECH centre who went to the Ekwendeni centre introduced a different technology to this centre. The technicians at Ekwendeni, who produce prostheses with the Jaipur technology exclusively, repaired the ICRC polypropylene prostheses, in some cases by creating changes in the form of combining them with the Jaipur technology (CIE09; observation 120807). The technicians can learn from seeing these different prostheses (CIE09). Even if they use a different technology, some changes are more general and can also be incorporated into a different technology (ibid.). An example was the holes made in the socket at the QECH centre to allow air to pass through, an idea that was picked up by a technician in Ekwendeni (CIE09). The same technician reported that he got the idea of padding the distal end of the socket or the soft insert from prostheses that had been donated to the centre from developed countries (ibid.).

6.2.2 Sharing and connections between technicians and manufacturers and funding bodies

In order for selection and promulgation to occur as described in the enabling innovation framework, product champions and market mechanisms are important. Manufacturers and funding bodies play a major part in providing these entities. It is therefore paramount to investigate the connections of them to users, in order to see if they are involved in selecting and promulgating changes created by users.

6.2.2.1 Within centres

Manufacturers and funding bodies can have a major influence on the production process of technicians. However, the centre at the Ekwendeni Mission Hospital has had no contact with the manufacturer of the Jaipur technology beyond receipt of the initial consignment and manuals when the centre opened (CIE08; CIE09). They are not in direct contact with the funding body, the Rotary Jaipur Limb Project or the local Rotary Club of Mzuzu (ibid.). In contrast, the QECH orthopaedic centre is in touch both with manufacturers and funding bodies for both the ICRC polypropylene and the Jaipur technology. The contact with the manufacturers is mostly through receipt of new materials or components and manuals, which the technicians incorporate into their production process (CIB02). In addition, the ICRC has provided several technicians at the centre with training courses in their centre in Ethiopia (CIB02; CIB03; CIB04; CIB06; CIB07). This connection also allows manufacturers to share their changes with technicians, as in the case of the extension assist. One technician made this extension assist for a patient, and reported having learned it from the ICRC training in Addis Ababa (Observations 120611, 120615). The ICRC requests monthly statistics for patients treated at the centre and twice yearly activity reports (Observation 120614). In addition, when ICRC officials have visited the centre, they were shown any problems with the technology, such as feet which have broken or worn very quickly (CIB03; CIB05).[18] The ICRC visits and training, however, are likely to be discontinued since the memorandum of understanding between the ICRC and the centre has not been renewed (International Committee of the Red Cross 2013a; CIB02). The head of the centre is in touch with the Rotary Club in Blantyre, which handles requests for materials and components (CIB02). There is also feedback from the technicians at the QECH centre to both manufacturers, mostly related to problems with the technology. The centre head collects feedback from the technicians and passes it on to the ICRC in Ethiopia or the Rotary Jaipur Limb Project (CIB02; CIB03; CIB04; CIB05; CIB06). The feedback to manufacturers, in some cases, has resulted in changes to the technology. An example is the feet which are part of the ICRC polypropylene technology and were reported as

[18] I was shown this box of feet when I was at the centre.

breaking easily; the next consignment of feet was more durable (CIB02; CIB03). In the case of the Jaipur technology, the feet were too wide and prone to breaking around the ankle area (CIB02). Both aspects have been adjusted (CIB02; Observation 120618). The changes relating to combining different technologies are purposefully not passed on to manufacturers, however; as one technician stated: “If I do something different, I haven't quite told them that I've combined their part with. Because I don't know how they would react.” (CIB02).

How these manufacturers can influence the changes made by technicians in orthopaedic centres is explained in detail in Chapter 7 Sections 7.2.1.

6.2.2.2 Between different centres

The centre at QECH uses both the ICRC polypropylene and the Jaipur technology and is in touch with both manufacturers and funding bodies (CIB02). The centre at the Ekwendeni Mission hospital employs only the Jaipur technology and is not in touch with the manufacturers or funding bodies of either technology (CIE08; CIE09).

6.2.3 Sharing and connections between patients and manufacturers and funding bodies

6.2.3.1 Within centres

I found no evidence of patients contacting manufacturers or funding bodies directly. The patients give feedback to the technicians, and the technicians at the QECH centre may then pass this feedback on to the manufacturers and funding bodies; generally it is passed on to the head of the department first, who then informs the manufacturers and funding bodies (CIB02; CIB04; CIB05). However, one technician reported not passing on feedback from patients (CIB03). The technicians from the centre in Ekwendeni have no contact with the manufacturer or funding body, and, thus, do not pass on patients' feedback (CIE08; CIE09). Patients are connected only indirectly to the manufacturers and

funding bodies via the prostheses they receive. Thus, manufacturers share the changes they create with patients, but not through direct contact.

6.2.3.2 Between different centres

As described above, I found no evidence of any connection between patients and manufacturers or funding bodies, except via the changes incorporated in patients' prostheses.

6.3 Summary

This chapter described the data on the changes shared between technicians, patients and manufacturers and funding bodies and the connections that exist between them. This shows on one hand how specific changes by users identified in this research were shared, and on the other hand the opportunities users have to share changes. This is important to show what selection and promulgation of the changes which users, both technicians and patients, create is occurring, and how. This includes showing the connections which can exist between users' learning selection processes, and thus how they do or do not profit from each other's changes. It is clear that the two orthopaedic centres have different levels of connectivity with others, technicians as well as patients. While the orthopaedic centre at QECH is involved in professional organisations and has connections with manufacturers and funding bodies, the centre at the Ekwendeni Mission Hospital has no such connections and is relatively isolated. Within the centres, technicians share many changes with each other, as do patients. Patients also offer each other general advice and encouragement. This is discussed further in Chapter 7, which presents the results of the data analysis on the factors that influence the creation and sharing of changes made by users and user innovation of medical technologies in developing country settings more generally.

7 Discussion

This chapter demonstrates how limitations the users are subject to influence their creation and sharing of changes to lower limb prostheses in two orthopaedic centres in Malawi, and the conclusions that can be drawn from this about user innovation of medical technologies in developing country settings more generally. In order to achieve this, changes by users and their connections as well as the conditions they are subject to were analysed. The description of the changes and connections is based on primary data, as indicated in the previous Chapters 5 and 6. Secondary data was only used to supply some factual background information and complement the data derived from interviewees describing the background, as described in Chapter 4.

Chapter 7 begins by focussing on factors that might influence user innovation of medical technologies in developing country settings according to the literature on frugal innovation and grassroots innovation. Limitations are identified as potential influencing factors and are classified into three categories. Specific limitations related to users of lower limb prostheses in the two orthopaedic centres in Malawi are described. How these limitations influence users to create and share changes to lower limb prostheses is assessed, including specific examples of changes identified in this research. This contributes insights to the concept of user innovation by identifying some of the factors which shape user innovation in regard to medical technologies in developing country settings. Based on these results, I propose some additions to the user innovation model introduced. How users share changes under limitations is assessed, and the influence of solidarity among users with regard to sharing changes is demonstrated. Finally, I show that the lack of structures to foster selection and promulgation of changes is one of the factors explaining the apparent lack of user innovation, despite innovative activities by users, in developing country settings more generally. The chapter concludes by summarising the main points discussed.

7.1 Factors influencing users' creation and sharing of changes to medical technologies in developing country settings

This work investigates user innovation of medical technologies in developing country settings, and the factors that influence it. Most work on user innovation is focussed on the conditions prevalent in developed countries, as elaborated in Chapter 2 Section 2.2.1. User innovation in developing countries has received little attention and therefore little work exists which aims to explain how user innovation in these settings is similar to or different from user innovation in developed countries. In order to investigate this, literature on innovation in developing countries was reviewed, namely work on frugal innovation and grassroots innovation. These concepts provide some insight into the additional factors that shape user innovation in such settings. Both concepts stress the importance of limitations for determining the characteristics of specific innovations created in these circumstances, and the reasons for their creation. Some argue that innovations are created not despite, but because of these limitations (Srinivas and Sutz, 2008: 131–132). Rather than being based on the available inputs, innovations may be driven by the lack of inputs (ibid.). This differs from the more common view that innovation occurs if significant resources are assigned to solve a problem (ibid.). When users' resources are scarce, their needs must be sufficient for them to innovate or make changes to a product, and to promote exploitation of spare resources to fulfil this need. In addition to the influence on innovation generally, limitations are highlighted in the literature on medical technologies in developing countries; their use and maintenance in such settings is shown to be significantly influenced by the prevailing limitations (Free, 2004; Malkin, 2007a).

The concepts of frugal innovation and grassroots innovation emphasise the effect of limitations, which can be expected also to have a significant influence on innovations and changes created by users in developing countries. However, neither concept relates explicitly to how limitations that influence innovations can be classified, and how they shape innovations in detail. Based on the data collected for this research, limitations were investigated in detail and three categories of limitations were identified. They are introduced below as

the basis for investigating whether and how these limitations influence how users create and share changes.

The information given in Chapters 4, 5 and 6 on the background to lower limb prostheses in Malawi and the creation and sharing of changes by users is analysed according to the model of the basic process of users innovation and the enabling innovation framework, as described in Chapter 3 Section 3.5. On this basis, I show how this context represents the different categories of limitations that the users in those settings have to deal with. First, I describe the categories and details of limitations generally, then I describe them in relation specifically to the two orthopaedic centres studied.

7.1.1 Three categories of general limitations

The literature on the concepts of frugal innovation and grassroots innovation and work on medical technologies in developing countries highlights limitations or barriers as important for the creation of innovations to and use of medical technologies in developing country settings. By investigating changes created to one kind of technology by different users and in different circumstances including the surrounding conditions, I was able to compare the changes and the reasons why they were made. This allowed me to identify different categories of limitations and how they influence the creation and sharing of changes by users.

The three categories of limitations that influence changes by users are:

- structural and organisational limitations;
- technological limitations;
- personal limitations.

The first two categories apply to all users who are part of a certain structure or organisation and who use the same medical technology. The third category refers to the limitations that apply to different degrees to individual users, mostly

patients. The differences among individual medical professionals in terms of education, for example, can be attributed to structural or organisational limitations rather than to their personal circumstances. Below, the three kinds of limitations are discussed.

First, structural or organisational limitations are considered. In many developing countries the provision of health services is mostly or partly dependent on donors, as described in Chapter 2 Section 2.1.1, which limits the choices of medical professionals and patients alike (Walt and Gilson, 1994; Walt et al., 2008). It may influence the healthcare structures in place, such as the number of health centres, and the medical technologies provided by those health centres. How many centres exist also influences how far patients have to travel and, thus, how easy or difficult it is for patients to take advantage of the services provided. The provision of lower limb prostheses in Malawi is mostly confined to four orthopaedic centres.

The influence of donors can also lead to constraints on both medical professionals and patients in relation to the choice of medical technologies as mentioned in Chapter 2 Section 2.1.1. This relates not just to the initial acquisition of a technology, but also the provision of spare parts, tools and consumables all of which may be needed for the sustained use of a technology. Because of the financial constraints of the Malawian government, all of the country's orthopaedic centres are supported by various donors, and are provided with the technology chosen by these donors. These centres are not free to order spare parts or materials to replenish stocks; they must apply for assistance from donors or apply to the general hospital administration.

In addition to the provision of the medical technologies, including spare parts, tools and consumables, trained personnel are required to ensure continuous and proper use of the technologies. Many developing countries are limited by the training costs for medical professionals and provision of training may also be dependent on support from donors. This situation is aggravated if there is no adequate domestic training available, which increases training costs. The limited funds of the Malawian Ministry of Health constrain the amount of

professional training that orthopaedic technicians at the orthopaedic centres receive. There are no domestic training programmes for orthopaedic technicians in Malawi, as described in Chapter 4 Section 4.2.1, which adds to the training costs. Many technicians who have received training were sponsored by donors (500 miles, 2013d; ICRC, 2010b).

In addition to the limitations already mentioned, there are structural and organisational limitations that influence how users share the changes they create. These limitations mainly relate to the established connections between technicians, patients and other interested parties described in Chapter 6. They can lead to users having little contact with other users or interested parties, which makes it more difficult for them to share their changes. Medical professionals working in the same health centre are likely to be in contact with one another and, thus, likely to share changes made to the medical technologies they use. However, the opportunities to share changes with medical professionals from other centres may be limited unless there are structures in place to facilitate this, such as professional organisations. For patients who are not connected to health centres through professional ties, structures are crucial to establish contacts through which they can share their changes with other users. Patient organisations can for example provide such structures. The orthopaedic centre at QECH takes advantage of existing structures which facilitate the connections of technicians at this centre with medical professionals outside the centre, while the centre in Ekwendeni does not. For patients using lower limb prostheses in Malawi generally, I did not identify any structures which specifically aim at bringing these users together and thus facilitate their mutual sharing of changes.

In addition to structural and organisational limitations, the medical professionals and patients are subject to technological limitations. These are due to the characteristics of the medical technologies. In some cases, it is necessary to customise them to suit the individual characteristics of the patient. The options available may be limited by the technologies which may offer few opportunities for customisation for individual differences. Customisation and maintenance, in addition, may be limited by the number of parts that make up a

technology and the difficulty to disassemble them. Both technologies used to produce lower limb prostheses in the two orthopaedic centres in Malawi, provide only one or at most two types of a certain component. All patients, irrespective of their weight, age, activity level and condition, need to be fitted with standard components. There is also no choice of colour: the centres are supplied with parts in one colour, most often a medium or dark brown.

The third category of limitations, that especially patients face, is personal limitations. These depend on the specific conditions of the patient and can differ between individual patients. Medical technologies can be especially important for patients with chronic conditions, who throughout their lives may be reliant on medical support, including technologies. As a result, the medical technologies they use will need maintenance or renewal over long periods of time. There are additional personal limitations that impede patients' mobility. Reduced mobility can make it difficult for patients to access the services available at the health centres that might improve their condition and allow them to seek paid work. Finding paid work can be especially difficult in settings where most jobs involve manual labour and are physically demanding. Patients in such settings may have little disposable income. They may also be poorly educated because of mobility and financial reasons. Many disabled patients suffer discrimination and marginalisation as an additional form of personal limitations. They may be ridiculed, refused employment and not respected. While much progress has been made worldwide to reduce the discrimination and marginalisation of disabled people, they persist in most societies. Some patients interviewed during the research reported suffering discrimination. Patients may be limited by others in their society because of their disability; they may be excluded from the labour force, and mocked and laughed at because they lack a limb. Patients may limit themselves by deciding to stay away from social activities or school for fear of the reactions of others. These issues can be exacerbated for patients living in contexts where tradition and belief in witchcraft continue to be strong, as described in Chapter 4 Section 4.4.3 on the beliefs and customs surrounding disability in Malawi.

The circumstances described above make it difficult for disabled people to obtain an education and find paid work, therefore leading to educational and economic limitations. Among those who do find work, the livelihoods of many Malawians depend on subsistence farming, as mentioned in Chapter 4, which involves physically hard work. Many household chores, such as pounding maize or fetching water, are also strenuous. Due to the dependence on subsistence farming, the disposable income of some patients is small. Many find it difficult to obtain the funds needed for transportation to an orthopaedic centre. Chapter 5 Section 5.2.3 showed that several patients mentioned the difficulties involved in getting to an orthopaedic centre as the main reason for them to create changes to their prostheses.

These personal limitations could be expected to also hinder patients' sharing of their changes with others. Their marginalisation by society may prevent them from speaking up, or the difficulties involved in travelling will limit their contact with other patients. Nevertheless, the interviews showed that patients not only shared their changes, but invested time and often scarce funds in order to do so. This phenomenon is discussed further in Section 7.2.2 on the influence of limitations on users sharing their changes.

In this section I have described the major structural and organisational, technological and personal limitations faced by patients and medical professionals. After introducing these limitations in general, the specific limitations faced by the orthopaedic centres at QECH and Ekwendeni Mission Hospital are discussed in the next section.

7.1.2 Limitations specific to the two orthopaedic centres

Specific limitations the two orthopaedic centres are subject to need to be considered, in order to be able to relate the differences in the changes created by users from the two different centres to the differences in limitations. The two orthopaedic centres in which this research was conducted share certain commonalities, such as the personal limitations of their patients. The two

centres differ in various aspects regarding structural, organisational and technological limitations, which are described below.

There are differences between the centres in terms of structural and organisational limitations. The orthopaedic centre at QECH is a department of this central hospital and, thus, overseen by the hospital administration and the Malawian Ministry of Health. Therefore, the Chief Rehabilitation Officer represents the interests of the centre in the Ministry of Health. The orthopaedic centre at the Ekwendeni Mission Hospital is part of this much smaller Mission Hospital administered by the local Synod of the Church of Central Africa Presbyterian (CCAP). This synod does not have a specialised position, such as Chief Rehabilitation Officer in the Ministry of Health, to lobby for the support of the orthopaedic centre. Thus, this centre has less influence on decisions about the support it receives. The centres also differ in size; the QECH centre is larger, and provides orthoses,[19] surgical footwear and wheelchairs as well as prostheses, and has four technicians who work specifically on prostheses. The centre at the Ekwendeni Mission Hospital is staffed by only two technicians and only provides prostheses.

As mentioned above, there are differences among the technicians at the centres in relation to the level of contact with donors and manufacturers. The connections between these groups were discussed in Chapter 6 Section 6.2.2. The differences in this respect between the two orthopaedic centres in terms of their structural and organisational limitations are briefly recapitulated here. The technicians in the centre at QECH are in touch with technicians from other centres, other medical professionals and manufacturers and funding bodies. There is cooperation with other medical professionals in the hospital and through a professional organisation. This professional organisation, the Malawi Orthopaedic Association (MOA), plays an important role in bringing together different orthopaedic professionals, such as during its general annual

[19] Orthoses do not replace a limb, but support an existing weak limb by providing an outer structure.

meetings.[20] Those technicians from the QECH centre belong to MOA and attend these meetings, who received their formal education at TATCOT. There is also contact with the donors, the ICRC and the Rotary Club. Contact with the Rotary Club is exclusively via the head of the centre; the ICRC sends delegations to the centre and also provides training courses in Ethiopia, which many of the technicians working at the centre have attended.

The technicians in the orthopaedic centre at the Ekwendeni Mission Hospital are rarely in touch with other medical professionals; their connection with fellow orthopaedic professionals was via one personal contact. They are not members of the MOA and so do not attend its meetings. They are also not in touch with their donor, the Rotary Club, since all contact with the donor is routed through the hospital administration. Hence, they are not able to give direct feedback to the donor or the manufacturer on their experience of the technology.

The differences in the technologies used by the orthopaedic centres are also important to understand differences in their limitations. As described in Chapter 4 Sections 4.3.2.1 and 4.3.2.2, the orthopaedic centre at QECH has both the ICRC polypropylene as well as the Jaipur technology available, while the orthopaedic centre at the Ekwendeni Mission Hospital has only the Jaipur technology available. The Jaipur technology provides fewer options than the ICRC polypropylene technology because it comprises fewer components (ICRC, 2006; observations 120528, 120529, 120601, 120627, 120730, 120802). Thus, the technicians at the Ekwendeni centre face more limitations.

In summary, the smaller Ekwendeni Mission centre has fewer resources – personal, technological and donor support – than the QECH centre. It is also more isolated because it has little or no formal contact with other medical professionals and donors. The patients of both centres experience similar circumstances. These differences between centres and their limitations lead to different changes created to prostheses and to differences in how these

[20] I attended the annual general meeting of the MOA and presented my research there (Observations 121005, 121006).

changes are shared. The changes created represent how users deal or cope with these limitations. Both of these aspects are discussed further in Section 7.2. Table 7-1 provides an overview and a comparison of the specific limitations of the two orthopaedic centres.

Table 7-1 Limitations of the orthopaedic centre at QECH and the orthopaedic centre at the Ekwendeni Mission Hospital

Categories of limitations	Orthopaedic centre at QECH in Blantyre	Orthopaedic centre at the Ekwendeni Mission Hospital in Ekwendeni
Structural and organisational limitations	Dependency on donor support for running the centre	Dependency on donor support for running the centre
	No free choice of technology, donor decides	No free choice of technology, donor decides
		Only Jaipur technology available
		No representation of rehabilitation issues at higher level
		Small centre, only two employees without formal[21] training
	Little contact with manufacturer	Little or no contact with donor and manufacturer and other medical professionals
Technological limitations		Jaipur technology made from fewer components
	Only standard components available	Only standard components available
	Parts only available in one colour	Parts only available in one colour
Personal limitations	Patients may face discrimination and marginalisation	Patients may face discrimination and marginalisation
	Patients have limited mobility	Patients have limited mobility
	Patients may have little education, work and therefore also disposable income	Patients may have little education, work and therefore also disposable income

Source: Constructed by the author

[21] Formal training here refers to training at TATCOT.

Table 7-1 shows that both orthopaedic centres face numerous limitations, although more are experienced by the Ekwendeni centre.

7.2 How limitations shape the creation and sharing of changes by users

Section 7.2 shows how the limitations described in Section 7.1 influence how and why users create and share changes to lower limb prostheses in Malawi and to medical technologies in developing country settings more generally.

7.2.1 Insights into the creation of changes by users

The data collected showed that many relevant changes could be identified. This section discusses how the limitations present, described above, shape the creation of these changes.

The changes created to prostheses both by patients and technicians were described in detail in Chapter 5. Here, I discuss how various limitations, described directly by users or inferred from the nature of the circumstances, were the reasons for these changes. Section 7.1.1 considered the limitations to which users of medical technologies in developing country settings are subject, and Section 7.1.2 discussed the limitations specific to the two orthopaedic centres in Malawi. A comparison of these limitations shows how additional limitations affect the incidence and appearance of changes created by users.

In order to demonstrate the influence of limitations, examples of some of the changes described earlier are given below which exemplify the three categories of limitations - structural and organisational, technological and personal.

First, changes created because of structural and organisational limitations are considered. Some changes are created due to these limitations in order to

make the technology functional again, because it has broken and no spare parts or tools are available or because of a lack of consumables. The fewer parts and materials available at the health centres, the more likely medical professionals will create changes. If there are several medical technologies available at the health centre, all of which would improve the same condition, this can lead users to combine different technologies. An example of a change created by combining technologies, due to structural and organisational limitations, is the case of an ICRC prosthesis. This prosthesis was brought to the Ekwendeni centre. This prosthesis had a completely worn out foot leaving only the peg and socket. As the centre at the Ekwendeni Mission Hospital has certain structural and organisational limitations, it did not have the spare parts to repair this prosthesis. The technicians would have preferred to make a new prosthesis, but were unable to do so because the worn out prosthesis had not been brought in by the patient but by an employee of Malawi Against Physical Disabilities (MAP). This shows how MAP, one of the disability organisations, discussed in Chapter 4 Section 4.4.2, influenced a specific change to a prosthesis by technicians. The technicians had to create changes to the prosthesis in order to repair it. They disassembled it, kept the old socket and fabricated a new Jaipur prosthesis using the ICRC polypropylene socket, thus, combining the two technologies. In summary, the technicians at the Ekwendeni orthopaedic centre repaired the prosthesis by creating changes that consisted of combining the two technologies. The centre at QECH had both technologies available, allowing it to repair prostheses produced with either the ICRC or the Jaipur technology, without making changes. Cases where technicians at the QECH centre solved the issue of missing spare parts and materials by combining technologies were due to temporary shortages of these spare parts and materials.

If the options a technology provides, due to technological limitations, are not satisfactory for the user, he or she may also create changes to it. For technologies which medical professionals use on patients directly, medical professionals may create changes in order to cater for an individual patient using the options the technology provides. Examples are changes created in both orthopaedic centres for patients with a curved or long stump and heavy

patients, as mentioned in Chapter 5 Sections 5.1.3 and 5.1.4. The more technological limitations that exist, the fewer ready-made options are available to users. This situation can change if the manufacturers of the technologies create changes that provide additional options. Then the changes previously made by users to accommodate certain conditions may no longer be necessary and will be dropped. One example was the long stump foot for the ICRC polypropylene technology which was provided to the orthopaedic centre at QECH. Previously, the technicians had cut out a polypropylene sheet in the shape of a foot and used this to replace the regular foot to make a shorter prosthesis, this change became obsolete once long stump feet were provided. Like the manufacturer of the ICRC polypropylene technology, the manufacturer, BMVSS, of the Jaipur technology created changes to improve knee joints and co-developed the Jaipur knee with Stanford University in 2009 (Bound and Thornton, 2012). However, the orthopaedic centre in Ekwendeni has not received these Jaipur knees and the technicians continue to make changes to the knee joints themselves, as described in Chapter 5 Section 5.1.4.

In all of these cases, a health centre with a free choice of technologies would have had the option to procure special parts to cater for patients with special needs. In summary, medical professionals who need to deal with the different conditions of the patients, may need to create changes if there are no ready-made options available for customising medical technologies.

Patients also have to deal with many limitations. Patients mentioned various personal limitations when asked about details of the changes they had made. For those medical technologies which patients use actively, these limitations can lead them to create changes. The changes they create depend on the need the technology is supposed to fulfil for them. Technologies used by chronic patients are more likely to be changed since they are in use for a long period of time. The more important the technology is for the patient using it to earn his or her livelihood and to relieve pain, the more important it is that the technology works well. If it does not work well, for example, because it has broken, the patient will make efforts to repair or improve it. One option is to attend a health centre where the personnel can solve the issue. In the case of personal

limitations such as restricted mobility or lack of funds for transport and service costs, patients may not have this option. In order to improve their situation, they may decide to repair or improve the medical technology themselves. If they do not have the matching spare parts, tools or consumables, which is often the case, they may create changes to the medical technology.

For lower limb prostheses, patients created changes to their prostheses in order to ensure their mobility. Some of these changes consisted of repairs such as reattaching the foot to the prosthesis. Some patients fabricated tools in order to carry out a repair or used alternative materials. Patients who made such changes sometimes did so because they were forced to in order to instantly achieve mobility again. This applied to a patient whose prosthesis broke while he was working, and he was forced to repair it in order to get home. Another patient needed to get to school to sit for an exam, and so found a way to repair his broken prosthesis. Some patients called on artisans, such as shoemakers, outside the orthopaedic centres to repair their prostheses, which then created changes to them in order to repair them.

If personal limitations hinder patients to access services at health centres, they may create changes themselves to a medical technology, if some technological limitations make the medical technology in its current state unsatisfactory. Below are some examples of improvements made to lower limb prostheses related to aesthetics and comfort. To hide her prosthesis and avoid discrimination, one patient developed a system of different coloured stockings worn over her prosthesis. This allowed her to overcome the technological limitation of lack of availability of materials in different colours. Other changes made by patients were improvements to the comfort of the prosthesis, such as the addition of cushioning in the sockets or slits in the soft insert to allow air circulation.

This section showed that the three categories of limitations identified, significantly shape both whether users create changes, and the characteristics of changes created. Limitations also influence whether and how users share their changes, as discussed in the next section.

7.2.2 Insights into the sharing of changes by users

This section draws on the descriptions of the changes shared among users and their connections, and shows how the limitations identified above influence this sharing. In order to illustrate this further, specific changes described in Chapters 5 and 6 are referred to. First, I show how medical professionals and then how patients share changes.

Medical professionals are likely to share changes with other medical professionals working in the same health centre. To share changes beyond their own centres, however, requires connections with medical professionals at these centres. If there are no structures to support such connections or medical professionals have no access to them, this kind of sharing can be difficult. This lack of access can be due to structural or organisational limitations, for example, if the medical professionals are not part of these structures, because they are not members in professional organisations. This is the case for the technicians at the Ekwendeni orthopaedic centre, which did not report sharing their changes with other medical professionals outside their centre.

Such structural and organisational limitations can also result in no or few connections with manufacturers and funding bodies, which can hinder medical professionals from sharing their changes with them. In addition, medical professionals may not share some of their changes on purpose because they may not conform to the regulations in the home country of the manufacturer. At the same time, this may also hinder manufacturers and funding bodies from sharing their changes with technicians. An example of this is the Jaipur knee discussed in Section 7.2.1. The orthopaedic centre at Ekwendeni has not received this changed knee component, because of the lack of connection to BMVSS who produces the Jaipur technology due to structural and organisational limitations.

Similar to medical professionals, how patients share their changes is also influenced by structural and organisational limitations. Patients can share their changes with other patients. However, if there are no structures in place that

bring patients in contact with each other, then they can only share their changes through personal individual contacts with other patients. They often share their changes with other medical professionals on visits to a health centre, where they may report their changes or the medical professionals identify them by inspecting the changed artefacts of the technology. If there are no established connections to manufacturers or funding bodies, patients cannot share their changes with them. However, technicians may share patients' changes indirectly via these channels.

In addition to structural and organisational limitations, patients are also subject to personal limitations. These can take the form of reduced mobility, lack of disposable income and discrimination, all of which can be expected to prevent patients from speaking up, seeking out other patients and sharing their changes. However, the data in Chapter 6 Section 6.1.2 show that patients do share their changes, investing time and in some cases money to do so. The reasons why patients incur time and costs will be further investigated in Section 7.3.2.

Sharing changes is one way for patients to help each other. They can pass on changes made to their own prostheses, either by themselves or by technicians, and suggest changes to others. However, due to the existing limitations, these shared changes may not be reproduced. An example is two patients I interviewed who were introduced to each other through common colleagues from the police. When they talked on the phone, the 'older' patient explained about the special suspension he was using, and advised the other to ask at the orthopaedic centre for a similar suspension, which he did. However, the special suspension had been donated from a developed country and no others were available at the time. Thus, the details of this change were shared, but it could not be reproduced. This description shows several influencing factors. First, it exemplifies the sharing of changes through informal, private contact between patients. It demonstrates how certain limitations, in the case above, the structural and organisational limitations of the centre in relation to not being able to purchase parts at will, influence how changes can or cannot spread. The patient selected the change as being good and shared it with

another patient who also asked for the change, but was told it was not possible due to a lack of materials.

Based on the results presented in Section 7.2 on the influence of limitations on the creation and sharing of changes, Section 7.3 will show how the limitations to which users are subject influence the process of user innovation created to medical technologies in developing country settings.

7.3 Insights into user innovation of medical technologies in developing country settings

Sections 7.1 and 7.2 identified three categories of limitations, discussed how these limitations influence changes created and shared by users, and showed how they encourage rather than hinder users to create and share changes. In what follows, I examine how these results contribute to work on user innovation of medical technologies in developing country settings more generally.

These results are related to the model of user innovation introduced in Chapter 2 Section 2.2.1. This demonstrates the differences that may exist in user innovation of medical technologies between developed and developing country settings. One aspect of this model is how users share their changes. As personal limitations have been shown to contribute to rather than hinder such sharing, I examine why this is the case. That users share their changes is important because it is the first step to allowing selection and promulgation of these changes and, thus, further development of the technology, as stated in the enabling innovation framework. How and why this further development occurs is discussed.

7.3.1 The influence of limitations on the model of user innovation

As mentioned earlier, user innovation has been studied mostly in the context of developed countries. User innovation in developing countries has received less attention and therefore little is known about how user innovation in such settings is similar to or different from user innovation in developed countries. The previous sections of this chapter show that there are three categories of limitations that can influence the way users create and share changes in developing country settings. These provide a basis for adapting the model of user innovation introduced in Chapter 2 Section 2.2.1, and thus for demonstrating how limitations can shape user innovation to medical technologies in such settings.

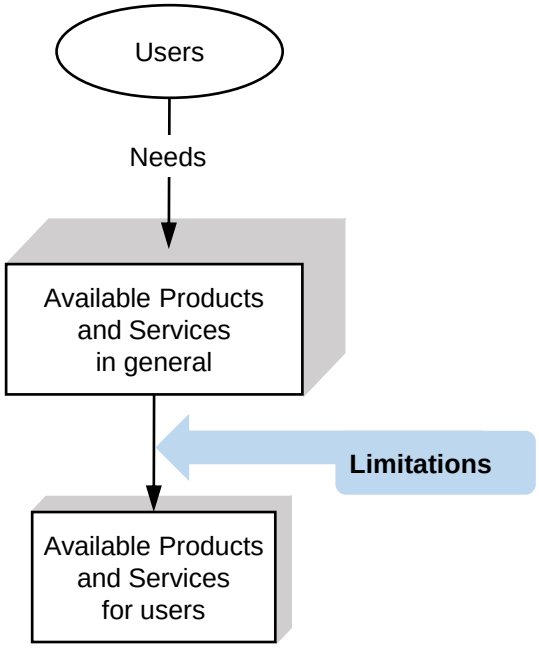
The concept of user innovation describes users as having needs which, in the first instance, they try to satisfy with the products and services available to them. If these products and services do not satisfy users, they either still use the available products and services and make do, or they instead create changes or innovations. Some users then share their changes or innovations with other users or other interested parties. This research shows that limitations are a major factor influencing the creation and sharing of changes by users to medical technologies in developing country settings. I examine their influence on the process of user innovation in order to show how this process might differ in these settings.

The first instance in this model where limitations have an influence is the availability of products and services for users to fulfil their needs. As shown in Section 7.2.1, the pool of products and services available to users can be restricted by limitations on the users. The available products and services are influenced by structural and organisational and technological limitations, and the users' personal limitations. Structural and organisational limitations can result in certain products and services not being freely accessible to users; they can restrict choices due to reliance on what is supplied by donors. The technologies may have limitations, which further reduce the solutions available to users, such as a lack of special parts or deficiencies in available parts and

materials. Personal limitations can restrict users' access to products and services.

The result of the influence of all three categories of limitations is a restricted set of products and services from which users can draw to satisfy their needs, which, in turn necessarily satisfies fewer needs. Users faced with unmet needs have the choice to continue to use the products and services available, or to create changes or innovations themselves. Therefore, these users may be more likely to create changes and to innovate than users who are not subject to such limitations. The changes or innovations users create under these circumstances in many cases are not new to the world, because they are created due to lack of access to an existing solution. Nevertheless, these innovations can have a major impact and may allow the user to help himself or herself, and others, outside of formal structures and without manufacturers supporting them with ready-made solutions. Figure 7-1 depicts the influence of limitations on this part of the process.

Figure 7-1 How limitations influence the availability of products and services for users



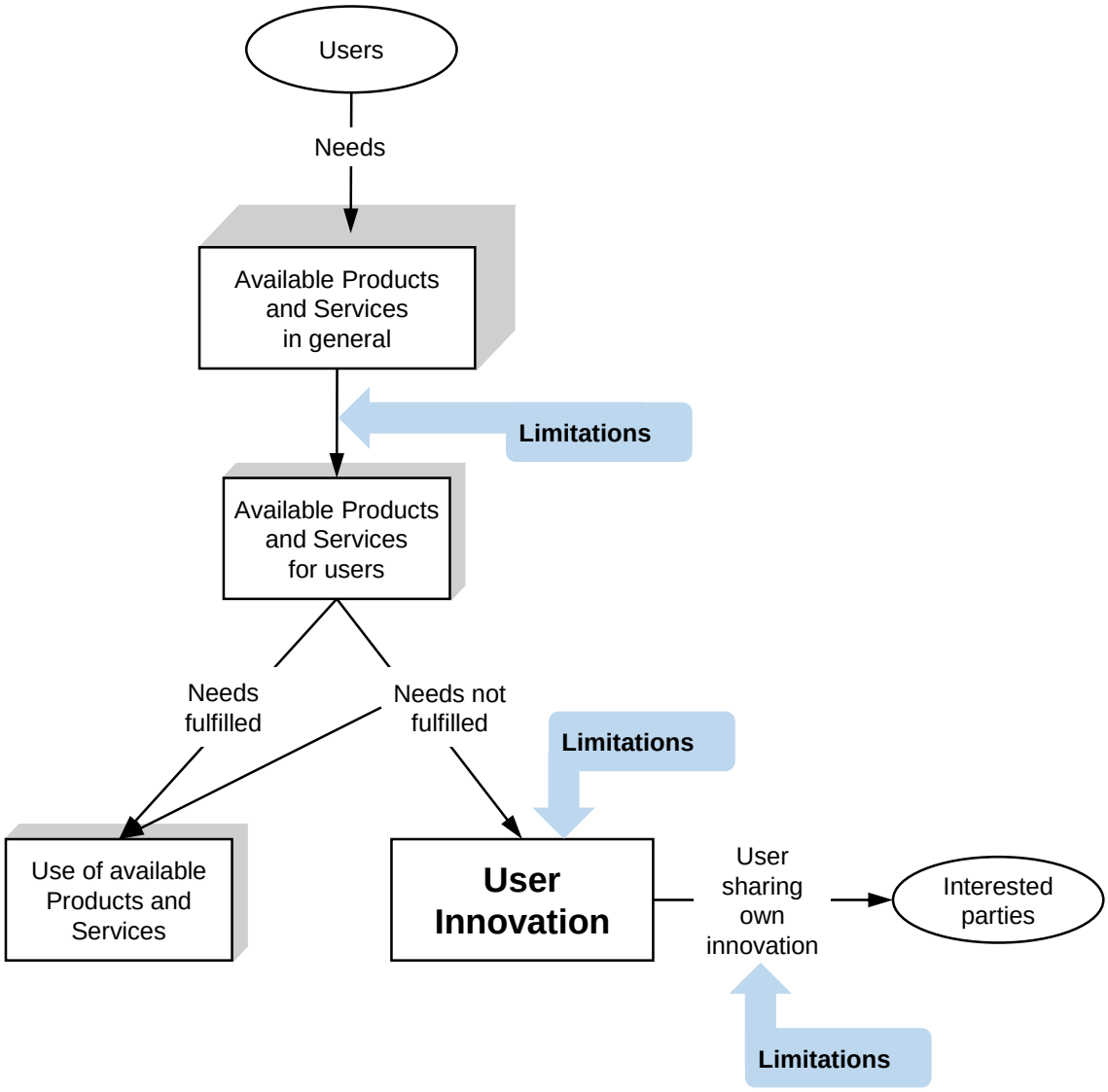
Source: Constructed by the author

In addition to encouraging users to create changes or innovations, limitations shape what innovations are created. Structural and organisational limitations may influence the tools and materials available to users and thus what changes they create. The technology shapes what changes can be created to it, and the fewer the number of its components and the more complex its disassembly, the fewer the opportunities to make changes. Personal limitations influence the changes made, as patients may create changes in order to overcome these limitations.

Limitations also influence whether and how users share their changes or innovations – either with other users or with interested parties such as manufacturers. I have shown that the more structural and organisational limitations exist in the form of lack of structures, the more difficult and costly it will be for users to share their innovations and that these structures are likelier to exist for medical professionals than for patients. In consequence, the costs to patients of sharing their changes can be relatively high; in the absence of supporting structures they need to seek personal contacts with other individual patients in order to share their changes. At the same time, personal limitations, especially for patients, mean that they often have little disposable income and have to rely on public transport for their mobility. This could be expected to hinder their sharing of changes. However, as analysed earlier, they incur these costs to share their changes. Why they choose to do this is discussed in Section 7.3.2.

I have now analysed each instance of the influences of limitations on the model of user innovation. Figure 7-2 summarises this by showing the influence of limitations on the entire process of user innovation.

Figure 7-2 Influence of limitations on the model of user innovation



Source: Constructed by the author

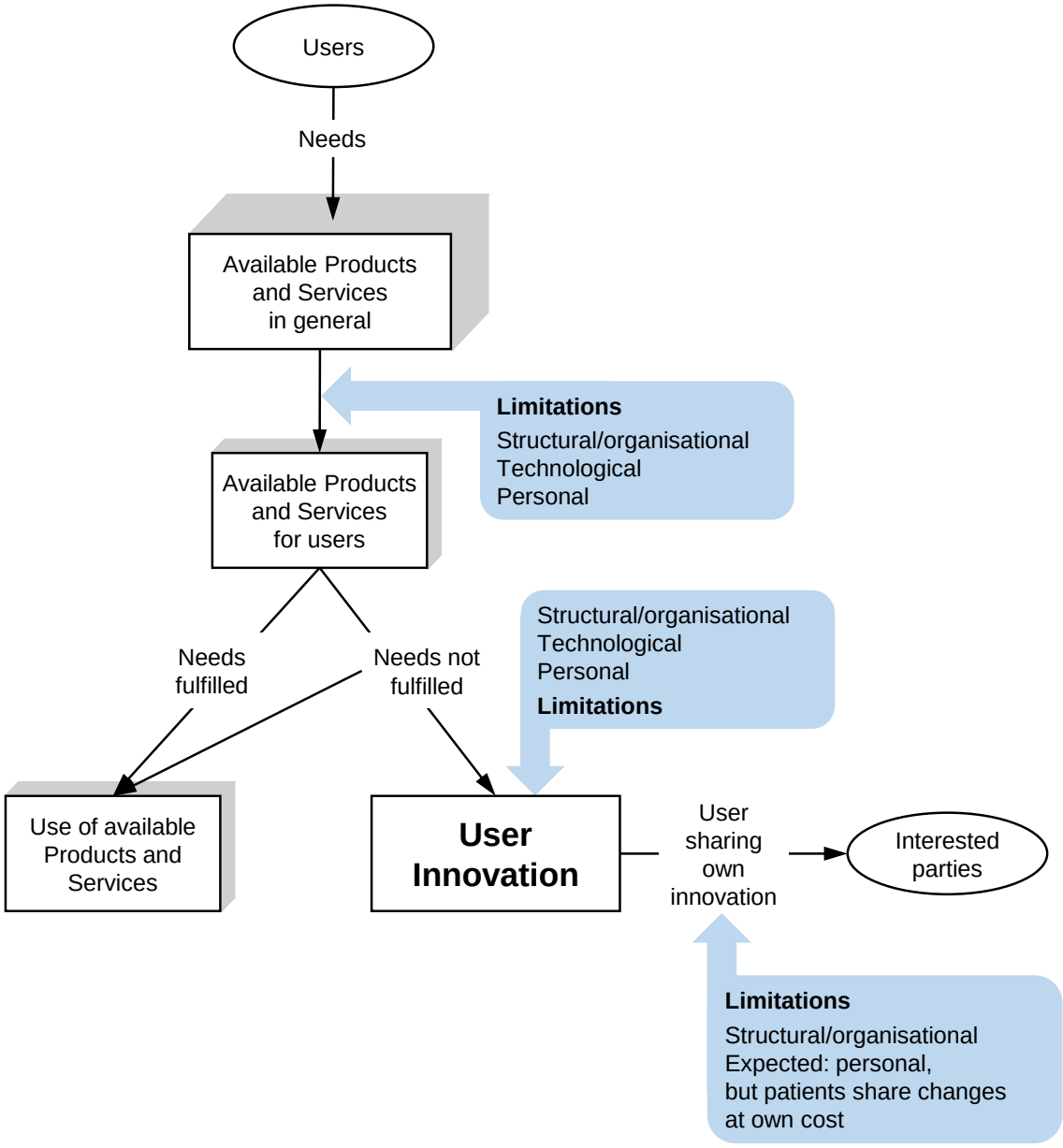
Limitations have been classified into three categories. As discussed above, all three types of limitations shape the creation and sharing of changes by users, but do so at different stages in the process.

Structural and organisational limitations have an influence at the three points in the process where limitations play a role. They limit the available pool of products and services, influence the specific changes being created and influence how users share them. The sharing by users depends on the

available structures in form of connections between users and other interested parties. Technological limitations also reduce the pool of available solutions and influence the specifics of the changes users can create. Personal limitations limit access to the available products and services and influence the changes users make. Personal limitations can be expected to influence the sharing of changes; if there are no structures in place to enable patients to get in touch with one another, they need to invest time and money in order to meet others and share their changes. The data show that many patients did share their changes despite personal limitations, as will be elaborated on in Section 7.3.2.

Figure 7-3 shows how the influence of limitations on the framework can be further qualified with details of the categories of limitations that influence the process.

Figure 7-3 Influence of the three categories of limitations on the model of user innovation



Source: Constructed by the author

This section has demonstrated the influence of limitations on the model of user innovation in general. I next discuss the sharing of changes by users in detail.

7.3.2 Sharing of changes by users under limitations

In addition to the creation of changes, I also analysed the sharing of changes by users. It was found that users do share their changes, sometimes at significant cost to themselves. Von Hippel in his work on user innovation, as discussed in Chapter 2 Section 2.2.1, concludes that users share their innovations and changes, often with no monetary compensation (von Hippel, 2005). The reason for this 'free-revealing' seems to be that it is the most rational way for the user to benefit from his or her innovation or change (ibid.). This applies especially when users are able to share them at relatively low cost,[22] such as via electronic communication, and if the innovations are taken up by manufacturers (ibid.). The benefits users receive from sharing their innovations need not be monetary, they can take other forms such as increased reputation among peers (ibid.).

In the case of lower limb prostheses in Malawi, technicians share changes based on professional collegiality, within their professionals networks and, thus, at relatively little cost. Technicians share their changes within and beyond their orthopaedic centre, because they have the opportunity to do so, either through personal contacts with their work colleagues, or through professional organisations. They share changes with the other technicians for reasons of professional collegiality and their professional reputation with their peers. Reputation is also a reason for sharing changes with other professionals involved in rehabilitation services, such as orthopaedic clinical officers or orthopaedic surgeons. This professional collegiality and networks of medical training are channels through which medical professionals generally spread medical technologies, as discussed in Chapter 2 Section 2.1 (Blume, 2010: 101, 103).

In the context of the present research, the costs for patients to share their changes are relatively high as there are few structures in place to support connections between users and they have to make efforts to establish personal

[22] However, some users may choose to invest money in diffusing their changes even though they could diffuse them without this investment.

contacts to share changes. This involves investment of time and sometimes money. The changes involved are often small and in most cases their sharing is based on personal satisfaction at having helped someone else. While it could be argued that reputation is another reason for this effort, the random nature of the connections among patients means that the sharer cannot assume his or her reputation to spread much beyond the individual helped. Work on user innovation does not adequately account for the phenomenon of patients bearing considerable costs to share their changes without the expectation of comparable reciprocal benefits.

The patients who shared changes have diverse backgrounds and occupations, but care about other patients and want to help them. Their common denominator is that all of them are missing a limb. How does this similarity translate into a bonding characteristic? Again, what is important is the influence of limitations. Because these patients are missing a limb, they experience similar limitations. A major personal limitation is the discrimination they face in society. This can take the form of being denied access to education, or considered “worthless” or a burden. This marginalisation based on their disability becomes a common bond among these patients.

Marginalisation becoming a common bond among members of a group has been studied in relation to disability and other contexts related to medical and other aspects. Among people with disabilities in the United States, 45% see themselves as belonging to a minority group, and 75% feel a common identity with other disabled people (Peters, 2000: 583). In addition to feeling they are a minority, people with disabilities experience oppression based on their minority belonging which motivates them to show solidarity with similar other disabled people (ibid. p. 589). Although none of the patients in the present study used the word 'solidarity', many described actions and reasons for those actions that revealed an attitude of solidarity with fellow patients with missing limbs. This phenomenon of solidarity among disabled people is described by Whyte and Muyinda (2007: 290–300), who found that disabled people in Uganda referred to each other as 'fellow disabled' or 'friend', and provided mutual help.

The term 'solidarity' has been used also to describe the bond felt by people marginalised by society because of other characteristics than disability, both medical and non-medical. Patients suffering from HIV are described as showing solidarity with one another (Nguyen et al., 2007). This solidarity can lead to patients volunteering for participation in drug trials out of a sense of duty to others with HIV/AIDS who may benefit from the drugs being tested (Nguyen, 2010: 92). In addition to solidarity for medical reasons, solidarity can be based on other characteristics, such as race. Racial solidarity among African-Americans has led to actions such as higher political participation (Chong and Rogers, 2005). Thus, among people who share characteristics that cause them to be in some way disadvantaged in society, a spirit of solidarity is often engendered.

In summary, medical professionals as well as patients share changes. Medical professionals do so based on professional collegiality and usually at relatively little cost. Professional collegiality and networks of medical training provide channels through which medical technologies can spread, as mentioned in Chapter 2 Section 2.1 (Blume, 2010: 101, 103). Patients share changes based on a sense of solidarity with one another. Thus, solidarity helps to explain the reasons why users share their changes despite their personal, structural and organisational limitations. Solidarity in turn is shaped by the personal limitations of users. This influence of solidarity on the sharing of changes by users, as discussed in this chapter, is one of the contributions of this work.

Changes shared between users can be selected and promulgated and, thus, contribute to the further development of a technology, as shown by the enabling innovation framework. In the next section, I analyse how this selection and promulgation occurs to changes by users to lower limb prostheses in Malawi and the conclusions that can be drawn in terms of further development of medical technologies in developing country settings more generally.

7.3.3 Accumulation of changes by users through selection and promulgation

In addition to individual users sharing changes and, thus, possibly inspiring new learning selection processes, the enabling innovation framework explains the accumulation of changes made to a technology through selection and promulgation mechanisms. These mechanisms can derive from different entities, as described in Chapter 2 Section 2.3.1. One of these is the product champion, an individual who is very familiar with the technology and is involved in its development (Douthwaite, 1999: 286). He or she detects changes made to the technology and then selects those changes that improve the technology, incorporates them into the technology and passes them on. The market also plays an important part. Users can choose which technology to buy by selecting among the variations of a technology the one they consider beneficial and hence spread it (Douthwaite, 1999: 330).

For some of the medical technologies used in certain developing country settings, there may be neither a product champion nor market mechanisms like the ones described above, due to various structural and organisational limitations. Medical professionals and patients may share their changes and adopt the changes shared, but unless this is done systematically the resulting selection and promulgation is likely to be weak.

It can be concluded that, despite the lack of a 'product champion' and certain market mechanisms, changes can still be shared in developing countries. The selection and promulgation that occurred in the cases investigated in this thesis were mostly due to other factors, such as professional collegiality and solidarity among patients. Therefore, selection and promulgation were on a smaller scale and rarely happened between orthopaedic centres due to the limitations in place, which are mostly structural and organisational.

The influence of limitations on connections between learning selection processes, and on the selection and promulgation mechanisms might help to explain the contradiction of observing low levels of innovation despite users

being very active in creating changes to the technology. The limitations, especially structural and organisational, can lead to the absence of structures that would encourage the accumulation of changes and, therefore, lead to more substantial innovations. The framework shows that a lack of effective selection and promulgation mechanisms means that users' innovative activities have less of an impact they otherwise could have. If the selection and promulgation mechanisms are missing, the connections between the learning selection processes may not be present. Therefore, different users may be expending effort on creating the same changes rather than building on others' changes, which would be a more effective use of their resources.

In addition, the accumulation of changes would ensure that the fitness of the technology which is changed increases over time. If the connections between the learning selection processes are interrupted, then changes are more likely to remain at the same level of fitness with no upward progression, which would indicate a higher degree of fitness in the framework. The lack of users' changes being cumulated into larger innovations might be one of the reasons these activities by users, in some cases, are overlooked. This accumulation is necessary also in developed countries for a number of incremental changes to lead to a major innovation (Kline and Rosenberg, 1986). To conclude that there is a complete lack of innovative activity would be wrong, as this thesis shows. The fact that there are not any major innovations could be due to the lack of structures rather than lack of innovative activity at the individual level.

In summary, this work shows that while innovative activity by users may well occur in developing country settings, the accumulation of small innovative efforts into larger changes may be missing. This necessity of cumulating changes is not limited to developing countries; the cumulative effect of small changes is what drives many, if not most, innovations in developed countries. The data show that it would be incorrect to claim there is no innovation in developing countries; it seems that there is quite a lot of innovative activity, but the lack of structures means it does not cumulate in major innovations.

7.4 Alternative explanations

I have argued that structural and organisational, technological and personal limitations influence the changes created and shared by users to lower limb prostheses in two orthopaedic centres in Malawi. Here, I consider some alternative explanations. As discussed in Chapter 3 Section 3.3, the medical technology and developing country setting for this research were chosen purposefully to allow theoretical generalisations and take account of alternative explanations.

First, it could be argued that the national context is more relevant to the creation of changes than differences in limitations between the orthopaedic centres analysed. While the national context certainly has a large influence, it was shown that, in comparing the changes made at both centres and the differences in their limitations, that a higher level of limitations can bring users, in this case technicians, to create changes. The technicians at the centre in Ekwendeni, which is subject to a higher level of structural and organisational as well as technological limitations, created changes that the technicians in the centre at QECH would not have had to create in order to solve the same issues.

It can be argued also that the differences between users who created changes and those who did not can be explained by gender, age and type of prosthesis (above knee, through knee or below knee) rather than the limitations they faced. I interviewed all the orthopaedic technicians involved in making the prostheses at the two orthopaedic centres, and all of them had created changes. They differed in age and technology used, and had been involved in working with all three types of prostheses. Thus, creation of changes cannot be explained by differences in these characteristics of the users. All the technicians were male. However, among male and female technicians with similar education and work settings, it is unlikely that only male technicians would create changes. The patients interviewed were chosen purposefully to represent a wide diversity of these characteristics, as elaborated in Chapter 3 Section 3.4.3.5. Thus, it could be shown that patients of both genders, all ages, different occupations and all three types of prostheses create changes.

7.5 Summary

In this chapter, on the basis of insights from the frugal innovation and grassroots innovation concepts, limitations were identified as factors which could influence user innovation in developing country settings. Three categories of limitations were distinguished. Details of these limitations were described in general as well as specifically for the two orthopaedic centres. By comparing changes created in the two centres I could show that limitations do influence changes by users, more specifically that users may create changes because of these limitations. Limitations also influenced whether and how users shared their changes. While structural and organisational limitations hindered this sharing, personal limitations did not.

With these insights I could distinguish the influence of limitations on the model of user innovation introduced in Chapter 2 Section 2.2.1, and add them to the model. I found that limitations reduce the pool of products and services available to users, leaving some needs unfulfilled. If as a consequence users create changes, the kind of changes they create and how they share them is also influenced by limitations. The sharing of changes was investigated in detail, especially by patients since, despite their personal limitations, they were ready to incur costs and devote time to meet with other patients and share their changes. This seems to be based on a sense of solidarity, which is in part explained by the marginalisation users face and thus their personal limitations.

That users share their changes is the first step towards their selection and promulgation and, thus, further development of the technology as proposed by the enabling innovation framework. While professional collegiality and solidarity lead to some sharing and, in the former case, can also lead to some selection and promulgation, the influence of limitations makes the resulting effect rather weak. The changes that are created are seldom cumulated into larger changes and innovations. The lack of selection and promulgation may be one of the reasons why few innovations by users, and innovations in general, originate in developing countries. The reason for this is not so much a lack of innovative activities by users, as shown in this work, but a lack of structures for their

accumulation. The chapter closed with considering alternative explanations. Chapter 8 highlights the main contributions of this research, and discusses some policy implications, some limitations and avenues for future research.

8 Conclusions

The findings presented in Chapter 7 provide a number of insights into user innovation of medical technologies in developing country settings. These are discussed in terms of the contributions of this doctoral research. They also provide several recommendations for policy which are described below. At the same time, this study has certain limitations, which are also discussed in this chapter. Directions for further research that would build on and complement the results are presented. The chapter closes with a summary.

8.1 Thesis contributions

This thesis contributes to our understanding of user innovation to medical technologies in developing country settings by identifying the role played by the influence of limitations.

The investigation of changes to lower limb prostheses created by users in Malawi confirms that limitations, as proposed by the concepts of frugal innovation and grassroots innovation, influence user innovation in a developing country setting. The limitations to which users are subject can lead to their creating changes rather than hindering them from this activity. An inclusive definition of innovation is best suited to identify these creations. The data analysis showed the influence of limitations by comparing changes among two groups of users, medical professionals and patients, who are subject to different limitations, in two orthopaedic centres which also have some differences in limitations. Three categories of limitations were identified: structural and organisational, technological, and personal limitations. While these limitations may differ for specific cases, the existence of at least some of these limitations for medical technologies is common in these settings, as the literature on medical technologies in developing country settings shows.

In consequence, there are three distinct points in the model of user innovation when limitations have an influence. First, they reduce the pool of products and services available to users, which limits users' access to existing solutions to their problems. Second, they influence the specific nature of the changes users create. Third, they influence users' sharing of changes. The data show that both medical professionals and patients share the changes they make to technologies. In the case of medical professionals, this sharing is facilitated by membership of professional networks and the structures in place that enable connections with other users of the same medical technology or other interested parties. This allows them to share their changes at relatively low cost. In the case of patients, structures to facilitate sharing are less likely to be in place in which case, changes are shared via personal contact with other patients instead. This entails higher costs of sharing than in the case of medical professionals because there are no formal structures or established connections to rely on. The personal limitations of patients, such as little disposable income and reduced mobility due to their condition, can be expected to hinder them from establishing personal contacts. However, this research also showed a contrasting effect of personal limitations, which leads patients to share their changes. This is based on solidarity with others with similar personal limitations. This sense of solidarity makes patients keen to share their changes and experience with others, and to invest financially and in terms of time to meet with other patients.

An important finding is that solidarity can motivate users to share the changes they create to medical technologies despite the significant costs this may entail. This finding might be valid for other contexts affected by similar personal limitations. One of the factors that engendered solidarity among the disabled patients in this research is that they are often marginalised by society. A sense of solidarity might exist among other groups that face similar marginalisation. If the group involved or a large enough proportion of it, uses the same or similar technologies, they will likely take the initiative to share their changes.

Thus, the limitations affecting medical technologies in developing countries can lead users to create changes to them. Since, the literature on medical technologies in developing countries shows that some of these limitations apply to other medical technologies in developing countries, this phenomenon is not limited to lower limb prostheses in Malawi. This raises an apparent contradiction: If innovative activity by users occurs, why do we not see more user innovation to medical technologies originating in such settings?

This thesis showed that in order to answer this question, the accumulation of changes created by users needs to be investigated. In order to become innovations, the changes made by individual users must be cumulative. In developed countries, many major innovations are based on the accumulation of small changes. As proposed by the enabling innovation framework, in order to accumulate changes, it is necessary for users to share their changes and for these changes to be selected and promulgated. As described in this thesis, there is some sharing of changes by users. However, in situations subject to various limitations the extent of this sharing may be constrained and confined to users in close physical proximity. The limitations thus reduce the level of selection and promulgation and in addition may contribute to the absence of structures to foster them. Therefore, the fact that many of the changes remain small in nature because they are not cumulated, may be due to these weaknesses of the selection and promulgation mechanisms in place.

Were these mechanisms and the structures that support the sharing and selection and promulgation of changes better developed and more systematic, it could be argued that the changes would accumulate and result in more substantial changes and innovations. Therefore, the lack of appropriate structures could explain the apparent contradiction between the level of innovative activity by users and the absence of major innovations. It would thus be incorrect to conclude that because no major innovations arise from such settings there is no innovative activity.

To extend this argument, the absence of facilitating structures for selection and promulgation of changes by users could then be one of the barriers to poor

and little developed countries, such as Malawi, benefiting from user innovation. This argument has wide implications for Malawi and similar developing countries: not only may their ability to benefit from user innovation be hindered by the absence of necessary structures but also important opportunities for building capabilities may not be fully exploited. These capabilities are crucial for development; with the result that a lack of the structures needed to build these capabilities based on user innovation can be one aspect which hinders the general development of the whole country. In addition to capabilities, innovations themselves can be crucial for development and the solutions to particular development problems.

User innovations are especially suited to solving such problems where manufacturers are geographically distant and in relation to technologies aimed initially at developed markets. Innovations that help to solve the problems experienced in developing countries and are relevant to the needs of poor people, can be described as inclusive innovations. If these economically poor users create changes, inclusive innovation might result from the accumulation of these changes. All of the aforementioned aspects have implications for policy, as discussed in Section 8.2.

8.2 Policy implications

There are several implications for policy from this research specific to the situation of lower limb prostheses in Malawi, as well as for other developing countries more generally.

I first discuss the implications for lower limb prostheses in Malawi, both for the Malawian government and the orthopaedic centres directly. A recurring theme in the interviews and observations conducted in this research was the low profile of orthopaedic services in Malawi, despite the considerably positive effects of these services on the lives of patients. This low profile applies to the funding for these services, knowledge about the services available, and the potential for a professional career in supplying these services. In order to

improve the situation of orthopaedic services in Malawi, all these aspects need be addressed.

As described in Chapter 4 on the background to this study, donors play an important role in the provision of healthcare in Malawi, and sponsor a significant part of the Malawian Ministry of Health budget. At the time of writing, funding for HIV/AIDS, tuberculosis and malaria is favoured over funding for orthopaedic services. While the former problems are indisputably important, orthopaedic services can have major positive impacts on people's lives.

To achieve an improved level of orthopaedic services, it will be necessary to mobilise adequate donor support. It is easier to mobilise support for HIV/AIDS, tuberculosis and malaria since the number of sufferers is known, and the effect of the money that goes into fighting them can be accounted for in statistics, such as lives saved. Numbers on disabilities are less readily available, and the effects of orthopaedic services less dramatic than saving patients from immediate death. However, orthopaedic services can bring major improvements to the quality of life of people with disabilities. In order to demonstrate these effects and mobilise donor support, the personal histories of patients could be utilised to showcase the effects of orthopaedic services. This would reflect the long-term effect of these services, which may not be life saving, but for example may allow disabled children to get an education and secure their later livelihood.

The support that orthopaedic services offer can be key to breaking the cycle of disability and poverty – of one condition exacerbating the other. It is therefore crucial for knowledge about these services to spread further. In particular, clinics should be conducted in rural areas, which provide information and support to people in need who are unaware of their options. These clinics require funding and, if in turn more patients seek out orthopaedic services, these services must be able to provide for greater patient numbers.

This will require adequate staffing levels, which, in turn, means that provision of orthopaedic services as a profession and a career needs to be

more widely advertised. Progress has been made through the establishment in 1985 of a national programme to train orthopaedic clinical officers, but the closest training facilities for orthopaedic technicians are currently in Tanzania. The lack of domestic training facilities adds to the cost and limits the number of people who can qualify as orthopaedic technicians and provide orthopaedic services. At the time of writing, plans were underway to establish a national training programme for orthopaedic technicians in Malawi; these plans should be supported.

In addition, this research has shown that patients are willing to – and do – help each other in many ways. This help includes advice on using a prosthesis and how to make changes to it, but also includes encouragement to other patients. The willingness of prosthesis users to invest time in helping other patients is a valuable resource that should be exploited and channelled systematically to reach more patients and not just those accessed through chance meetings. Patients could act as trainers for new patients. If these efforts were organised, they could help 'fellow patients' as they describe them, and, multiply the positive effects that patients described the help and encouragement of other disabled patients having on them. Similarly, technicians see many of the changes that patients create, but there is no system in place to collect, discuss and exploit these changes to improve prostheses. Also, technicians' changes are not collected in a systematic matter. Accumulating these changes formally, and discussing them could help to improve prostheses. It would allow the experience of the technicians to be retained and passed on to other technicians at the same or different centres. This could potentially lead to the creation of more major innovations and further capabilities, as discussed earlier.

Similar structures could be established for other medical technologies in different developing country settings. The existence of structures to help the sharing, selection and promulgation of changes by users, would improve medical technologies in these settings, and lead to improved capabilities. Better capabilities would allow improvements and adaptations to be made to imported technologies and, eventually, could lead to local manufacturing of medical

technologies, resulting in a positive impact on the country's general development.

Finally, while much has been achieved to reduce the stigma of disability, discrimination still exists. The combined effects of improved provision of services and reduced discrimination towards people with disabilities might halt the cycle of disability and poverty and improve the quality of disabled people's lives.

This research shows that medical professionals are willing and committed to rendering good services, and patients are willing to invest in using, repairing and improving medical technologies and to help fellow disabled. The existence of structures to exploit this potential, including structures for sharing, selecting and promulgating changes, could significantly improve the provision of medical technologies in developing country settings and, possibly, the general development of these countries.

8.3 Limitations of the research

While the utmost care was taken to make this research methodologically and theoretically sound, it nevertheless has some limitations. Interviews as a method of data collection are potentially problematic in that participants may not mention all the changes made, either deliberately or because they forget them. This problem was reduced by triangulating the interview data with the data based on observations of the production processes and the artefacts of the prostheses. However, in a few cases this was not possible.

In relation to the sharing of changes, most instances of sharing could not be verified by another source, with the exception of one example where I interviewed both the patient who shared a change made by a technician and the patient who received this information. While the sharing of specific changes in many cases could not be triangulated with additional data, I was able to

validate some of the connections between users, which could be occasions for sharing changes, based on information given by the experts interviewed.

While there are limitations related to the various medical technologies in developing countries, in some cases it is not immediately obvious that these limitations would influence the creation and sharing of changes by users in comparable ways. Patients can only change the technologies that they actively use. They are also more likely to show solidarity with others with a similar condition. Both medical professionals and patients can only make physical changes to technologies of a certain level of complexity.

While it was appropriate to focus the data collection in this research on two orthopaedic centres, it would have been beneficial to this study to collect additional data on a short visit to the orthopaedic centre at the Kamuzu Central Hospital in Lilongwe. Limitations occurred here as a result of the dynamics between orthopaedic centres. The orthopaedic centre at the Kamuzu Central Hospital in Lilongwe is not managed by the Malawian Ministry of Health, but by the Scottish charity '500 miles', as described in Chapter 4 Section 4.2.3. Although the Malawian Ministry of Health had officially approved my research I was not allowed by 500 miles to include this centre in the research. I was allowed a one-day visit, but was asked explicitly not to use any of the information gained for my research. During the data collection phase in Malawi, it became clear that there were certain tensions among key people responsible for orthopaedic centres in Malawi, which might have explained why I was not allowed to include this centre in my research.

8.4 Avenues for future research

This doctoral research analysed how limitations influence user innovation of medical technologies in developing countries, and classified these limitations into three categories. Medical technologies in developing countries may be subject to specific limitations, such as their high regulation, the dependency of their provision on donors and the personal limitations their users face. It would

be interesting to expand this concept by investigating the influence of limitations on users of other technologies, which are not subject to these specific conditions, to create and share changes.

The present research shows that users of lower limb prostheses, technicians as well as patients, change these prostheses within the limitations to which they are subject. It was demonstrated that they make considerable effort to create and share these changes. By further investigating how the provision of structures can support the sharing of such changes, it could be shown how this can enable the building of capabilities over the long term. These capabilities might then serve to make medical care provision in developing countries more independent of donor assistance, and have a more positive impact on the developing country involved. As discussed in this thesis, user innovation can have such a positive impact on a developing country, and it would be beneficial to investigate this further.

The present research shows that, in a situation where various limitations apply, a sense of solidarity among patients as one reason for them to share their changes. It would be interesting to investigate whether this solidarity extends to other situations with fewer limitations, such as in developed countries, and its influence on the sharing of changes by users there.

8.5 Summary

This thesis has argued that user innovation is key to creating medical innovations suited to developing country settings where local manufacturing is scarce. Therefore, further understanding of how user innovation occurs in such settings is necessary. This work contributes to this understanding by investigating the factors that influence the creation and sharing of changes by users and how their accumulation can in turn create more major innovations. The empirical basis of this investigation was the specific changes created to lower limb prostheses by users at two orthopaedic centres in Malawi. In consequence, three categories of limitations were identified as influencing

factors on user innovation of medical technologies in developing country settings more generally: structural and organisational limitations, technological limitations and personal limitations. These limitations lead users – medical professionals as well as patients – to create changes. They also influence how these changes are shared. Limitations tend to hinder sharing, although the personal limitations imposed on patients lead to a feeling of solidarity with similar others and drive them to share their changes regardless of cost and time. While this shows that there is innovative activity by users occurring, few innovations emerge from developing country settings. This thesis revealed that this apparent contradiction is explained by a lack of accumulation of these changes. The analysis in this thesis, informed by the enabling innovation framework, showed that this lack is due to missing structures to foster selection and promulgation of changes. This thesis thus contributes to the literature on user innovation by showing how limitations lead users to create and share changes to medical technologies in developing country settings, and how despite this innovative activity a lack of accumulation hinders these changes to manifest themselves in more major innovations.

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10 Appendices

10.1 Appendix A – List of interviews conducted

Interviewee	Date	Location	Duration hours:minutes	Interviewee identifier
Patient	08.06.2012	Blantyre	00:53	PIB01
Technician	14.06.2012	Blantyre	No recording[23]	CIB01
Patient	19.06.2012	Blantyre	01:17	PIB02
Patient	19.06.2012	Blantyre	00:44	PIB03
Technician	20.06.2012	Blantyre	01:19	CIB02
Patient	21.06.2012	Blantyre	No recording[23]	PIB04
Technician	21.06.2012[24] 26.06.2012	Blantyre	00:16 01:30	CIB03
Technician	22.06.2012	Blantyre	01:53	CIB04
Other medical personnel from QECH	22.06.2012	Blantyre	00:39	EI01
Patient	25.06.2012	Blantyre	00:48	PIB05
Patient	28.06.2012	Blantyre	00:45	PIB06
Patient	28.06.2012	Blantyre	00:40	PIB07
Expert from an organisation concerned with disability	29.06.2012	Blantyre	00:37	EI02
Technician	03.07.2012[24] 12.07.2012 19.07.2012	Blantyre	00:51 00:31 00:30	CIB05
Technician	05.07.2012	Blantyre	01:24	CIB06
Patient	09.07.2012	Blantyre	01:09	PIB08
Patient	10.07.2012	Blantyre	01:08	PIB09
Other medical personnel from QECH	10.07.2012	Blantyre	01:21	EI03
Patient	12.07.2012	Blantyre	01:20	PIB10
Beit CURE	12.07.2012	Blantyre	00:49	EI04
Technician	16.07.2012	Blantyre	00:54	CIB07

[23] No recordings exists only for those participants which did not consent to being recorded.

[24] A few interviews were spread over two or three days. This was done in those cases where a continuation of the interview would have disrupted the work in the orthopaedic centres significantly, and the remainder of the interview was postponed to a more suitable time.

Interviewee	Date	Location	Duration hours:minutes	Interviewee identifier
Expert from an organisation concerned with disability	16.07.2012	Blantyre	01:31	EI05
Patient	18.07.2012	Blantyre	01:06	PIB11
Other medical personnel from QECH	18.07.2012	Blantyre	00:33	EI06
Technician	18.07.2012	Blantyre	00:17	CIB04[25]
Technician	19.07.2012	Blantyre	01:44	CIB02[25]
Other medical personnel from QECH	23.07.2012	Blantyre	00:53	EI07
Expert from Beit CURE	24.07.2012	Blantyre	00:39	EI08
Patient	26.07.2012	Ekwendeni	00:39	PIE12
Patient	26.07.2012	Ekwendeni	01:06	PIE13
Patient	27.07.2012	Ekwendeni	01:09	PIE14
Patient	27.07.2012	Ekwendeni	00:55	PIE15
Patient	16.08.2012	Ekwendeni	01:26	PIE16
Patient	17.08.2012	Ekwendeni	00:46	PIE17
Patient	28.08.2012	Ekwendeni	02:15	PIE18
Expert from an organisation concerned with disability	05.09.2012	Rumphi	00:58	EI09
Patient	05.09.2012	Rumphi[26]	01:15	PIE19
Patient	05.09.2012	Rumphi[26]	01:19	PIE20
Patient	05.09.2012	Rumphi[26]	01:14	PIE21
Patient	14.09.2012	Ekwendeni	02:06	PIE22
Technician	17.09.2012	Ekwendeni	01:50	CIE08
Technician	18.09.2012 19.09.2012	Ekwendeni	01:22 00:55	CIE09
Expert from the Ekwendeni Mission Hospital	19.09.2012	Ekwendeni	01:11	EI10
Expert from the Ministry of Health	28.09.2012	Lilongwe	01:09	EI11

[25] With two technicians, I conducted two separate interviews because there was additional information I wanted to acquire from them.

[26] These were patients who had their prostheses from the orthopaedic centre in Ekwendeni. Since all lived close to Rumphi, it was easier to interview them all there instead of asking them to come to Ekwendeni.

Interviewee	Date	Location	Duration hours:minutes	Interviewee identifier
Expert from the Ministry of Disabilities	01.10.2012	Lilongwe	01:19	EI12
Expert from an independent orthopaedic centre	18.10.2012	Blantyre	00:36	EI13
Expert from an organisation concerned with disability	19.10.2012	Blantyre	00:56	EI14

10.2 Appendix B – Interview guides

The detailed interview guides can be found below. They are divided into three columns, which serve different purposes. The first one describes the overarching topic of this part of the guide. The second column is concerned with memos, which are specific aspects of a part that should be covered in the interviews. Those points were mentioned only if the interviewee did not mention them himself or herself. The third column contains specific questions, which are an aid for the interviewer. The exact wording of the questions and their order could be adjusted for the specific interview. There are two different interview guides, one for centre personnel, also called orthopaedic technicians, and patients, and a second one for experts. Not all of the questions in the latter guide where asked in each interview, as the experts had different areas of expertise.

Interview guide for centre personnel, also called technicians, and patients

I focussed my interviews on those persons which were in direct contact with the prosthesis and could therefore potentially create changes to it, which were the technicians working at the orthopaedic centres and the patients.

Part	**Memos**	**Specific questions**
Introduction	Thanks Duration, recording Right to withdraw Focus of interview	Thank you for being willing to let me interview you, it is a big help and I appreciate it very much. The interview will last about one hour and I will record it. This is just to help my memory and will be treated strictly confidential. I am grateful for all you want to tell me, but you do not have to answer any questions you do not want to and you can end this interview at any time. The interview is about the prosthesis you are wearing/working with and I am most interested in how it is used and your personal view on it.

Part I – Personal learning selection process		Technicians: Can you tell me how you came to use the technologies for lower limb prostheses employed in this centre?
	Experience	Patients: Can you tell me when you first heard about prostheses? What happened then?
	Making sense	When and how did you first try out the prosthesis?
	Drawing conclusions	How did that trying out go? Did it work? What did you think of it?
	Action	If you thought it could work better, did you try to improve it? How – did you do something yourself or did you ask somebody else?
	Network	What exactly did you then change? How did the change(s) work? Did you share this experience with anyone? If so, with whom, how and what exactly? Did you recommend this change to somebody else? Did somebody else recommend you a change? If so, what and who? Who has seen the modified prosthesis? What was their opinion?
	If necessary, repeat with further learning selection cycles	
Part II – Characteristics of wider adaptation process	Adaptations from others	Apart from the changes you mentioned, were there any other made to the prosthesis that you know of?
	Actors	Do you know who suggested these changes? Who else has contact with prosthesis? Who do you think would be a good person to talk to about these changes?
	Outcome	Do you know which, if any, of these changes were included in the technology in the end?

Part III – Use	Training	Where you trained for the use of prostheses? If so, how?
	Level of use	Do you think prostheses are used a lot or not? Why is that the case? What would need to happen so they are used more? Do you think anybody who wants a prosthesis can get one?
	Alternatives	Are there alternatives available using a prosthesis? What are they?
	Alternatives to centres	Where else except here could you/somebody go to get help with their (physical) disability?
	Reasons for non-use	Are there patients who don't use prosthesis? What do you think are their reasons for doing so?
Part IV – Acceptance	Critique	Do you know about any critique of the prosthesis you are using? From whom? What do you think about this critique?
Conclusion	Brief recap of important points mentioned in interview	
	Additional interviewees	You suggested I also talk to x, y, z about these changes. Do any other persons come to mind?
	Omission	Did I not ask about something that you think is important? Can you think about something else that might be interesting? Would you like to add something?
	Follow-up	May I get back to you if I should have further questions?

This was the general interview guide which questions was asked to all of the interviewees, irrespective of what group they belong to. Below are specific questions for certain groups.

Additional questions for patients	Expectations	What do you want from a prosthesis? What should you be able to do with it?
	Evaluation	Are you using any aid(s) to move around? If so, what aid(s) are you using? What are strengths and weaknesses of that aid(s)?
	Problems	What problems do you have because you are missing a foot/leg / your feet/legs? How grave are they? How does that affect what part of your life?
	Cost, payment	Who pays for your aid(s)? How much does it cost?

Additional questions for centre personnel	Adaptations from others	What changes did patients make to prostheses? What can they change?
	Network	What feedback mechanisms exist to the manufacturers of the technologies you use? What feedback do patients give and where does this feedback go? Do you have contact with orthopaedic technicians from outside of this orthopaedic centre? Are you a member of any professional organisations? If so, do you take part in meetings and what contacts do you have there? Who do you talk to about prosthetics outside of this orthopaedic centre?
	Communication with	What do you ask patients, and what do they tell you?

	patients Training	 What training did you receive?

Personal information:

Name, Gender
Age
Reason for disability
Occupation
Place of residence

For patients:

Disability – which leg, degree (which joints are still existent, e.g. knee)
Condition of the stump

Interview guide for other experts

This interview guide was used for policy makers, physicians, and all others who are not personnel or patients at an orthopaedic centre. With these interviewees I investigated details about the whole system lower limb prostheses are embedded in in Malawi. The questions therefore related to characteristics of the system rather than individual experiences with prostheses, as these were covered by the interview guides for centre personnel and patients.

Part	**Memos**	**Specific questions**
Introduction	Thanks Duration, recording Right to withdraw Focus of interview	Thank you for being willing to let me interview you, it is a big help and I appreciate it very much. The interview will last about one hour and I will record it. This is just to help my memory and will be treated strictly confidential. I am grateful for all you want to tell me, but you do not have to answer any questions you do not want to and you can end this interview at any time. The interview is about the healthcare system and foot prostheses in Malawi.
Part I – Healthcare	 Structure Finance Aid Urban vs. rural	If somebody loses his or her leg, could you talk me through what then happens? How does healthcare system in Malawi look like? Including traditional/alternative medicine, care structure (hospitals, clinics,...) How is healthcare financed? Who decides how money is spent on different healthcare issues, including how much prosthetics get? Does Malawi receive aid? Are they supplied directly with technologies? If not, who is deciding what to get? Who do they receive aid from and how much? How does health/referral system differ from urban to rural areas?

		Is there a system of health workers going to the villages?
	Insurance	Is there health insurance in Malawi? If so, how does it work?
Part II – Technologies for disabilities	Professionals Training	Which professional groups are involved with prosthetics? How are they trained? What are their tasks? (Production, fitting, training, physiotherapy,...)
	Production + location	Who makes and supplies prosthetics and where are they made? (Imported vs. locally made) Could there be made more on the ground than is now? What materials are there locally available?
	Location for fitting	In what facility are prosthetics provided, if at all? Are there alternatives to the official orthopaedic centres?
	Finance	How much do prostheses cost? Who pays for prostheses – for material, for fitting, for repair?
	Information	How do people come to know of the possibility to get prostheses? Are they referred? Who chooses which patients get a prosthesis? According to what criteria?
	Research	Is there research done in Malawi about prostheses? If so, where and what kind?
	Regulation	Is there any regulation as to what training somebody needs before he or she is allowed to supply prostheses? Is this controlled? If so how and how often? How are prostheses allowed for use?
	Alternatives	What are alternatives to prostheses? Prostheses produced with other technologies, crutches, wheelchairs, being carried, …

Part III – Disability in general	Statistics	How many people have missing limbs and why do they have missing ones? (War, accident, disease, …) Implications for work, family life, place in society, hobbies, … of disabilities What are relations among disabled people themselves?
	Advocacy	Is there any advocacy of disabled people? Are there any patient organisations apart from the ones I found? Any specific to Malawi? How much influence do they have? Has anything changed on the situation for the disabled in the last x years?
	Social security, work Laws	What difference does it make for people to have a prosthesis or not? Is there a social system that sustains you if you cannot work because of a missing limb? Are there special occupations for disabled people? Are there any reasons why patients would not want a prosthesis?
	Challenges	What is the biggest challenge for people with disabilities?
Conclusion	Brief recap of important points mentioned in interview	
	Additional interviewees	You suggested I also talk to x, y, z about these changes. Do any other persons come to mind?
	Omission	Did I not ask about something that you think is important? Can you think about something else that might be interesting? Would you like to add something?

	Follow-up	May I get back to you if I should have further questions?

Personal information:

Name, Gender

Age

Occupation

Place of residence