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User Entrepreneurs for Social Innovation: The Case of Patients and Caregivers as Developers of Tangible Medical Devices

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Abstract

Prior research has shown that some patients and caregivers such as relatives are innovating in relation to their unmet medical needs. However, there is little evidence whether and how these ideas are later implemented into market-ready solutions and subsequently commercialized. We analyze cases of patients and their caregivers becoming user entrepreneurs – persons who develop and market medical devices according to their own and/or their relatives' needs. We apply the framework of opportunity recognition and exploitation and conduct 14 case studies with medical device developers who have successfully brought their product to market. Our findings show that these innovation opportunities were mostly recognized during time-consuming and exhausting daily routines when no suitable medical device or other solutions were present. In 12 cases, the inventor founded a company to commercialize a product; in the remaining two cases, the idea was licensed after IP was secured. In all cases, the innovation had significant impacts on the quality of lives of the patients and, in case of caregivers, on both the patients and relatives. Since technical knowledge was not present in most cases, knowledgable friends and relatives were consulted and often integrated into the product development. The most prevalent motivation for further development and diffusion turned out to be the aspiration to validate the product idea and to deliver the benefits to others with the same ailment. This finding on innovation's social component complements current research on lead-users, as the solution of one's own problem was previously regarded as the key motivation. One major constraint to diffusing a medical device are regulations in the healthcare sector. Ten of 14 products in our sample were approved medical devices, with five classified as a higher-risk products and five as lower-risk products. We observe that patients and caregivers who recognize and exploit their ideas in the medical devices market did so despite particularly high market entry barriers in this sector. Few patients and caregivers were capable to bring even higher-risk medical devices to the market. This is unsurprising, because neither patients nor cargivers are experienced or trained to go through these time-consuming, demanding, and sometimes costly procedures. Healthcare companies should establish measures to support innovative patients and to systematically integrate them into their innovation processes.

Keywords: User innovation, social innovation, user entrepreneurship, patient, caregiver, medical device, opportunity recognition, opportunity exploitation

1 Introduction

Rare diseases are a major burden to society and to each individual and their peers who live with such a disease. In 1990, a five-year-old boy suffered from a spontaneous retinal detachment and lost sight in his one eye. His father noticed that the state-of-the-art techniques ophthalmologists had at the time to examine the residual eye were insufficient to properly assess the retina's condition. In his already established firm, this father and his colleagues began to work on a technology to do ultra-widefield retina scans so as to be able to detect spontaneous detachments. After a first patent was granted, the father sought to sell the concept to established manufacturers; all declined cooperation. Aware of his product's benefits, he continued developing it further and, 10 years after the incident, brought to market a machine for ultra-widefield retinal scanning. Some years later, his self-developed machine helped to recognize a retinal detachment in his son's second eye early enough; this time, the doctors were able to save his sight. In 2015, the company was acquired by a Japanese camera and optics company for around US$400 million.[1]

Healthcare professionals have long been recognized as a valuable source of innovation for the development of medical devices. Both companies and scholars have found substantial evidence that involving them can lead to successful new product developments (Lettl et al. 2006). Particularly valuable are healthcare professionals who have already developed medical devices (Lüthje and Herstatt 2004) and procedures (Hinsch et al. 2014) for their own needs, or who discover new, off-label uses for drugs (von Hippel et al. 2016).

While the contributions to innovation of healthcare professionals and medical device manufacturers as providers of medical devices and services have been intensively described, the roles of patients and caregivers in innovation in the healthcare sector has seen little attention in academia and industry. Current research indicates that patients' role in healthcare is transforming from that of a passive consumer of healthcare to a knowledgeable and critical recipient of healthcare products and services (Oliveira et al. 2015; Pols 2014). This development is levered by two major trends: First, the prevalence of digital health services such as the health-related information resources that are available online, patient-centered online communities, and mobile health services that give patients access to information and control over their own data (Amann et al. 2016; Dwivedi et al. 2016). Second, the dramatic increase in chronic diseases that require patients to often think about their disease and to eventually implement behavioral changes to daily activities (Goodman et al. 2013).

[1] Source: https://www.optos.com/en-gb/about (accessed November 22, 2018).

Significant unmet medical needs, better access to medical information, and the more active roles of patients and their caregivers often results in innovation in the healthcare sector that holds great potential for scholars and practitioners. We investigate innovative users who develop medical devices for their own unmet medical needs and who subsequently become user entrepreneurs.

Users have been proven to be a major source of innovation. While manufacturers expect to benefit from selling a product or a service, users expect to benefit from using their innovations (von Hippel 2009). A sound body of literature on user innovation has emerged over the past decades, and it indicates that users are at the source of many important innovations in diverse industries such as healthcare, sports, banking, scientific instruments, and the humanitarian sector (Goeldner et al. 2017; Oliveira and von Hippel 2011; Baldwin et al. 2006; Lüthje et al. 2005; Riggs and von Hippel 1994). Most of the studies have focused on the incorporation of user-developed ideas into incumbents' research and development (R&D) activities (Franke et al. 2006; Lüthje et al. 2005). This focus on the firm's perspective has neglected the endeavors of individuals to commercialize their self-developed inventions themselves (Hienerth et al. 2014).

Drawing on this gap, Shah and Tripsas's (2007) research on user entrepreneurship has extended user innovation theory by appending the commercialization process of user-developed ideas by the innovators themselves. User entrepreneurship has been studied in only a few industries, such as juvenile products (Shah and Tripsas 2007) and sports (Baldwin et al. 2006; Franke and Shah 2003). According to Shah and Tripsas (2007), enjoyment during the development and commercialization process as well as low opportunity costs have been identified as the main drivers of user entrepreneurship. Further, they stated that they would not expect innovative physicians to develop medical devices on their own, but rather assume that such innovations will be developed by established firms or startups, with the healthcare professional barely involved. Several studies have confirmed this finding, showing how product concepts developed by healthcare professionals contribute to corporate innovation in the medical device industry (Chatterji and Fabrizio 2012; Chatterji et al. 2008; Lettl et al. 2006). There is very little evidence that healthcare professionals can become successful entrepreneurs (Smith and Shah 2013). Based on these ambivalent findings, we would not expect to identify patients and caregivers who develop *and* commercialize medical devices for their own needs; yet, first empirical evidence indicates that they innovate for their own or their relatives´ needs, thereby contributing to innovation in the healthcare sector (Goeldner and Herstatt 2016;

Oliveira et al. 2015), but there is no scholarly evidence of the commercialization activities of patients and their caregivers concerning their self-developed innovations.

We address two gaps: First, we seek to extend the user entrepreneurship literature by showing the prevalence of innovative patients and caregivers – developers of medical devices according to their own or their caregivers' needs. Second, we provide data on how these users recognize and subsequently exploit entrepreneurial opportunities in a social innovation associated with their health burden. We conducted 14 case studies on user entrepreneurs who developed and commercialized tangible medical devices. We contribute to the – emerging – patient-driven innovations and social innovations research streams.

We make two primary contributions: First, we shed light on the under-researched phenomenon of patients and caregivers as user entrepreneurs. Having needs knowledge about their unmet medical needs, patients and caregivers have developed medical devices on their own and have acquired solutions knowledge, particularly technical knowledge, legal knowledge, and regulatory knowledge if needed during the stages of the development process. To meet their medical needs, patients and caregivers have even developed high-risk medical devices that require significant efforts to gain approval by regulatory agencies. Thus, we propose that the greater the need for a solution, the greater the effort individuals are willing to take.

Our second contribution relates to the emerging social innovation research stream and its connection to user innovation. The users in our sample did not maximize their profits, but rather sought to market their devices at reasonable prices so as to offer many other patients access to these devices (Battilana et al. 2012), in order to increase quality of life. In this extreme case, patients and caregivers maximize their utility as non-pecuniary benefits of increasing their own and others' quality of life – a common indicator for social innovation scholars (Pol and Ville 2009) – that substitutes somewhat for pecuniary remuneration. This benefit outweighs the barriers of high opportunity costs and the little turbulences in the market for medical devices – as initially proposed by Shah and Tripsas (2007).

The remainder of this article is organized as follows: In Section 2, we discuss the study's theoretical framework and derive our research questions. In Section 3, we sketch the methods we used and the dataset. In Section 4, we present the empirical findings; in Section 5, we discuss these findings; in Section 6, we propose implications for theory and practice and outline avenues for further research.

2 Theoretical Framework and Research Gap

2.1 Opportunity Recognition and Exploitation in Entrepreneurship

Entrepreneurship scholars seek to better understand how and by whom opportunities for future goods and services are discovered, created, and exploited (Shane and Venkataraman 2000; Venkataraman 1997). Entrepreneurial activities can be seen as a two-step process: opportunity recognition followed by opportunity exploitation (McMullen and Shepherd 2006). Eckhardt and Shane (2003, p. 336) defined entrepreneurial opportunities as "situations in which new goods, services, raw materials, markets, and organizing methods can be introduced through the formation of new means, ends, or means-ends relationships." Shane (2000) was one of the first to argue that opportunities are recognized rather than searched for. Prior knowledge is crucial to be able to recognize opportunities, especially less obvious opportunities (Gregoire et al. 2009). For instance, prior employment or a family member suffering from a chronic disease can provide unique insights. Thus, some individuals are in unique positions to recognize entrepreneurial opportunities (Shah and Tripsas 2007). Similarly, Shane and Venkataraman (2000) emphasized the need for good information and the cognitive properties to value such information. Because several opportunities may emerge at a similar point in time, the selection process (including assimilation, organization, categorization, and prioritization of information) must be highly selective (Dutta and Crossan 2005) and is positively influenced by an entrepreneur's social ties (Ellis 2011). George et al. (2016) summarized six critical factors that strongly impact on opportunity recognition: prior knowledge, social capital, cognition, environmental conditions, entrepreneurial alertness, and systematic search.

Opportunity exploitation is determined by the nature of an opportunity as well as an entrepreneur's characteristics, perceptions, and capabilities (Kohlbacher et al. 2015; Shane and Venkataraman 2000). It is hard to balance opportunity recognition and exploitation – the literature suggests having a short exploration time for innovations with low novelty, while more novel ideas should be carefully exploited as soon as knowledge about the innovation is also available to others (Choi et al. 2008). Being able to exploit an opportunity depends not only on users' abilities and motivations – De Jong (2013) found that positive attitudes, subjective norms, and perceived control must be instantaneously present for a successful exploitation to be able to emerge. Choi and Shepherd (2004) found that entrepreneurs are more likely to exploit an opportunity if they have more rather than less knowledge about customer demands. In the case of user entrepreneurs, we assume that such users have high needs knowledge and thus exhibit one of the key requirements for the successful exploitation of their inventions.

2.2 User Innovation and User Entrepreneurship

During the past three decades, user innovation has evolved from a niche in innovation management to a meaningful activity to generate new and commercially relevant products and services that has drawn noticeable attention from both scholars and practitioners (Gambardella et al. 2017; Bogers et al. 2010; von Hippel 2005; von Hippel 1986). In short, users benefit from using a product or a service they invented, while manufacturers expect to benefit from selling it (Baldwin and von Hippel 2011). The strong empirical evidence of user innovation raises the questions which characteristics these individual innovators have: Von Hippel (1986) defined these innovators as *lead-users* if they have two primary characteristics: First, they have the capability to innovate, since they identify needs much earlier than most users in a market segment. Second, they are motivated to innovate, since they profit strongly from the innovation (Lüthje and Herstatt 2004; von Hippel 1986). A recent review of measurement of lead-user characteristics by Hienerth and Lettl (2017) summarized four additional features of lead-users: Lead-users are domain-specific and trend-specific, and measurement of the construct is not dichotomous, i.e. the extent of lead-userness is pivotal for measurement. Further, lead-userness is not a trait – it may emerge or vanish within a user or an organization over time.

Successful innovation generally requires two distinct knowledge sets: need knowledge and solution knowledge (Schweisfurth and Raasch 2018; von Hippel 1994). While solution knowledge is associated with the (technical) realization of an innovation, need knowledge is much more latent, unstructured, and sticky. Owing to their usage experience, user innovators have high need knowledge in relation to their innovation (Hienerth and Lettl 2017), but not necessarily high solution knowledge, since this typically prevails in companies (Schweisfurth 2017).

User entrepreneurs are user innovators who commercialize their innovations once they have developed them for their own use. Shah and Tripsas (2007) found that the development, adaptation, and initial diffusion of an idea is done prior to formal evaluation as a business opportunity. Having a prototype of an innovation, public interactions and community interactions supply an innovator with feedback that ultimately triggers the entrepreneurial process (Shah and Tripsas 2007). Haefliger, Jäger, and Von Krogh (2010) revealed that, in some cases, user entrepreneurs develop products based on assets they had acquired in one industry and have then applied in another industry through user innovation. Although there is some initial evidence of innovative healthcare professionals who develop medical devices (Lettl et al. 2008), Shah and Tripsas (2007) stated that user entrepreneurship occurs more often in turbulent industries with low opportunity costs for innovators and unclear demand.

However, the market for medical devices is fairly stable, with high investments needed for successful market entry (Chatterji 2009).

Studies in various empirical fields have shown that user innovation is widespread across industries, such as banking (Oliveira and von Hippel 2011), sports (Tietze et al. 2015; Lüthje et al. 2005), software (Lakhani and von Hippel 2003; Franke and von Hippel 2003), and healthcare (Hienerth and Lettl 2011; Hinsch et al. 2014). User entrepreneurship has been studied only in few industries, such as animation (Haefliger et al. 2010), juvenile products (Shah and Tripsas 2007), and sports (Baldwin et al. 2006; Franke and Shah 2003).

2.3 User Innovation and User Entrepreneurship by Patients and their Caregivers

In healthcare, the user innovation literature has been mostly focused on healthcare professionals as users (von Hippel et al. 2016; Svensson and Hartmann 2016; Chatterji et al. 2008; Lüthje and Herstatt 2004; Shaw 1985). First evidence has shown that patients and caregivers develop enhancements to improve the management of their diseases. In a study of 500 patients with rare diseases, Oliveira et al. (2015) found that 36% developed a product or service to improve their health outcome. However, most of these innovations were not tangible products, but activities relating to treatments or changes in strategies or behaviors associated with the disease. Bullinger et al. (2012) revealed a similar picture, with most innovations developed by patients and caregivers being software, followed by tangible devices and service concepts.

Innovative patients and their caregivers often have extended knowledge of their disease (Elberse et al. 2011) as well as technical knowledge, mostly through education. Some individuals identify opportunities because they are able to perceive connections between seemingly unrelated patterns (Baron 2006). In healthcare, barriers such as regulations and high capital requirements for clinical testing hamper opportunity exploitation more than in other industries (Chatterji et al. 2008). Patients and their caregivers, particularly those with chronic conditions and who have strong constraints in daily life or face dead-end situations (Habicht et al. 2013), often face challenging tasks in their daily caring routines. This prior knowledge may help patients and caregivers to identify more and other entrepreneurial opportunities than professional medical device developers or healthcare professionals (Gregoire et al. 2009). Owing to constraints such as regulatory approval, fairly high capital requirements, and challenges associated with diffusion, it is often hard to exploit medical device ideas in the healthcare sector (Braun and Herstatt 2008). Thus, studies of patients and caregivers as user innovators found only evidence of peer-to-peer diffusion to other patients or sometimes to healthcare professionals (Oliveira et al. 2015). In this paper,

we further analyze diffusion endeavors of self-developed medical devices by patients and caregivers.

2.4 Social Innovation

Social innovation is a nascent field in innovation research that has emerged laterally to other research streams on innovation: The scientific discourse on social innovation has mainly focused on definitions (Edwards-Schachter and Wallace 2017; van der Have and Rubalcaba 2016; Cajaiba-Santana 2014; Pol and Ville 2009) rather than integrating social innovation to other fields of innovation. Many innovations are labeled *social*, for instance, innovation in the public, humanitarian, educational, or healthcare sectors or in the maker movement (Edwards-Schachter and Wallace 2017). As Mulgan (2006) noted, the underlying rationale is the importance of the social dimension of innovation compared to business innovation, which seeks to maximize profit. Scholars agree that the two fields are not disconnected but overlap, with a shared basis: In their review of social innovation and business innovation, Pol and Ville (2009) discuss four conceptions of social innovation. Their analysis of social innovation and institutional change, social purposes, the public good, and needs not addressed by the market revealed that these four have in common the improvement of the quality or the quantity of life (Pol and Ville 2009). In his review of social innovation, Cajaiba-Santana (2014) identified two viewpoints on social innovation: an individualist perspective, which draws on individuals and their characteristics to develop social innovation, and a structural perspective, which focuses on social structures, organizations, and the barriers these organizations face. The conjunction between both perspectives opens interesting opportunities for research into social innovation.

The social entrepreneurship field (Short et al. 2009) is another avenue for scholars to investigate how social innovations are developed and which barriers and enablers these innovators encounter along the way (Lettice and Parekh 2010). In their review, Peredo and McLean (2006) found that social entrepreneurs seek to create social value, have the capacity to envision an opportunity, employ innovation, accept above-average risk, and have scarce resources to pursue a social venture (Peredo and McLean 2006).

2.5 Research Questions

To date, there has been very little research at the intersection of user innovation and social innovation (Kruse et al. 2019) and on how user-entrepreneurs contribute to social innovation. We investigate cases of patients and caregivers as user-entrepreneurs for social innovation. To evaluate the opportunity recognition and exploitation processes of patients and caregivers, we developed two questions that

address the individual perspective (RQ1) and the structural perspective (RQ2) on social innovation:

RQ1: What are the reasons for user innovators to further develop their medical device ideas, recognize a business opportunity, and become user-entrepreneurs?

RQ2: How do innovative patients and caregivers exploit their business opportunities, despite the constraints of the healthcare system?

By answering these questions, we analyze user entrepreneurship in a highly regulated industry that poses significant barriers to users. Thus, we study *extreme* cases of user entrepreneurship and seek to draw conclusions that are valid for social innovations beyond the healthcare sector (Eisenhardt 1989).

3 Methodology

We will now outline the methodology we used for data acquisition and analysis, as well as describe the procedures we applied to ensure internal validity, external validity, and reliability (Gibbert et al. 2008). Inductive theorizing based on qualitative data is particularly appropriate for new and complex empirical contexts with little previous work (Bansal et al. 2018). This applies to user entrepreneurs in social innovation and particularly for the cases of patients and caregivers as innovators of medical devices. We used case studies as our research strategy to build theory for the observations we made during our research (Yin 2013). We opted for a multiple-case study design to gain a better understanding of user entrepreneurs in social innovation (Chandra and Leenders 2012; Hienerth and Lettl 2011; Lettl et al. 2008). A case study design is well suited to our study's explorative character and to develop reliable and generalizable propositions (Eisenhardt 1989). Multiple cases are commonly regarded as more robust than single-case studies, since cross-case comparisons foster validity and reduce the findings' context-dependency (Goffin et al. 2019; Gehman et al. 2018; Lettl et al. 2006; McDermott and O'Connor 2002). We investigate the motivations and triggers as well as the development and commercialization processes of medical devices developed by patients and caregivers. To ensure our findings' validity, we explored each case with three data sources (Gibbert et al. 2008): semi-structured interviews with the inventor, secondary data such as articles or websites, and patent data. This is in line with other scholars who selected similar approaches (Schweisfurth and Herstatt 2016; Kalogerakis et al. 2010; Howells 2006).

The case sampling focused on diseases where user-entrepreneurs and social innovation were observed (Eisenhardt 1989). There is no sampling frame for patients and caregivers who develop medical devices, and the screening of user innovators and

particularly innovative patients and caregivers is costly owing to their low frequency in the population (de Jong et al. 2018). Thus, we collected a sample that included cases from several countries and various target diseases in order to increase our findings' external validity (Yin 2013). The research into patients and caregivers as innovators has shown that only very few patients and caregivers commercially diffuse their inventions (Oliveira et al. 2015). According to their study on patient innovation in rare diseases, most such innovations are shown to other patients or shared in a social network, but very few innovators further commercialize their innovations. One reason is that only 10% of the 182 innovations was tangible products, while the remaining 90% was descriptions of an activity relating to the treatment or a changes in strategies or behaviors relating to a disease (Oliveira et al. 2015). We know from previous studies that patients and caregivers have developed medical smartphone applications according to their needs (Goeldner and Herstatt 2016; Bullinger et al. 2012). Yet, the commercialization process of a medical app differs greatly from a tangible device, because production, marketing, and regulatory approval are much easier for entirely digital products and services (Goeldner and Herstatt 2016). We focused on tangible medical devices, and excluded all developers of software and medical apps without a corresponding medical device. Thus, we had to use several data sources in order to identify a meaningful set of innovators.

Since we seek to develop theories that are generalizable to other patients, caregivers, and – ultimately – to social innovation, we purposely selected a variety of user innovators. Specifically, we used mixed purposeful sampling, as described by Onwuegbuzie and Leech (2007), including criterion sampling, extreme case sampling, and snowball sampling. Thus, we reached out to a diverse set of interviewees, who varied concerning their roles in the innovation process (patient or caregiver), age, gender, medical device class, and disease. We approached 17 patients and caregivers, of which 14 participated – an 82% return rate. Of those 14 innovators, three were identified in newspapers, three via Internet searches, five via personal recommendation of patients or caregivers we spoke to, and three through the Internet platform patient-innovation.com[2]. The first set of three interviews was held between December 2014 and January 2015, and the remaining 11 in March and April 2016. Since we analyzed several diseases and medical devices of different complexities, our data has high variance. Thus, we added stepwise new cases and reached data saturation after 14 cases (Morse 1995), resulting in an optimal sample size for cross-case analysis in phenomenological qualitative research (Onwuegbuzie and Leech 2007; Eisenhardt 1989). We did three interviews face-to-face, and the remainder via telephone.

[2] Source: www.patient-innovation.com.

Our first data source was interview data from 14 semi-structured interviews with developers of tangible medical devices from Austria, Germany, Israel, Sweden, Switzerland, the UK, and the U.S. who had successfully launched their medical devices in the market. The interview guideline is primarily based on established constructs obtained from previous studies: First, we asked how the opportunity for the innovation was recognized (Franke et al. 2006; McMullen and Shepherd 2006; Lüthje et al. 2005; Shane 2000). Second, we examined the exploitation of the innovation (von Hippel et al. 2016; Habicht et al. 2013; Bogers et al. 2010). Also, we asked a questions set on the disease addressed by each device and every inventor's educational background.

The second data source was archival data obtained from websites, newspapers, product information provided by the interviewees, as well as other online resources such as TED Talks videos. This data initially helped to confirm whether the inventor is a patient or a caregiver, and in many cases gave us a sound understanding of the product functionalities. We used this data to confirm and validate the findings obtained from the interviews, since we consider this data to be more objective.

The third dataset was patent data on the interviewees' patents. We downloaded the patents or patent applications from publicly available online sources and used this data to complement the first two data sources.

The sample included nine patients and five caregivers; four were female developers, while 10 were male.[3] At a ratio of about 30%, the number of female developers is similar to other studies of user innovations (Magnusson et al. 2016; Tietze et al. 2015). The innovator age ranged between 17 and 58, with an average of 41 years. The interviews lasted between 20 and 74 minutes (average: about 42 minutes). All interviews were transcribed and coded using the software MAXQDA 11. For data reduction, we followed an inductive approach with three sequential steps: we started with open coding, categorized the themes in a second step and then linked them in a third step (Gioia et al. 2013; Miles et al. 1994). We sought to ensure our results' rigor: Investigator triangulation was achieved, since multiple researchers did some interviews together, and parts of the analysis were done independently and cross-checked (Gioia et al. 2013; Gibbert et al. 2008). Although we mainly used interview data for further analysis, we scanned archival data, websites, and patent data to triangulate the data, increasing validity (Goffin et al. 2019; Shah and Corley 2006). This

[3] Two couples developed an innovation for their children. However, in both cases, we interviewed the fathers, although both innovations were co-developed by both parents.

was more objective and had less potential for retrospective sensemaking bias (Eisenhardt and Graebner 2007).

4 Results

4.1 Descriptive Results

Our findings indicate that patients and caregivers are a potential source of innovation for medical devices. The innovations reflected the variety of medical devices in the market: nine innovations targeted chronic conditions, while the remaining five diseases were fairly acute but also had significant negative impacts on the patients' quality of life (see Table 1).

Medical devices[4] are classified according to the EU-Directive 93/42/EEC (2007)[5] into four classes, according to the risks of their use on humans – classes I, IIa, IIb, and III. A wheelchair poses a low risk to a user (class I medical device) and is only subject to general controls such as Good Manufacturing Practice (GMP) examination, while a pacemaker or any other device which remains in the body for more than 30 days, bears the highest risk (class III medical device) and requires intense clinical testing so as to assure safety and effectiveness prior to market launch (Kramer et al. 2012). In 10 of 14 cases, regulatory approval was obtained either by CE certification (in Europe) or FDA approval (in the U.S.). Four innovators stated that their product required no regulatory approval. Of the 10 approved medical devices, five were class I, two class IIa, one class IIb, and one class III.[6] Thus, patients and caregivers developed not only low-risk medical devices, but there is evidence that some also develop medical devices that require a long-lasting and capital-intensive regulatory approval.

Examples of medical devices in our sample are: two of the non-classified medical devices were a wearable sensor that notifies caregivers if an elderly person leaves their bed and a wheelchair supplement that allows users to drive their wheelchair in snow. The timer attached to an insulin pen is a class I medical device that helps diabetics to

[4] "A medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means." (EU-Directive 93/42/EEC 2007).

[5] Similar guidelines issued by the Food and Drug Administration (FDA) apply in the U.S.

[6] The distribution of medical devices into several risk classes in Europe reveals a similar picture: in 2012, 56% of all medical devices brought to the European market were class I, 27% class IIa, 12% class IIb, and 5% class III. Source: https://de.statista.com/statistik/daten/studie/325915/umfrage/medizinprodukte-in-europa-verteilung-nach-risikoklassen (accessed on July 3, 2018).

not forget their last insulin intake. The waterproof T-shirt that allows patients to take a shower after surgery is a class I medical device. The inhalation device for children with pulmonary diseases linked to a computer game is a class IIa medical device. The smart insulin pen that tracks insulin intake and exchanges data with a smartphone is a class IIb medical device. The only class III medical device in our sample was the customized surgical mesh implanted around the patient's aorta, where it supports both the aorta and heart valve, preventing the enlargement and rupturing of a dilated aorta.

The innovators' educational backgrounds were very diverse: the interviewees had completed studies in engineering (5), business (2), psychology (1), medical journalism (1), social work (1), education (1), and musicology (1). One interviewee had a high school education; another was about to finish high school in the next year. Three of the engineers were working in healthcare; one in a field not related to the invention, and the other two in a field relating to the invention. Since one of the latter was diagnosed with the disease, he found that his employer's products did not fit his needs, which led him to start his own business.

Table 1: Interviewees' Characteristics

ID / role	Country of origin	Disease	Medical device class
Patient 1	Germany	Back pain	Not classified
Patient 2	Israel	Rehabilitation after stroke	I
Patient 3	Sweden	Diabetes	I
Patient 4	U.S.	Paraplegia	Not classified
Patient 5	Switzerland	Paraplegia	Not classified
Patient 6	UK	Aortic dilatation	III
Patient 7	U.S.	Post-surgical wounds	I
Patient 8	U.S.	Post-surgical wounds	I
Patient 9	U.S.	Diabetes	IIb
Caregiver 1	Germany	Cystic fibrosis	IIa
Caregiver 2	Israel	Neuromuscular disorders	I
Caregiver 3	U.S.	Alzheimer's	Not classified
Caregiver 4	UK	Retinal detachment	IIa
Caregiver 5	Germany	Febrile seizures	IIa

Based on four established constructs (Franke et al. 2006), which we adapted to suit our study[7], we asked the interviewees to estimate their lead-userness concerning their

[7] 1. I have needs that relate to the disease that are not covered by the products currently on offer in the market. 2. I am often irritated by the lack of sophistication in certain pieces of available medical devices regarding the disease. 3. I can help other patients to solve problems associated with their disease. 4. I am handy and enjoy tinkering.

medical devices. On a seven-point Likert scale, the average value was 6.7, indicating a very high lead-userness in the sample patients and caregivers.

In most cases (9 of 14), a company was incorporated right before the first patent application was filed. In 10 cases, the user founded their own company and commercialized the product themselves. In two cases, the founder had already founded a company (not targeting that specific disease) and was able to do the development in this company. In the two remaining cases, the idea was licensed out to a company; however, in both cases it was hard to find a manufacturer, since major medical device manufacturers in the relevant areas refused to accept a patent-pending prototype that was developed by a patient or caregiver. Two other innovators could not find a partner for development and then decided to advance the device until it was ready for sale within the own small business. In most cases, the innovators aimed to develop the medical device on their own.

> *I just liked building things, and this was a challenge for me. It's important for me to do it myself. In general, I'm a bit humble, but I thought I could do it the best way. (Patient 2)*

4.2 Unmet Medical Needs

In all cases, the innovation process started with a strong unmet medical need that was not served by existing medical devices. All the sample inventors searched for solutions on the market that suited their needs, and all were unsatisfied with the existing devices (if there were any).

> *I kept thinking, women have been going through mastectomy surgery in this country for years. Why is there no product to protect me? This really confused me. (Patient 7)*

Since nine out of the 14 patients suffered from a chronic condition, they were even more dissatisfied.

> *I got frustrated that these ninety-three percent of people [who do not use an insulin pump], of which I was one, were being left out in the cold. (Patient 9)*

This dissatisfaction was the starting point of their innovative endeavor.

4.3 Opportunity Recognition

4.3.1 Ideation

We observed several opportunity recognition patterns: Four interviewees stated that there was a special single moment when the idea for the medical device appeared serendipitously (Yaqub 2018) during their daily routine.

My aunt, who was my grandfather's primary caregiver, was very stressed when she took take care of him (…) Once, I sat night watch for my grandfather. When I saw him stepping off the bed. The moment his foot touched the floor, I came up with the idea… (Caregiver 3)

I happened to be on a train, sitting between two seats, and I was surprised at how good this felt. At home, I got some pieces of wood from my brother and tried to redesign such a seat. (…) This moment in the train was really memorable. (Patient 1)

In the remaining 10 cases, the idea was developed slowly and was re-iterated over a longer period in time-consuming and exhausting daily routines. This took between two months and three years.

This is particularly stressful for the parents: You need to persuade your child to inhale twice a day for ten minutes, and you need to sit right beside them to check whether they are really doing it. (Caregiver 1)

Three of the 10 abovementioned innovators stated that they used a structured process to find a solution to their problem.

Public health scholars have emphasized the significant knowledge gains of patients and their caregivers (Pols 2014; Joseph-Williams et al. 2014) during sickness periods. We also found that the sample inventors gained significant medical knowledge while treating their own or their peers' disease.

When you're in a hospital for three years in rehabilitation, you see many, many patients, and you learn a lot about physiotherapy. (Patient 2)

4.3.2 Prototype Development

Next, prototypes were built and the device was used for the first time. The prototyping was done at home, in a private workshop or, in three cases, in the already existing own company. In three cases, universities were consulted and their product development capabilities were used. In three cases, makerspaces were visited, because additional manufacturing was needed for prototyping. The development work was mostly done in spare time, and it took between six months and more than five years until a prototype with all required functions was available.

We did it all in our spare time. For a year, we worked every other weekend and in the evenings. (Patient 3)

Three of the caregivers were able to do the prototyping completely on their own, while the remaining two caregivers and all nine patients needed external help – solutions knowledge – to be able to develop the prototype. Experts as well as friends and family

with the needed complementary knowledge were consulted in order to obtain this knowledge.

I consulted experts during all the development steps. (Patient 5)

The innovator's personal network was important in all cases and was a prerequisite for the successful prototyping.

My neighbor helped me. I paid her a consulting fee and she helped me develop the prototype. (Patient 8)

Others were inventors without a formal engineering education:

This is my gift. Some people have a gift for music or for drawing. I have a gift for inventing things. I have invented things before. I've written patents in other fields. And I'm good with the engineering. I have no formal engineering education, but I'm good at it. (Patient 2)

After a first prototype was available, in 13 of 14 cases, it was used extensively by the inventor or the person they cared about. In one case, the prototype was no longer needed, because work on the prototype started only after the person in question's rehabilitation was completed. Soon, the interviewees recognized the possibilities of their idea. Seeing potential early on, nine of the inventors decided during prototype development that they would try to commercialize their idea later. The remaining five inventors developed a prototype for own use only and realized or decided later that their idea would also be valuable to others.

It makes no sense to me that I'm the only one in the world with a solution to this problem. Thousands of people have the same problem. (Patient 5)

The interviewees had also been asked to produce more prototypes, because friends and other peers affected by the same disease also wanted to use the device.

A friend asked me for a prototype, but he had some requests I first had to incorporate. (Patient 1)

These requests were a key reason for the interviewees to enhance their idea beyond own usage. Since they themselves had a need, it was clear to them all that their solution would also be valuable to others with the same ailment. Requests from others fueled their desire to further develop their innovation and to finally diffuse it as a product in the market.

It was very stressful to us as parents to convince our son to take his medication. (…) And it's the same in all the other affected families. (Caregiver 1)

4.3.3 Intellectual Property

Financial considerations or a business plan were conducted only on a small scale, if at all. The sample patients and caregivers were convinced of their idea from the outset and spent little effort on calculating potential returns on their investments. However, all the innovators emphasized the importance of early intellectual property (IP) protection during the opportunity recognition process. In seven cases, the patent application was submitted within the first year after they had recognized the opportunity and had begun to work on the device.

> *One night I was at my drawing board and I came up with the idea how to lift the wheelchair's casters off the ground. Well, I filed for the patent the next day. (Patient 4)*

In the remaining cases, it took two years (three cases), three years (two cases), or five years (two cases) to apply for a patent. Of the 14 innovators, 12 hired a patent attorney to help them to file the patent, while two filed on their own. Until mid-2018, 12 of 14 patent applications were approved by the authorities, indicating that these inventions were not obvious compared to prior art. The high costs associated with a patent application were a hurdle in the development process, but all the interviewees managed to get funding. About half received initial funds during opportunity recognition from investors or governmental funds, while the other half covered the costs on their own or with the help of family and friends.

4.4 Opportunity Exploitation

Exploiting product ideas in the medical device sector is challenging, since many barriers occur during development. After the decision to further develop beyond own use and the securing of IP, the prototype was often shared with others. However, the initial feedback often disappointed developers.

> *I showed the prototype to investors. I showed it to factories. (…) And no one took it seriously. (…) The only ones who took me seriously were some physical therapists who wanted to use the device. (Caregiver 2)*

Established producers of related medical devices were also not necessarily interested in acquiring the IP generated outside their company boundaries.

> *I went to see some representatives of the largest producer of such devices. I was convinced they would be very interested and would buy the patent. But they just said no. (…) It really surprised me. (Caregiver 1)*

Two of the inventors finally found a partner for further development and licensing, while two others (who wished to partner with a third party) continued developing the medical device on their own.

4.4.1 Product Development

The resources needed to further develop their products came from different sources, depending on the complexity of the manufacturing process and the product's medical device class. The resources spent varied from several thousand euro to more than 10 million euros. While seven of the developers were able to finance the development completely on their own or only with support from family or friends, the remaining ones received external funds from investors or governmental funds. Yet, this was hard to achieve, since particularly high-risk medical devices developed by non-professional developers are not considered to be secure investments.

> *It wasn't possible to raise money from conventional venture capital because they thought there was no market for this product. Over ten years, I was turned down at least once by every venture capital firm in the UK, Europe, and North America. (Caregiver 4)*

This external money was mostly delivered only after the proof-of-concept had been successfully demonstrated. In the opportunity exploitation phase, all interviewees (except the two who licensed the idea to an external manufacturer) decided to quit their job and started working on their medical device full-time. In most cases, staff was hired and more external partners were involved in the development. It was in this phase that the transition from user innovator to user entrepreneur occurred.

Different sources of external knowledge were needed in this stage to complement the innovator's competences: Technical knowledge and regulatory knowledge was needed in 11 of the 14 cases. In nine cases, the innovators presented their prototype to healthcare professionals and further discussed their concept so as to gain additional medical knowledge.

> *That doctor from Harvard Medical School […] sent a really incredible and inspiring email saying, 'This is a huge problem. We need a solution. Please solve this and do something about it.' (Patient 3)*

> *I showed it to physiotherapists I knew, and they told me on the spot that if there was a machine like this, every physiotherapy department would buy one. (Patient 2)*

4.4.2 Regulatory Approval

After the product was finalized, regulatory approval had to be sought. For class I medical devices or non-classified devices, the regulatory burden was acceptable – only a fairly low number of tests and documentation is required. For higher-risk medical devices, the regulatory approval was a considerable barrier to the developers. One decided to license the idea to an established manufacturer because he feared the high costs associated with class IIa approval. Another developer stated that the ongoing discussion with authorities and hospitals was nerve-wracking:

It is great to transform people's lives and I am very happy to know that I saved many people. But I am mentally tired of all the arguing and fighting with the hospitals and the regulatory agencies. (Patient 6)

Since the formal structures for the medical device approval are designed for companies, small startups and independent developers struggle with the resources needed for receiving regulatory approval (Chatterji 2009). Ultimately, all five high-risk products (classes IIa, IIb, and III) in our sample achieved official approval.

A friend is the CEO of an electronic components manufacturer. I told him about my idea and he said that he could deliver ten-thousand units in the next days. Obviously, this was very helpful for further development. (Caregiver 1)

We had very good connections in the U.S. that came from this investor. He said: use this legal firm and use this FDA liaison officer. They will ensure that will present yourself properly. (Caregiver 4)

This regulatory knowledge is key, since regulatory approval, particularly for class IIa or higher products, is a significant burden to non-professional developers of medical devices.

4.4.3 Production and Distribution

Initial manufacturing was ramped up mainly in the investors' home country – only two interviewees stated that they began to manufacture in a country with lower labor costs. Reasons for a production site close by were higher expected quality, better responsiveness to changes, fear of infringements on IP in other countries, and already established manufacturing processes for medical devices.

In five cases, we found that the production was done within the company, while in nine (including the two cases where the idea was licensed to an incumbent manufacturer from the outset), production was outsourced.

I am producing on my own, to be more independent. I need to control what is happening. (Patient 5)

Two of the five self-producers later outsourced their production to a manufacturer.

I no longer produce them in my garage. I found a manufacturer to build them in higher numbers with better efficiency than I could. (Patient 4)

Before launching the medical device in the market, the innovators struggled to determine a price for the device. Owing to their market research, all the innovators knew that their medical device is unique and not yet available on the market. However, most interviewees emphasized their innovation's social component.

Because their main goal was to diffuse their device to other patients, they sought to keep the price reasonable.

> *We argued a lot and finally agreed on this price. I had to tell them clearly that no one would buy the device if is too expensive. (Patient 5)*

> *I thought about the other parents, who would want to get it at a reasonable price. (Caregiver 2)*

Others just decided on the price on their own.

> *The price? I just guessed. (Patient 3)*

Most of the devices were priced according to the value the product delivers or based on existing devices that were somewhat comparable to their new invention.

> *We came up with this price based on what we thought the product's value is. (Caregiver 3)*

The innovations' social character were also supported during later stages of the development process: some innovators were supported by suppliers and other stakeholders, because the motivation for developing the device had a social element. All interviewees except one told their stakeholders about their own ailment.

> *My suppliers are very friendly and accommodating. They even offered me reduced prices. (…) Everybody tried to show some goodwill. (Patient 5)*

Still, many inventors were frustrated during the later stages of the development process, particularly concerning business planning.

> *So, the business side of it has been very challenging and quite frustrating at times. But personally it's very rewarding. (Patient 3)*

Then, sales channels had to be identified. Again, these differed in relation to the medical device's associated risk: Two inventors of high-risk products built an own distribution network owing to their products' high complexity and uniqueness. The three remaining inventors of high-risk products collaborated with an established company for distribution. Further, one of these three inventors offers the product for sale online. Concerning the low-risk products, two are available online only, three via an established medical device distributor and online, and four through an established distributor only.

> *I sell it mainly online. (…) I am really satisfied by literally thousands of responses from customers who say, 'This is the best piece of wheelchair equipment I ever bought.' (Patient 4)*

Online distribution is particularly important for selling a device abroad, since it is challenging for inventors to identify suitable distributors around the globe. Nonetheless, many sample inventors have managed to build a distribution network with an established partner in many countries. Further, two inventors successfully launched a crowdfunding campaign to receive funds for the initial production and to directly distribute to first customers for the initial product batch.

4.5 Market Launch

The timeframe from the start of the ideation process to market launch varied between one and 19 years, and took on average 5.4 years, of which 3.7 accounted for opportunity recognition and 1.7 for opportunity exploitation. Although there is no actual data available in the literature, it is estimated that medical device development within the medical device industry is substantially faster (Fargen et al. 2013). We assume that particularly opportunity recognition is carried out considerably more rapidly in the medical device industry.

The final and most significant barrier for the sample innovators appeared only after market launch: the health insurance reimbursement process. In many of the inventors' countries of origin, healthcare services are mostly delivered to patients for free or at very little cost. Thus, this is only true for products that are reimbursed by health insurances. Since all the sample medical devices came to market without reimbursement, this was an unexpected and therefore a significant barrier.

> *Most Diabetes patients in Europe (…) get everything for free. They are not used to paying. Even if they are willing to pay, there aren't many channels where you can pay for these things. Most pharmacies don't have Diabetes products. None in Sweden do or they are very limited. Because people get it all for free. (…) The mechanism of paying for stuff doesn't exist. (Patient 3)*

This results in significant efforts to convince patients to buy their devices without reimbursement. Nonetheless, all the interviewees stated that they are managing to sell a sufficient number of devices to have a viable and sustainable business. Most interviewees confirmed that the positive feedback is a major reason why they are very satisfied with their new business and want to continue to further develop the device or even to develop new medical devices for the same target group.

Of the 14 interviewees, 13 used their product, significantly improving their own quality of life.

> *It definitely improved my quality of life. I mean, I have used it every day for five years now. So, I have probably used it fifteen thousand times. (Patient 3)*

Well, my life is different. My life is very different […] I use it all the time, I love it. (Patient 8)

Only one interviewee had no need to use the device, since his rehabilitation process had been completed by the time he began to develop it. All the interviewees stated that the final result was worth all the efforts invested during the recognition and exploitation of their opportunity.

5 Discussion

We have sought to advance the understanding of the opportunity recognition and exploitation of user entrepreneurs who developed a medical device for their own need or for a person they cared for. In all observed cases, opportunity recognition and exploitation was stimulated by a trigger (Morris et al. 2000), the unmet medical need, and by market launch (see Figure 1).

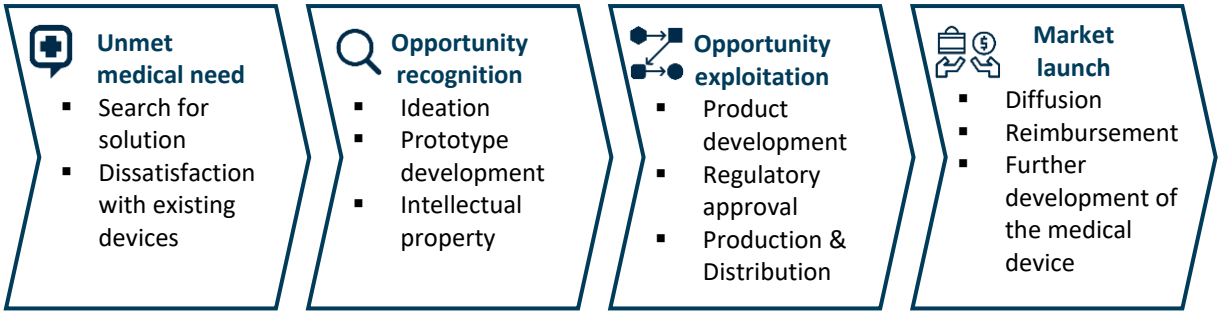

Figure 1: Process Overview of Opportunity Recognition and Exploitation

All the sample innovators did extensive market screening before starting their innovative endeavor. Since no suitable medical device was available, they began to solve their own or their relatives' medical problem on their own. Thus, the sample innovations are unique or even superior to alternatives on the market, if there were any at all. This confirms Oliveira et al. (2015), who showed that patients are able to develop innovations that are novel with respect to prior art.

The sample patients and caregivers had to rely on external knowledge to further develop their prototype. Owing to their own experience with a disease, their medical knowledge is typically highly developed. A medical doctor was involved in only one case as a co-developer with the patient. This confirms that the sample innovators already had high medical knowledge after having long dealt with an unmet medical need (von Hippel 1994). Yet, they lacked solution knowledge (Schweisfurth 2017) – sometimes technical knowledge, in almost all cases legal knowledge and regulatory knowledge – to further develop the device into a marketable product. The case of a gas and pipe engineer who developed a support structure for his aorta illustrates how previously available technical knowledge was mainly transferred from an existing

knowledge domain into the medical device area (Haefliger et al. 2010). The same is true for a pressure sensor needed for an inhalation device. The inventor, a professional parachutist, took a pressure sensor from a reserve parachute and modified it to suit the needs of the inhalation device he designed for his son, who has cystic fibrosis.

The sample patients and caregivers limited their development activities to not only fairly simple medical devices (class I or non-classified), but also contributed to complex, riskier, and invasive medical devices (classes II and III). A recent study of makerspaces in Swedish hospitals revealed a similar picture: healthcare professionals developed 81% of lower-risk medical devices and 19% of higher-risk medical devices (Svensson and Hartmann 2018).

Scholars of user innovation have long emphasized the own benefit a self-developed innovation delivers to the user (von Hippel 2005; Lüthje and Herstatt 2004). After the own problem is solved, users generally have no incentive to further develop their prototype. Research into user entrepreneurship has shed some light on the commercialization process of user innovations: As outlined by Shah and Tripsas (2007), users receive feedback on their innovation by interacting with the public and with communities. In our cases, all the innovators knew that many other patients have the same condition. Interactions with the public and communities had already taken place before the innovation was developed.

Chronic, non-communicable diseases are reaching epidemic proportions and are a big burden to societies worldwide (Daar et al. 2007). In 9 of 14 cases, the sample innovators addressed such a chronic disease, presumably because there is no prospect of a cure, which increased the need for a solution. Confirming extant research (Oliveira et al. 2015), 13 of 14 sample innovators stated that their quality of life was increased after they or the person they cared for had used the self-developed medical device. This is striking, because people with chronic diseases tend to have a lower quality of life than the general population (Wikman et al. 2011; Rothrock et al. 2010). Scholars from both public health (Steptoe et al. 2015) and social innovation (Pol and Ville 2009) have emphasized the importance of improving quality of life as a key outcome of innovation. To summarize this section on the individualist perspective, in our view, an increase in quality of life is the main motivation to further develop the medical device idea, to recognize the business opportunity based on the strong unmet need, and to become user-entrepreneurs in order to solve their own problems and those of others with the same disease.

Regarding users' motivations to exploit their self-developed medical devices, our results contradict Shah and Tripsas (2007), who did not expect medical devices to be brought to the market by innovators owing to the high opportunity costs and the

turbulences in the market for medical devices. Our 14 case studies convey initial evidence that, in some cases, particularly if there is a high (unmet medical) need, there is a higher likelihood that such barriers can also be overcome, even if opportunity costs are high or if the market is relatively stable. We propose that Shah and Tripsas (2007) mainly considered healthcare professionals as users in the healthcare system who often face patients with unmet medical needs. For them, leaving their medical office and starting a venture carries high risk. Although there are some anecdotal examples of healthcare professionals who start a venture with their self-developed medical device (Smith and Shah 2013), most develop their innovations with incumbents (Chatterji et al. 2008; Lettl et al. 2006) and continue their regular work. Yet, patients and caregivers often do the development on their own, since established medical device manufacturers don't accept their concepts for integration into their firms' development activities.

The expected benefits for patients and caregivers are more multifaceted than for companies, which mainly seek to maximize profit. Patients and caregivers seek to help themselves and, if they successfully solve their problem, also others with the same condition (Habicht et al. 2013). Since patients and caregivers often offer their medical device for a below-average price in the market, the non-pecuniary benefits of successfully helping others seem to partly substitute for pecuniary remuneration (Shah and Tripsas 2007; Podolny and Scott Morton 2002). This is a well-known pattern and has been addressed by social innovation scholars (Murray et al. 2010; Mulgan 2006). Nonetheless, from a structural perspective, high barriers such as patent application, regulatory approval, market access, and reimbursement by health insurances remain challenging to manage for non-professional developers of medical devices.

6 Implications, Limitations, and Further Research

6.1 Theoretical Implications

We have made important contributions to the entrepreneurship literature generally and to the topic of user entrepreneurship in the social innovation literature in particular. First, we have shed light on a very under-researched phenomenon: user entrepreneurs for social innovation, particularly cases of patients and caregivers who develop a medical device. The innovative behaviors of patients and caregivers are rooted in their medical needs, which are unmet by existing medical devices. Likewise, von Hippel et al. (2016) identified a similar market failure in the case of medical doctors and off-label drug discoveries. We have emphasized the importance of patients and caregivers who, in most cases besides healthcare professionals, are the de facto users of a medical device. With needs knowledge of an unmet medical need, they have

developed the device on their own and have acquired solutions knowledge, particularly technical knowledge, legal knowledge, and regulatory knowledge if needed during the stages of the development process. To meet their medical needs, patients and caregivers even develop high-risk medical devices that require significant efforts for approval by regulatory agencies. Thus, we propose that the greater the need for a solution, the greater the effort individuals are willing to take. This extends the scope of user innovation research to user entrepreneurs' opportunity recognition and exploitation process.

Our second contribution relates to the emerging research field of social innovation (van der Have and Rubalcaba 2016; Cajaiba-Santana 2014) and the poorly understood connection between user innovation and social innovation (Kruse et al. 2019). Building on an unmet medical need, users such as patients and caregivers go beyond their own problem space and address the needs of many others. Although it is well known that users share their ideas with their peers in communities (Hienerth and Lettl 2011; Henkel 2006; Lakhani and von Hippel 2003), developing and bringing an approved medical device to market is a big burden to individuals. Yet, the sample users did not stop their innovative endeavor after they had completed the prototype for own usage, but continued the development over a significant period, because they were aware of the market demand for their device and the market failures of established medical device manufacturers. Financial considerations did not play a decisive role during opportunity exploitation. We argue that, in this extreme case of user-entrepreneurship, patients and caregivers maximize their utility, since non-pecuniary benefits of increasing their own and others' quality of life partly substitute for pecuniary remuneration (Battilana et al. 2012; Pol and Ville 2009). This benefit outweighs the barriers of high opportunity costs and the turbulences in the market for medical devices, as initially proposed by Shah and Tripsas (2007). Following the argumentation of Pol and Ville (2009) that social innovations are for the public good, and concerning needs not addressed by the market, we can confirm that the sample user entrepreneurs did develop social innovations: The innovations in our sample were priced below industry average in order to increase diffusion of the innovation (de Jong et al. 2018), were developed over an above industry timeframe under high uncertainty and ultimately led to an increase in quality of life of the sample innovators. Although there is a sound body of research into social entrepreneurship (Lettice and Parekh 2010; Short et al. 2009), the links between user entrepreneurs and social entrepreneurs must be further explored. Our study is a first step to combining these two research streams. This opens opportunities for further research for scholars from both fields.

6.2 Managerial Implications

Our study has shown that patients and caregivers develop medical devices according to their own needs. While healthcare professionals often work with incumbents to further develop their concepts (Chatterji et al. 2008), there have been very few interactions between medical device manufacturers and patients during the different stages of the product development process (Shah and Robinson 2007). Although there is evidence that opening a firm's boundaries is valuable in the healthcare sector (Bullinger et al. 2012; Melese et al. 2009), we found that established medical device manufacturers have not yet developed mechanisms to integrate patient-developed concepts into their R&D processes. Manufacturers are generally skeptical towards concepts not developed within the own organization (Katz and Allen 1982), particularly if development was done by a non-professional developer, such as a patient or a caregiver (not-invented-here syndrome). Yet, the integration of patients, caregivers, and healthcare professionals into the R&D process would allow medical device manufacturers to profit from usage-related resources that companies typically do not own (Schweisfurth and Herstatt 2016). This may be particularly valuable for new idea generation, but also for concept generation and testing.

The financial impacts of such user-developed innovation are hard to assess. There is initial evidence from several countries that the overall user spending on innovative user-developed endeavors is close to or even exceeds firms' R&D spending in a country (von Hippel 2017; von Hippel et al. 2011). Svensson and Hartmann (2018) found that innovations developed by healthcare professionals in a hospital-based makerspace had an about 14 times higher economic impact than the costs of establishing and maintaining the makerspace. Although we did not have access to the sample companies' financial statements, the interviewees stated that their innovations generated sufficient returns for the inventor and for the firm's operating costs.

Innovation policy has primarily focused on supporting manufacturers. Supporting users and particularly patients and caregivers to develop medical devices for their own needs would encourage thousands of people to tackle their unmet medical needs by developing innovations that otherwise would not have been developed or that would not have been further developed owing to a lack of solutions knowledge or a lack of resources (Svensson and Hartmann 2018). Makerspaces at hospitals that are open to patients, caregivers, and healthcare professionals would be a meaningful option for further development and exchanges among users, and could also serve as an interface for companies to interact with users during development.

While our findings focus on the healthcare sector, they can be transferred to other sectors in which individuals develop solutions for their own unmet needs, such as the

public sector or the humanitarian sector. Particularly the latter offers a range of opportunities to meaningfully combine user innovations and social innovations (Goeldner et al. 2017).

6.3 Limitations and Further Research

Despite our findings' originality and validity, our study has limitations, which may serve as cues for further research.

First, our interview findings are limited to 14 individuals and need quantitative validation. A large-scale survey among founders in the medical device industry would be very valuable to quantify the number of user innovators, their motivations, and the barriers they face. These could be mapped regarding the opportunity recognition (individual perspective) and opportunity exploitation (structural perspective) stages of social innovation. Second, we only analyzed successful innovators who managed to launch their medical device onto the market. A separate study with inventors who could not diffuse their medical device ideas would give important clues to better understand our study results and to learn more about the significance of the barriers during the opportunity recognition and exploitation process. Despite limitations, our paper has contributed to the user innovation and social innovation literatures and has opened many avenues for further research at this vibrant intersection.

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