Utrecht University

TAILORING REMOTE CARE SYSTEMS TO THE SPECIFIC NEEDS OF USERS

A multiple case study in the Netherlands

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SUMMARY

This qualitative research capitalizes on the frequent mismatch between offered services for the remote management of chronic patients and the requirements of users, including care providers and patients, which often hinders successful implementation and upscaling of these services. In order to acquire inputs about user-specific requirements, it is deemed essential that technology suppliers closely involve users in the innovation process. However, the tailoring process may be hindered by suppliers' own need to make their technologies generic. Further, the use of design standards for remote patient management (RPM) systems or components can increase the interoperability between different technologies, thereby increasing the flexibility to configure RPM systems according to user-specific requirements. However, empirical evidence for the actual contributions of standards to tailoring RPM solutions is limited, and it is unclear whether standards may also lead to rigidities regarding the response to some user-specific requirements. This has led to the following research question: ***How do user involvement, generification strategies, and the use of design standards influence the tailoring of remote patient management systems to user-specific requirements?*** In a multiple-case study, the development and implementation processes of five different RPM systems in the Netherlands were examined. The notion of configurations was adopted to better understand how RPM systems - which include a variety of both technical and human components - may be adapted to user-specific requirements. Also, theoretical insights regarding the three independent variables guided the researcher during conducting and analyzing 22 semi-structured interviews with a variety of respondents per case, which were complemented by secondary documents. As found, all three independent variables may both stimulate and hinder the tailoring process, and for user involvement and generification strategies this depends on how and why they are applied. Firstly, user involvement stimulates the tailoring, as it may be aimed at learning how to serve the variety of users and make improvements. However, user involvement can also negatively influence the tailoring process, as it may provide a way for suppliers to learn about a broader user population, hence to develop relatively standardized solutions that are robust among this user population, and thus being applied as part of a generification strategy. Secondly, generification strategies of suppliers are on the one hand potentially hindering the tailoring, as client-specific RPM applications are generally built up from generic platforms, and suppliers generally respond to articulated user-specific requirements only when respective adaptations are deemed relevant for a larger amount of clients. However, room may be left for tailoring RPM systems to user-specific requirements, provided that flexibility is left within system settings and options are offered to integrate the systems with additional components such as measuring devices or established information systems, if necessary. In fact, standardization may even stimulate the tailoring process, as it may save resources in the development and maintenance of different products, allowing suppliers to focus their efforts on improving the generic platforms according to the needs of users. Thirdly, the use of design standards is found to be an important facilitator in the tailoring of RPM configurations to user-specific requirements in terms of efficiency and configurational choice, though the unwillingness of some parties to connect their systems may still obstruct the realization of integrations. On the other hand, indications are found that the use of design standards may potentially hinder the tailoring of RPM systems to certain users' specific requirements, in terms of not complying with their preferred ways of data exchange. Room is left to further investigate whether and when this occurs, and how this issue is then being addressed by suppliers. Various implications follow from the current study. For instance, a desirable balance between individualization and standardization of RPM solutions may be stimulated through the continued development and adoption of both generic platforms and third party applications that focus on more specific requirements - i.e. niche markets - and which can be integrated with the platforms. Also, tailoring RPM systems to user-specific requirements is not only an issue of designing and redesigning by suppliers, but it also requires adequate feedback on how to use the system and a change in routines and attitudes towards RPM.

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1 INTRODUCTION

Globally, healthcare systems face multiple challenges including rising costs, inefficiencies and poor access. When for instance, the Dutch healthcare expenditures continue to grow with the same pace, they may increase from 13% to 31% of the GDP between 2012 and 2040 (van Ewijk et al., 2013). In order to secure the sustainability of healthcare, a proper balance is needed between the demand for care and the capacity to supply it (Janssen & Moors, 2014). Ageing populations and an increasing amount of people inflicted with chronic diseases demand for less labor-intensive and more cost-effective methods to deliver healthcare (Deloitte, 2014; Tabak et al., 2012). Rapid technological advances for remotely managing a variety of highly prevalent chronic diseases, such as diabetes and respiratory and heart disorders, provide an important way for addressing these challenges. Hence, healthcare systems are undergoing a radical paradigm shift from patient care in the hospital and professional-centric systems to patient care at home and preventive systems in which patients actually become active participants in their care process (Arnrich et al., 2010; Calabretta, 2002).

Remote patient management (RPM) or telehealth systems[1] enable the monitoring of vital signs of patients at a distance, as well as the provision of instructional, educational and motivational feedback to the patients (Tesanovic et al., 2009). A large set of scientific research points to the profits that can be made from targeted feedback on remotely collected data - especially in the care for people with chronic illnesses. For instance, it enables regular provision of data on the status of chronic patients, thereby allowing for early warning of exacerbation events or deterioration, increasing the stability of chronic diseases and reducing the rate of hospital admissions, thereby lowering healthcare costs in the long term (e.g. Paré et al., 2013, 2007; Forducey et al., 2012; Cullen et al., 2011; Coye et al., 2009; Seto, 2008; Finkelstein et al., 2006; Noel et al., 2004). Therefore, the Dutch government has stated aims for 2020 that 75% of the chronically ill and frail elderly should be able to carry out independent measurements, often in combination with the remote data monitoring by the care provider (MVWS, 2014).

Problem description

However, despite the potential benefits of RPM, the wide availability of different applications for RPM, and the large investments made over the last two decades, the adoption of RPM services in healthcare practices is only slowly increasing, and implementation often fails due to insufficient adaption to practical contexts (Tabak et al., 2012; May et al., 2011). May et al. (2011) argue that healthcare professionals have emphasized a frequent 'mismatch' between telehealth services and the characteristics of individual patients, as well as the everyday routines of service users. Besides, they suggest that suppliers do not sufficiently respond to the need for flexibility and choice for different types of patients, as well as the opportunity for care providers *"to select and design services specifically geared to the local context and aims"* (May et al., 2011, p.7). This stresses the issue of RPM systems not being adequately tailored to the local context. As Elwyn et al. (2012, p.900) put it, "*telehealth has not yet achieved a good fit with the life world of patients nor into the professional, organizational procedures of health service delivery systems"*. Limitations on existing RPM systems have been widely discussed in the scientific community, and the need to better tailor such systems to specific contexts-of-use is increasingly recognized (e.g. Boyne & Vrijhoef, 2013; Elwyn et al., 2012). However, the efforts being taken by suppliers in order to address this issue remain rather unexplored, and this research aims to fill this gap.

[1] This research primarily uses the terms "remote patient management (RPM)" and "telehealth" to refer to services and associated systems for remotely management chronic diseases. A variety of other terms such as "health information technology", "telemedicine", 'm(obile)-health", "telecare" or "e-health" are often used to refer to the same or similar healthcare services, though the meaning and usage of these terms has not yet settled into consistent use. Moreover, some of these umbrella terms encompass a wider set of care processes than the monitoring and managing of chronic diseases.

RPM systems - and medical technologies in general - involve a variety of users such as physicians, nurses, data workers, patients and patients' families. These user groups exist in a wide variety of social, cultural and personal settings, and they may have heterogeneous needs and disparate views on a technology (Oudshoorn & Pinch, 2003). In order to tailor RPM systems to the specific requirements of users and achieve successful implementation, the variety of user perspectives are important to be taken into account. However, there is a tension between the desire to develop heterogeneous RPM solutions in order for different users to be met in their specific needs and the necessity to offer more homogeneous solutions and ensure them to be economically viable, for instance.

Importantly though, RPM systems are configurations, which are *"more or less unique assemblies of components, some standardly available, others specially developed, built up to meet the particular requirements of a user"* (Fleck, 1993, p.19). They are socio-technical systems that integrate multiple components in a chain between measuring and acting in response to test results, including measuring devices and information and communication technologies (ICTs)[2], but also data records, organizational arrangements and working practices (Nangalia et al., 2010). The configurational nature of RPM systems implies flexibility in how different components in the RPM chain can be configured, whereby many choices are available and individualized solutions can be offered that meet specific requirements of users (Fleck, 1993). RPM configurations can for instance be shaped depending on the nature of the disease and the intensity of the care and expertise involved (Lehoux, 2008). As discussed in the following, several factors are important to consider when looking at the tailoring of RPM configurations to user-specific requirements, namely the need for user involvement by suppliers, the possibility that suppliers apply a generification strategy and the use of design standards to achieve interoperability between different technologies that can be integrated into a RPM configuration.

Firstly, in configurational innovation, it is deemed essential that technology suppliers closely cooperate with users to acquire inputs about their specific requirements and successfully implement the technology and build up configurations (Fleck, 1993). However, despite its importance, user involvement is not straightforward. May et al. (2011) suggest that the *"lack of negotiation with service users in configuring new systems remains problematic"* (p.9) and that suppliers of RPM technology have a general lack of understanding of the diversity of users' needs. Non-use and suboptimal use could be partly caused by the poor communication between user groups and developers (Widya et al., 2010). In this line, Kiran (2012) suggests that users may find RPM technologies to be ill suited to their own situation because design stages of RPM technology development often emphasize technical requirements rather than users' requirements (Vollenbroek-Hutten & Hermens, 2010). Furthermore, Elwyn et al. (2012, p.901) point out that RPM innovations are *"more likely to become embedded into practice when they attend to social and organizational as well as to technical criteria"*. This suggests that user involvement is not only important during the design of technological components of RPM systems, but also during the implementation process when integrating or configuring RPM systems into specific social and organizational contexts.

Secondly, in spite of the widespread recognition of the benefits of personalization and adaption of RPM systems to practical contexts, suppliers of RPM systems are found to be generally offering one single system to all users and thereby following a one-size-fits-all approach (Boyne & Vrijhoef, 2013; Tesanovic et al., 2009). Accordingly, Peine & Moors (2015) found that designers in the field of personal health systems - which is closely related to RPM - have difficulties in reconciling insights about user-specific requirements since the provision of options for personalization collides with their own generification strategy, i.e. need for offering standardized solutions. Moreover, Peine & Moors (2015) argue that user involvement may also be a way for designers to learn how they can reach a broad spectrum of users with

[2] ICTs decrease the need for frequent physical meetings between caregivers and patients (Oudshoorn, 2012; Varshney, 2007).

rather standardized solutions. This raises the question whether certain user-specific requirements, if they are even assessed through user involvement, are actually being responded to within the design of RPM systems.

Thirdly, standards for developing e-health solutions (including RPM technology) are suggested to increase the interoperability between different technologies, thereby allowing for a better match with previously adopted technical solutions and, importantly, increasing the flexibility to configure RPM systems according to user-specific requirements (Galarraga et al., 2007; Warren et al., 2004). Without interoperability there is no interaction or information exchange between different systems, such as electronic health records and measuring devices (Burghouts, 2012). However, while the use of standards may increase flexibility to tailor RPM configurations to user-specific requirements, it is unclear how much rigidity in the functionality and architecture of RPM systems the use of design standards brings along (e.g. Peine, 2009). Too rigidly designed technology may namely imply lower flexibility to offer personalized RPM solutions and fewer users to find them suitable for their needs (Kiran, 2012).

The three factors mentioned above are thus potentially stimulating or hindering the tailoring of technological RPM solutions to user-specific requirements, but evidence for their practical influence on the tailoring by suppliers in the specific field of RPM technology is limited. Moreover, it is increasingly recognized that RPM systems need to be better tailored to user-specific requirements, but there is limited evidence for the recent efforts taken by suppliers in order to address this issue. Through a qualitative multiple case study, this research aims to fill these gaps. Therefore, the central question that this research aims to answer is:

How do user involvement, generification strategies, and the use of design standards influence the tailoring of remote patient management systems to user-specific requirements?

Scientific relevance

This research aims to provide empirical evidence for the efforts made by the industry to address the poor alignment between RPM solutions and the requirements of different contexts-of-use (e.g. May et al., 2011). Science and Technology Studies (STS) have demonstrated that users are important and active actors in socio-technical change rather than passive consumers. However, the focus has dominantly been on contribution of users to product innovation (von Hippel, 2005), rather than configurational innovation (Peine, 2009). Moreover, various studies have been devoted to identifying the variety of user perspectives on RPM technology (e.g. Oudshoorn, 2012; Percival & Hanson, 2006), but little empirical research has investigated the conflict between the need for personalization of technological solutions and the generification strategies of designers (e.g. Peine & Moors, 2015). Lastly, the importance of using standards to ensure interoperability is widely recognized, but empirical evidence for the actual contributions of standards in creating flexibility to deliver customized solutions is limited, and it remains unexplored whether the use of standards also leads to limitations regarding the response to certain needs (e.g. Peine, 2009; Galarraga et al., 2007). This research provides an empirical contribution to these literature gaps, by exploring whether and how the involvement of users and the use of design standards help suppliers to shape and modify configurational RPM systems according to user-specific requirements, and by providing evidence about whether suppliers aim to respond to the potential heterogeneity in users' needs, or how this is potentially hindered by their aim to offer standardized solutions. Overall, this research provides better understanding of how suppliers of RPM technology cope with the tension between individualization and standardization.

Societal relevance

This research is concerned with improving the alignment between systems for remote care of chronic diseases in the Netherlands and the specific needs of users, in order to stimulate the adoption and successful implementation of these systems. Thus far, studies have focused on detecting and describing

the misalignments between RPM systems and the requirements of users (e.g. May et al., 2011; Boyne & Vrijhoef 2013). Yet, research has not focused on the efforts that have over the years been made by suppliers to address this issue. This research aims to provide handles and inspirations for policy makers and innovative actors – including suppliers and implementers - on how to improve the alignment between offered RPM services and the specific needs of users. More specifically, this research may provide insights on how to improve the role of users and their involvement by suppliers during innovative processes in healthcare ICT in order to better tailor solutions to user-specific requirements, how to stimulate a desirable balance between personalization and generification strategies for RPM solutions, and how to optimally exploit the potential benefits of using standards and resulting interoperability. Increased flexibility for offering tailored RPM solutions is beneficial for (potential) users, but also for technology suppliers and society more broadly. The increased rates of adoption and more optimal use of RPM technology that may hereby be achieved lead to increased patient empowerment and more efficient care, thereby contributing to more sustainable healthcare systems. Also, it can greatly improve the quality of life of chronic patients (e.g. Coye et al., 2009).

Outline

This thesis is structured as follows. The next chapter discusses the theoretical insights that guide this study, and finally presents the conceptual model. Chapter 3 then discusses the methodology for this research, including the tools used for collecting and analyzing data, and the cases under study. Subsequently, chapter 4 gives an overview of the empirical results collected in the multiple cases, in order to prepare the reader for the analyses of results presented in chapter 5. In this analysis chapter, the researcher provides the more general theoretical conclusions that follow from the concrete findings in the multiple cases. Chapter 6 then unites the diverse findings into a coherent conclusion on the research question. Finally, the discussion in chapter 7 treats the various limitations and implications arising from this study.

2 THEORETICAL BACKGROUND

This chapter discusses the theoretical directions taken and the concepts guiding this study. Section 2.1 elaborates on Fleck's notion of configurations and discusses how this relates to the field of RPM. This helps to understand the setting in which socio-technical changes in RPM systems come about, and how RPM systems may entail some openness in their architecture, leaving room to adapt to user-specific requirements. Subsequently, theoretical insights on user involvement (section 2.2), generification strategies of designers (section 2.3) and the use of design standards (section 2.4) are presented, which guide this research in answering the research question. In section 2.5, the conceptual model is presented.

2.1 CONFIGURATIONS

Configurations are *"technical systems with no generic identity, i.e. they are the subset of technical systems for which the pattern of how to arrange the components (architectural knowledge) is defined during implementation"* (Peine, 2009, p.396). RPM configurations can be understood as assemblies of both technological and non-technological components that together form a functioning entity; both human and non-human actors are components of a configuration (Fleck, 1993). In line, Lehoux (2008) considers healthcare delivery models for chronic patients as being *"socio-technical configurations in which healthcare managers, care providers, patients and their relatives interact with, or through, various technologies for care to be provided and information shared"* (p.86).

Components from which configurations are built up are mostly pre-existing, but integrated in different ways in order to fit a specific local context. Sometimes innovative components are needed to respond to specific requirements. Local contingencies are relevant for the very identity of each solution and the pattern of how to arrange components of a configuration can only be defined when the requirements of a specific context of use - i.e. 'local practical knowledge' - become known (Peine, 2009; Fleck, 1993). Such local practical knowledge can, for instance, be understood as the nature of the disease being managed, or the intensity of the care and expertise involved (Lehoux, 2008). However, it can also be taken to an even more personal level, such as a patient's personality, cognition, level of education and literacy (Boyne & Vrijhoef, 2013; Tesanovic et al., 2009), or the spatial context of the configuration, such as the interior of a patient's home, as well as its inhabitants (Oudshoorn, 2012). Tesanovic et al. (2009) argue that it is only possible to develop personalized RPM systems or rules to adapt them if the key characteristics of patients are taken into account. Besides, as such characteristics potentially change over time, it may be important to track them continuously.

Theoretically, the configurational nature of RPM systems offers possibilities to design and build systems that are tailored to user-specific requirements. The specific conditions and requirements of one particular use situation may make it difficult to develop more generic solutions (Fleck, 1993). Therefore, configurations are supposed to have a greater necessity for user involvement in their development than generic systems (Fleck, 1993). The variety of different users of RPM systems (patients, caregivers etc.), which may have different relations to the configuration, must be involved in order to gradually identify the local contingencies and configuration that must be built up around these contingencies. Interactions with and between users are crucial in determining the shape of the configuration. In fact, through iterative interactions and mutual adaption of human and non-human actors involved, configurations may evolve and stabilize (Fleck, 1993). Simultaneously, ideas generated through user involvement may also stimulate innovation within components that are part of a configuration. As Fleck (1994) explains, configurations entail 'learning-by-trying', meaning that *"improvements and modifications have to be made to the constituent components before the configuration can work as an integrated entity"* (p.638). Further, whereas generic systems are developed through an innovation process, followed by a process of

diffusion, Fleck (1993) suggests that in a process of 'innofusion', significant innovation in configurations takes place during implementation, as *"new characteristics may be explicitly developed in response to requirements or environmental exigencies, by recombining existing components, and then directly transmitted to succeeding generations of technology"* (p.28). Also, Fleck (1993) recognized that the configurational character of systems or technology is a matter of degree, with configurations and generic systems being two ideal types at the extremes of a range of openness in design architecture. Eventually, increasing maturity may or may not cause configurations to stabilize into more generic structures in which components may be more or less stabilized and interdependent – i.e. they have an underlying coherence which governs how components relate and are integrated, and explicit system standards specifying functions and performance (Fleck, 1993).

The above explains that RPM configurations leave flexibility for innovation at the architectural level - i.e. the arrangements between components - in order to tailor the configurations to user-specific requirements. Besides, innovation may be necessary at the level of individual components in order to tailor RPM systems to user-specific requirements. This research explores how the three independent variables that are discussed in the following subsections are influencing the tailoring of configurational RPM systems according to the user-specific requirements (i.e. dependent variable), both at the architectural level and at the level of individual components.

2.2 USER INVOLVEMENT

User involvement has great potential to increase the acceptance of innovations and facilitate their adoption and implementation (Boon et al., 2008; Smits & Boon, 2008; Moors et al., 2008; Shah & Robinson, 2007). In line with the notion of 'interpretative flexibility' (Pinch & Bijker, 1984), Oudshoorn (2012, 2008) explains that the same RPM technology can do and mean different things at different places and for different types of users and social groups. This research therefore assumes that it is essential for designers to involve heterogeneous user groups and deliberate on their views to acquire a representative and broad picture of the requirements that RPM systems should meet.

Ways of user involvement

Nahuis et al. (2012) have provided a useful distinction between different ways of user involvement. They distinguish between seven types of user-producer interactions (UPI), which are *"interactive learning processes between users and/or producers leading to or aiming at the reduction of uncertainty about the relation between product and demand characteristics"* (p.1122). These are the following:

Constructing linkages means that linkages between users and producers are formed, in order to create channels through which information can pass. Any other UPI presupposes adequate linkages among and between users and producers (Nahuis et al., 2012).

Broadening aims to ensure that actors become more aware of how technologies might affect others. It might move actors in the same directions and establish a consensual frame among social groups. However, the articulation of diversity and dissent can also be key outcomes (Nahuis et al., 2012). This UPI seems especially relevant in the context of this study, since RPM systems generally have a variety of heterogeneous users that may have disparate views on the same technology.

User characterization gives a representation of what supposed users are and what they want. This can be captured explicitly by marketing research through feedback and feed forward links between design and marketing (Nahuis et al., 2012; Akrich, 1995), but designers can also make predictions about future users – i.e. the 'projected user' (Akrich, 1992). However, it may be difficult to fully understand user needs and preferences because users are not always able to articulate their needs, preferences or wishes (Prahalad & Hamel, 1994; Griffin, 1996). Accordingly, Hyysalo (2003) argues that user preferences become clear and develop over time only gradually while making actual use of the technology - i.e.

learning-by-using (Rosenberg, 1982). Hyysalo (2003) suggests that predicting the use of highly complex technologies requires situated use through pilot projects that clarifies unexpected uses and mutual adaptation of users and technology.

Upstream involvement is a learning process to enable users to state their demands, and it means that users themselves become participants in the process of research, design and development (Nahuis et al., 2012). This UPI is also referred to as 'co-creation' (e.g. Peine & Herrmann, 2012). Users can be actively involved through upstream 'demand articulation', meaning that stakeholders try to unravel preferences for and address what they perceive as important characteristics of an innovation (Boon et al., 2008). It can be important to involve spokespersons or representative organizations in demand articulation processes, because they are usually better organized and informed than actual users and have better access to upstream development (Rip, 1995). The creative potential and experiential knowledge of users might also benefit forming new technologies and put demands on the agendas of business and governments – i.e. agenda building (Boon et al., 2011).

First user enrollment is a marketing lab where selected users undertake the experience of using a product. The producer can monitor the reaction of users, in order to gain a competitive advantage in adaptation of the product and under increasing returns to adoption (Mangematin & Callon, 1995; Nahuis et al., 2012). This is of crucial importance just before market launch.

Feedback on the other hand, begins after new products are actually used, and contributes to further demand articulation, for instance through learning-by-using, focusing on technological performance characteristics. Another form of feedback denotes the necessary encouraging of users and teaching them how to use the technology (Nahuis et al., 2012). This can be very important in the field of RPM, because it introduces a reconfiguration of healthcare, delegating new responsibilities to different actors (Oudshoorn, 2012; Coye et al., 2009).

Downstream innovation occurs when users implement technology in their local situation and come up with creative ideas for product development or even make improvements themselves. A favorable condition for downstream innovation is when industries fail to recognize a need or design possibility, or when the industry is very much oriented at mass products despite a high level of heterogeneity among users and their demands and the necessity for personal customization of products (Nahuis et al., 2012). Therefore, this UPI seems very relevant in the context of this research. When such user innovation occurs, though, new or existing manufacturers could try to appropriate these possibilities because of economies of scale (Nahuis et al., 2012; Hienerth, 2006).

The above described UPI can help technology suppliers to deliberate on the perspectives of heterogeneous user groups during design processes. The respective user knowledge obtained can provide suppliers with directions for how to shape or modify the design of configurations or individual components within configurations, in order to tailor them to user-specific requirements. This research uses these types of UPI as a heuristic tool to methodically explore which interactions have taken place between RPM technology suppliers and the variety of users. It must be denoted that different contexts or circumstances demand different types of UPI (Nahuis et al., 2012), whereby these types may not necessarily all apply to the field of RPM. Importantly though, the aim is not to check or confirm existence of certain types of UPI. Rather, the concepts described in this section serve as a starting point for the investigation of the nature of user involvement in terms of how it is applied, and how these ways of user involvement influence the tailoring of the systems to user-specific requirements.

Non-users

In addition, this research includes non-users as a relevant and important user group to involve in design processes. Non-use is traditionally portrayed as a deficiency or irrational act, but it is increasingly

recognized that non-users can also be relevant social groups in design processes because they can have good reason not to use a technology (Wyatt, 2003). A growing strand of literature is examining the role of resistance and non-use in design processes and socio-technical change (e.g. Baumer et al., 2013; Verdegem & Verhoest, 2009; Selwyn, 2003; Wyatt, 2003; Lægran, 2003). As Wyatt (2003, p.69) puts it: *"there is something to be gained from [....] an examination of those who choose not to travel down particular technological roads."* This is especially true for the field of RPM, because the *"decision to resist a new technology may be more consequential when it concerns health rather than leisure or other forms of consumption"* (Oudshoorn, 2012, p.126). Thus, it might be beneficial for both suppliers and people that (potentially) resist to use RPM technology to deliberate on factors that cause such resistance, and eventually improve their technology accordingly, in order to cause a lower amount of (potential) users to resist the technology. Therefore, next to the different ways of user involvement distinguished by Nahuis et al. (2012), this research explicitly searches for interactions between technology suppliers and non-users or potential non-users, with the aim to learn whether and how these interactions influence RPM technology and the respective tailoring of the systems to the specific requirements of these non-users.

2.3 GENERIFICATION STRATEGIES

Peine & Moors (2015) found that designers in the field of personal health systems have difficulties in reconciling insights about user-specific requirements since this collides with their own need to make their technologies generic. They explain that *"despite elaborate attempts to understand and consider the complexities of everyday life, and investigate them through various methods of user involvement and research*" (p.12), designers dominantly come up with generic technical solutions, rather than that they respond to the variety of user-specific requirements. The same happened in the field of smart home technology during the 1990s, where innovators "decontextualized" design solutions and focused on a broad spectrum of users to be reached at once (Peine, 2009). Only after failure of such standardization attempts, innovators had more thorough appreciation of use practices and user requirements. Both the technological fields of smart homes and personal health systems closely relate to RPM, whereby it seems reasonable to expect that innovators in RPM technology also have difficulties in letting their technical solutions comply with the variety of user-specific requirements, due to a conflict with their own generification strategies. Moreover, as discussed in the introduction, various scholars already point to the relatively generic systems that have been offered thus far (e.g. Boyne & Vrijhoef, 2013; Tesanovic et al., 2009), reinforcing this expectation. Yet, since the importance for RPM system supplier to respond to the more specific needs of users is increasingly acknowledged (e.g. Elwyn et al., 2012), it is useful to explore whether a trend towards personalization, and away from generification, may actually be taking place. Moreover, this research does not presuppose that a generification strategy applies to all RPM system suppliers, and it is assumed that it may differ for suppliers how such strategies ultimately influence their products. Therefore, this research investigates the nature of generification strategies in terms of whether and how suppliers apply generification strategies, and how this influences the tailoring of RPM systems to the variety of user-specific requirements.

Furthermore, generification strategies of suppliers may be moderating the influence of user involvement on the tailoring of RPM systems to user-specific requirements. Peine & Moors (2015) namely argue that user involvement may also be a way for designers to learn about the broad spectrum of users to be reached at once, and that user involvement should be understood as an element of a wider generification strategy, *"configured by the need to develop solutions that are robust across a variety of local circumstances"* (p.12). In other words, user involvement may not necessarily and exclusively be a strategy to learn how RPM systems can be optimally tailored to user-specific requirements. Simultaneously, or instead thereof, suppliers may be involving a variety of users to learn about the differences and similarities between their requirements, and to detect the common denominators, for

instance, hence to develop standardized solutions that are robust among the variety of users, and thus apply a generification strategy. Hereby, Peine & Moors (2015) suggest to be challenging the widely adopted idea that user involvement brings technology design closer to the 'lived realities' of users. Therefore, this research also explores this potentially moderating influence of generification strategies on user involvement processes, as this can help clarifying how user involvement actually influences the tailoring of RPM systems to user-specific requirements. This means that it is tried to determine whether suppliers involve a variety of users with the aim to learn about their heterogeneous requirements and define how they will try to serve the variety of users with standardized solutions.

2.4 THE USE OF DESIGN STANDARDS

Wartena et al. (2009) explain that it is often necessary for RPM systems to work with a variety of measurement devices, such as blood pressure monitors, glucose meters, weighing scales, pulse oximeters, ECG monitors, peak flow meters, and etcetera. The lack of common standards for data exchange - e.g. in terms of language or transport mechanisms (e.g. Bluetooth, USB, etc.) - leads to "*a daunting task for a telehealth system vendor to make its system work with all of these different devices from different vendors"* (Wartena et al., 2009, p.14). Besides, Craft (2003) explains that a lack of design standards also decreases the number of options users can choose from, and this could eventually lock them into certain solutions (Craft, 2003). Without interoperability between different technologies, organizations that integrate the components into one RPM system and implement these systems in care practices cannot easily extend RPM systems with additional clinical capabilities (i.e. components) or adapt to the introduction of new technologies or user-specific requirements *"because each new technology may require a significant engineering investment to make it work in the vendor's existing system"* (Craft, 2003, p.4). Thereby, a lack of standards possibly hinders the tailoring of the RPM configurations to user-specific requirements.

The lack of interoperability between different technologies is an important difficulty in creating RPM systems that optimally fit with the needs of users. Wartena et al. (2009) argue that in practice, RPM configurations often work with only a limited set of measurement devices, meaning that users typically do *"not have much choice in the combination of the telehealth equipment; it is often a single package deal"* (p.17), referring to a generification strategy. This issue does not only apply to measurement devices, but also to electronic and personal health records (EHR/PHR), which are often integrated with RPM systems and thus part of the configurations. Such systems are namely often supplied by other vendors than the supplier of RPM systems (Wartena et al., 2009). Moreover, the European Commission (EC) suggests that health authorities and professionals often select and implement their own individual e-health systems, whereby the solutions provided are tailored only for one specific location or service provider, bearing the risk that such systems are non-interoperable elsewhere (EC, 2014a, 2014b).

In order to address this challenge, many efforts are put into the development of design standards for e-health systems, for instance by the EC, or by a variety of dedicated projects in which different suppliers work together, such as the Continua Alliance (Continua, 2015) and HL7 (Health Level Seven) International (HL7, 2015). When using certain design standards or guidelines, RPM system builders can relatively easily reconfigure a system with other devices, without significant adjustments in the hardware or software, provided that the supplier of the newly integrated devices implements the same standards. Thus, in theory, the adoption of common design standards facilitates component-based infrastructures to be easily (re-)configured, which potentially decreases costs and offers possibilities to better match these systems to user-specific requirements (Galarraga et al., 2007; Warren et al., 2005, 2004). This research examines the use of standards in practice, and how the configurational flexibility they may bring along allows RPM systems to be better tailored to user-specific requirements.

Simultaneously though, from a theoretical point of view, there is reason to expect that there may also be a downside to the use of standards. As Peine (2009) suggests, configurations imply that no design standard exists on the system level, i.e. there is no dominant design of the configuration. He suggests that *"standardization should not fix the mapping of functions onto components, since the level of applications would collapse into pre-defined technological solutions"* (p.406). Configurations should retain a degree of functional openness, and interoperability between components should therefore be facilitated through 'open standards' (Peine, 2009). Next to the investigation of the use of design standards by suppliers, and how this influences the tailoring to user-specific requirements when designing and configuring RPM systems, this research therefore also explores whether or not standards sometimes lead to limitations in the response to certain user-specific requirements, and how much 'slack' is left by standards for suppliers to respond to the variety of user-specific requirements.

2.5 CONCEPTUALIZATION

The aim of this research is to further explicate *the nature of user involvement, the nature of generification strategies,* and *the use of design standards* by suppliers in the field of RPM technology, and to determine the influence of these three factors on the dependent variable – i.e. the tailoring of RPM systems to user-specific requirements. This is shown in the conceptual model in figure 1.

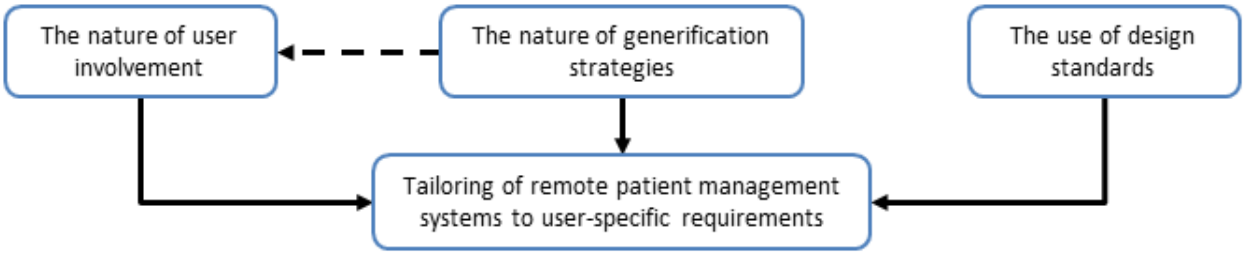

Figure 1: Conceptual model; the dashed arrow denotes a potentially moderating effect.

The theory described in this chapter will be taken as a starting point and guideline to investigate this, and the aim of this study is to further enrich the conceptual model and respective theory. Section 2.1 explains that RPM configurations may be tailored to user-specific requirements through adaptations at the levels of both their architecture and individual components. Section 2.2 provides a distinction between different types of user-producer interactions, which guides this research in defining the ways of user involvement by RPM technology suppliers, for which it will be examined how they influence the dependent variable. Section 2.3 explains that generification strategies of suppliers may hinder the tailoring of RPM systems to user-specific requirements, and this research investigates whether and how such strategies apply in the field of RPM technology, and how they then influence the tailoring to user-specific requirements. Additionally, section 2.3 discusses the potentially moderating effect of generification strategies on the nature of user involvement, which is searched for in order to better understand the overall influence of user involvement on the dependent variable. Section 2.4 discusses that using design standards is expected to positively influence the dependent variable, because the interoperability that results from using design standards may create more configurational flexibility for tailoring configurations to user-specific requirements. Next to the investigation of how the use of common design standards influences the dependent variable, this research also explores the theoretical possibility that design standards may also hinder the tailoring of RPM systems to certain user-specific requirements.

3 METHODOLOGY

This chapter describes and justifies the methods and techniques used in this research, including a description of the research design, case selection, data collection and analysis.

3.1 RESEARCH DESIGN

A qualitatively, explorative research design was chosen to be most appropriate to study this topic, because this enabled the researcher to learn and provide new in-depth insights about the theoretical concepts and their relations in the context of RPM technology, which have remained relatively unexplored. The qualitative approach enables the assembling of detailed and relatively unbiased information, which possibly helps explaining the relation among variables. An interpretivist epistemology was chosen because *"the stress is on the understanding of the social world through an examination of the interpretation of that world by its participants"* (Bryman, 2008, p.366).

A multiple-case study strategy was applied, allowing the in-depth examination of development processes of different RPM systems. Multiple cases provide more observations of the same phenomenon, allowing to critically assess data through comparing it among several cases, and possibly providing a wider variety of insights about concepts and their relations (Yin, 2003). Additionally, as discussed in section 3.3.1, during data collection some data was gathered that goes beyond the scope of the cases under study, but which is nevertheless relevant to help answering the research question. This data is therefore additionally used as contextual background information on the research phenomenon.

The unit of analysis of each case is the process of developing and implementing a RPM system. This research considers a RPM system to be a set of integrated components, including measuring device(s), ICTs, data records, care providers, patients, etcetera, that together carry out tasks related to the remote measurement of patients with chronic illnesses. Thereby, this research examines complex healthcare systems which encompass more than just purely technological components, and in which different components can be (re-)configured in order to adapt the RPM systems to specific needs or preferences of users. Furthermore, multiple organizations are generally involved in the development of one RPM system, as different components are often developed and integrated by different organizations. Such organizations are part of a supply chain, which is a system of organizations involved in moving a product or service from supplier to customer (Nagurney, 2006). Thereby, this research examines innovation processes of RPM systems or components within multiple organizations that contribute to the configuring of a RPM system.

3.2 CASE SELECTION

3.2.1 Selection criteria

Five different RPM solutions are examined, which all have in common that they connect patients with their care providers through ICTs, in order to remotely manage chronic illnesses. Another prerequisite for the RPM structures under investigation is that they are to some extent configurational in nature. This criterion is implicitly met by examining platforms which are configurational in essence. Nevertheless, it was also determined whether the systems are built up from multiple components that can - in potency - be differently arranged in different practices, rather than that the RPM system components are fully stabilized and interdependent (Fleck, 1993). For practical reasons and constraints in time and resources, the case selection is restricted to RPM systems that are developed - at least partly - and implemented in the Netherlands. Furthermore, some variety among cases is ensured, which may provide a wider variety of insights and possibly explains how the influence of the independent variables on the dependent variable varies in different situations. The variety among cases is ensured within the following selection criteria:

- ***Type(s) of disease(s) managed***: a variety of chronic illnesses being remotely managed by the different systems.
- ***Amount of different diseases***: either one specific chronic illness or multiple chronic illnesses being remotely managed by the system.
- ***Phase of development***: the RPM systems being either relatively established or relatively new and in phases of pilot research or early implementation. Thereby, all selected RPM systems are in stages of development or implementation during which at least some parties are using (or testing) the system.[3]
- ***Size of the supplier(s)****:* the system component(s) being developed by either a small to medium-sized enterprise (SME), or by a large global organization; this may imply possible differences among cases with respect to available resources for user involvement, for instance.
- ***Nature of the technology***: the RPM system being primarily built up from either a software application (e.g. data portal, RPM program, mobile application) with which additional components (e.g. measuring devices) can be integrated, or from RPM hardware component(s) with which additional components can be linked.

3.2.2 Selected cases

The cases are shortly described below, and more thoroughly described in the case profiles given in results chapter 4. For reasons of confidentiality, and in order not to lay the focus on the activities of particular companies, but rather keep the data as objective as possible, all cases are anonymized. This means that no names of products, organizations and respondents are given.

Case 1: Interactive platform with standard hardware components that remotely monitors weight, blood pressure and heart rate of chronically ill heart patients, and connects them with specialized nurses. This platform is developed by a large international company.

Case 2: Online e-coaching software programs for a variety of chronic diseases, including heart failure, COPD, asthma, diabetes type II, inflammatory bowel diseases, Parkinson's disease and oncological diseases. The web-based programs are being developed by a Dutch specialist e-health company with under ten employees, and with a track record of more than 7500 patients. This case primarily includes a more in-depth focus on two programs for heart failure and inflammatory bowel diseases.

Case 3: Interactive and web-based self-management platform for an integral approach of chronic care for patients with heart failure, COPD and diabetes type II. While partly actuated by a Dutch independent foundation that is dedicated to stimulating the upscaling of remote care, the platform is developed and being commercially marketed by an internationally operating Dutch company with around 140 employees, and which develops software for the healthcare market.

Case 4: Anticoagulation self-management approach, including a web-based software platform and a measuring device that support patients and anticoagulation clinics in (remotely) determining the dose of anticoagulation medication within the therapeutic framework. INR (International Normalized Ratio) values can be measured with a measuring device of a large international supplier of diagnostic equipment. These values and other relevant information can be entered into a software system from a Dutch supplier, enabling the patient or healthcare provider to adjust the anticoagulant treatment.

Case 5: Remote management of diabetes type I management, focusing on children and adolescents, through a mobile application. The application in relatively early phases of development, and development is currently mostly focusing on optimizing the measurement and prediction of glucose

[3] Because significant development in configurations – according to user-specific requirements - may take place after implementation (Fleck, 1993), this selection criteria may pre-imply variation between cases in the degree to which the respective systems are already tailored to user-specific requirements, and the degree of user involvement that has taken place.

values. The development is initiated by a small Dutch entrepreneurial firm which is later acquired by a venture capitalist from the United States.

3.3 DATA COLLECTION

3.3.1 Interviews

Interviews are used for most part of the data collection. For each case, interviews are conducted with a variety of respondents, including representatives of the system supplier(s) – i.e. developer(s) of the RPM system or component(s) – key persons from healthcare institutions that are implementing and using the system, and other involved organizations, such as patient advocates or foundations aimed at stimulating the upscaling of self-management in the Dutch healthcare system. Hereby, each case is considered from both the supplier and user perspective.[4]

For each case, the first respondents were generally approached via contact information found on their websites. At many times, the first respondents or other early contacts provided a way to identify other participants with valuable information that were relevant to and available for an interview. Sometimes, contacts invested considerable time and efforts in arranging interviews with others. A total of 22 semi-structured interviews was held, ranging from 3 to 5 per case, with an average of roughly 85 minutes per interview. The number of interviews and variety of respondents aims to ensure that some degree of data saturation is achieved for every case. After writing down the results of the cases and contextual background section (chapter 4), all interviewees were sent a document with the respective case results, in order to allow them to make remarks on the interpretation of the interviewees. Responses were given by 13 of the 22 interviews, and if no response was given, respondents implicitly gave their approval.

During the data collection process, opportunities came forward to have interviews with representatives of expert organizations that were partly involved in the innovation process of RPM systems under study, but largely dedicated to upscaling the use of ICT in healthcare in general. While conducting certain of these interviews, it appeared not to be possible to focus questions (and receive answers) exclusively on the unit of analysis of the cases under investigation. Thereby, two interviews (partially) yielded information within the scope of the variables under study, but beyond the scope of the specific cases under study. This data is considered valuable for answering the research question, whereby it is chosen to include this data in the additional contextual background section 4.6.[5] Moreover, the contextual background information also helps to better understand the cases themselves. Furthermore, during data collection, there appeared to be some interrelatedness between cases 1 and 3, because the system of case 3 is being developed as part of an initiative of the supplier in case 1, whereby there is a degree of mutual learning between these cases. Nevertheless, data collection for these cases is done completely separately.

All interviews were recorded and transcribed in order to fully capture the value of interviewee accounts and enable to thoroughly analyze the data afterwards. All transcripts were assembled in one file of the software program QSR-NVivo 10 which is meant for organizing and analyzing qualitative data – this is

[4] For case 3, it was not possible to conduct an interview with (potential) users (e.g. patients or care providers) or representatives from healthcare institutions using the system (potential) end-users, because the protocol of the respective project did not allow this. Yet, an interview was held with a research institute that investigates the user perspective of this particular platform, on behalf of the initiator of this platform development (involved organization T). Thereby, a relevant and representative interview was still held that provides information about how the perspectives of users have had a role in the innovation process.

[5] Interview 17 partially yielded relevant data beyond the scope of any of the cases. Interview 15 was held with a specialist organization in healthcare ICT with respect to a sixth case. However, this case was later excluded from this research, because during data collection it turned out not to be possible to conduct appropriate interviews for this case. Because interview 15 provides relevant data regarding the use of design standards by RPM technology suppliers and its influence on the dependent variable, it was chosen to use this interview as an expert interview.

available on request from the researcher. Appendix I displays the list of anonymized interviewees with their function and type of organization, and the codes that are used for the interview number (e.g. IN#1 = interview 1) and types of organizations of the respondents (S = system supplier, U = user organization, IO = involved (user) organization). A running number is assigned to each interview transcript, providing a reference when interviewees are quoted or referred to in the results chapter 4.

Semi-structured interviews

The interviews were semi-structured to obtain an in-depth exploration of particular topics and experiences and allow enough space for exploring other interesting aspects and new ideas that came up during the interviews. Simultaneously, it preserves some coherence in data collection between the five cases. The aim was to gather information about how the three independent variables' influence the design of the RPM systems – if possible by means of examples – and thereby contribute to the tailoring of RPM systems to user-specific requirements.

In preparation of the interviews, background information about the respective RPM system and organization was sought in order to be able to focus on a more in-depth understanding of the case in light of the theoretical framework. Nevertheless, the interviewees were also asked for some general background on themselves, their organization, and their relation to the RPM system component(s), amongst others. Also, information is gathered about the dependent variable – i.e. the tailoring of RPM systems to user-specific requirements. As discussed in chapter 2, the theoretical background is taken as a starting point for the investigation of how the three independent variables influence the dependent variable. Therefore, the theoretical concepts 'user involvement' – i.e. the types of user involvement distinguished by Nahuis et al. (2012) and the concept of 'non-users' - 'generification strategy' and 'design standards' were used as sensitizing concepts that provide *"a general sense of reference and guidance in approaching empirical instances"* and *"directions along which to look"* when collecting and analyzing data (Blumer, 1954, p.7). These concepts are reflected in the following framework of interview topics explored:

- General historical background on the interviewee and respective organization.
- Description of system or component(s) developed or used by the organization.
- Flexibility to (re-)configure the system according to user-specific requirements.
- User involvement during development and (after) implementation, respective insights obtained, and respective decisions on system design; including user insights that are not directly obtained from user involvement, but for instance learnt from other organizations in the supply chain, or from implementation problems due to misalignments between system design and user-specific requirements.
- Perceived room for improvement regarding user involvement and follow-up in design process.
- Use of design standards to ensure interoperability with other technical components.
- Contribution - either stimulating or hindering - of design standards and their implementation to the flexibility to (re-)configure systems to user-specific requirements; thus also specifically focusing on potential limitations in design modifications due to the use of standards, as well as the perceived room for improvement regarding the use and availability of standards. This research aims not to delve deep into the influence of specific standards, but rather to explore the influence of standards in general.
- The perceived heterogeneity in the needs of the targeted user group and extent to which these needs are met by the system supplier (this may partly emerge from the above topics).

These topics were used to structure the interviews in a flexible way, and interviewees were asked for concrete examples associated with these topics as much as possible. The interview script with specific interview questions that were derived from the given interview topics is given in appendix II.

Use of interview structure

In principle, the interview structure was used for all interviews, yet some important notes must be made on the flexibility of using the interview structure:

- The interview questions proved very useful as a checklist for making sure that important themes had been sufficiently covered. Some variation was made in the sequence of questions asked, but the order of themes gave a good structure for the interviews. Also, the questions were applied in a loose manner so as to avoid disturbing the flow of the stories told, and allowing more room for what interesting information the interviewees were willing to give on the research phenomenon. Although many respondents had their own specific area of expertise and/or interest, in most cases it seemed possible and useful to go through the themes in a pre-set order.
- The questions asked in interviews 8 and 15 were largely focused on the role of design standards during the development of RPM systems. The respective interviewees namely indicated in advance that they were exclusively able to talk about the respective subtopic.
- Although the researcher intended to focus on the innovation process of the specific RPM systems under investigation, some respondents were inclined to refer to their way of operating, involving users and using design standards in a more general way rather than only during the development and implementation of the specific RPM system under investigation. Thereby, some of the answers given in some of the interviews were slightly broader in scope than just the decision-making process on the specific RPM system. In these instances it was discussed – sometimes implicitly, sometimes explicitly - with the interviewee whether this information is representative for the decision-making process of the respective case.

3.3.2 Secondary documents

Interview data is complemented with secondary documents from multiple sources like websites, press publications and articles, and containing information regarding the independent variables or decisions with on the design of the RPM systems. The researcher has searched for secondary documents through a desktop study - in which amongst others websites of suppliers, user organizations, and other involved organizations have been searched out - and in a few instances, interviewees made available data pieces that contained information on the case. Secondary documents were particularly used to prepare for interviews, and to understand and describe the context of the case. The secondary documents were also encoded to the independent variables, but in practice information on the independent did not often emerge from the secondary documents. Ultimately, some secondary documents were included in the results, but most of the documents found did not provide sufficiently relevant data to be eventually included in the results. Most of the included secondary documents were anonymized as (SD….) and included in a separate list of references (appendix III), in order to use the same anonymity rules as for the interviews.

3.4 DATA ANALYSIS

Some coding procedures were adopted from grounded theory to ensure systematic categorization and comprehensive analysis of data. Coding refers to *"the operations by which data are broken down, conceptualized and put back together in new ways"* (Flick, 2009, p.296). In the following, it is outlined which steps in the coding process were taken to ensure that some coherence between separate data pieces and cases may arise throughout the analysis process, and to avoid the cutting of raw data pieces into labels that lose touch with the specific context of the specific case that is examined.

In the first phase of coding clearly irrelevant data were not given labels, and thereby these data pieces were excluded from further data analysis. Possibly relevant data was systemized around categories of data using ***open coding***; raw data was segmented into parts that could be interpreted separately and to

which labels were attached (Flick, 2009). Conceptually similar actions/events/interactions were grouped together to form categories and subcategories (Corbin et al., 1990). Because the separate cases studied here generally have different contextual backgrounds, the research has drawn up case profiles during the first phase of coding, which generally describe the goals and functionalities of each RPM system, the loose or interlinked components from which the systems are built up, and indications of whether and how the RPM systems can be tailored to user-specific requirements (therewith the dependent variable). The case profiles serve to better understand the context of each case, and they support the comparison of cases later on in the analysis process. Data regarding the influences of the independent variables on the dependent variable are described separately from each other where possible, notwithstanding that the data may sometimes be overlapping multiple independent variables. Similar to as done in the data collection process, the theoretical concepts are used as sensitizing concepts to direct data analysis, meaning that in a process of ***theoretical coding***, raw data was compared with the theoretical background in chapter 2. Simultaneously, the open coding leaves room for the emergence of theoretical constructs that are not captured in the theoretical background. Secondary documents were analyzed in the same manner of open and theoretical coding.

In the second phase of the analysis process ***axial coding*** was applied, meaning that provisional categories of data from the various data sources of each case were analyzed and compared with each other and with theory, and the data was checked for contradictory arguments provided by different respondents, in order to gradually elaborate them (Strauss & Corbin, 1998). Categories that after all did not seem to be relevant for answering the research question - i.e. explaining relations between concepts - were excluded. In the axial coding process all interviews were repeatedly reviewed until ***theoretical saturation*** was reached in this specific dataset. The labeled data pieces and their relations were prioritized in their relation to the research phenomenon, in order to provide a detailed overview of empirical results (chapter 4), but simultaneously prevents recurrence and description of irrelevant data. Interview quotes were collected and included in the chapter of empirical results to corroborate certain arguments made by the respondents. All quotes are literally translated from Dutch, except for the anonymized names and the quotes from one interview that was conducted in English.

Once all interviews had been conducted and each case was fully analyzed, ***cross-case analyses*** were made to examine whether there is coherence between the findings among multiple cases. This step is essential to help make findings more generic and avoid that theoretical conclusions are idiosyncratic to the specific case (Eisenhardt, 1989). However, it is not the aim to only include findings that apply to the majority of the cases, because the cases have great substantive differences due to the case selection criteria applied, and more case-specific factors can also be interesting to highlight. In the analysis chapter, it is described what patterns and concepts emerge in the collected and labeled data, including how the various cases are comparable in their findings, and how these findings help answering the research question.

Importantly, data collection and analysis were interrelated processes, meaning that the researcher followed an iterative process of data collection, data reduction, data comparison and drawing conclusions. This iterative process of ***constant comparison*** between the emerging theoretical conclusions and the data finally lead to a comprehensive understanding of the five cases addressed in this study.

4 OVERVIEW OF EMPIRICAL CASE RESULTS

In this chapter, a comprehensive description is given of the data collected in 22 interviews and secondary documents, moving from raw transcripts and documents towards theoretical concepts. For each case a thick description is provided, starting off with a case profile that includes a general description of the configurational RPM system and its phase of development or implementation. Then, it is discussed what insights for the case were gathered regarding the three independent variables and their influence on the dependent variable, i.e. tailoring of RPM systems to user-specific requirements.[6] After the discussion of case results, a short section is given with the relevant contextual background information that was gathered additionally.

4.1 CASE 1

4.1.1 Case profile

The interactive platform of supplier 1 (S1) was largely developed in the United States (US) and launched on the Dutch market in 2007. In the Netherlands, it is primarily used for the remote management of chronic heart failure by secondary care providers at the hospital. Figure 2 provides a visualization of the configurational system that is built up from the platform.

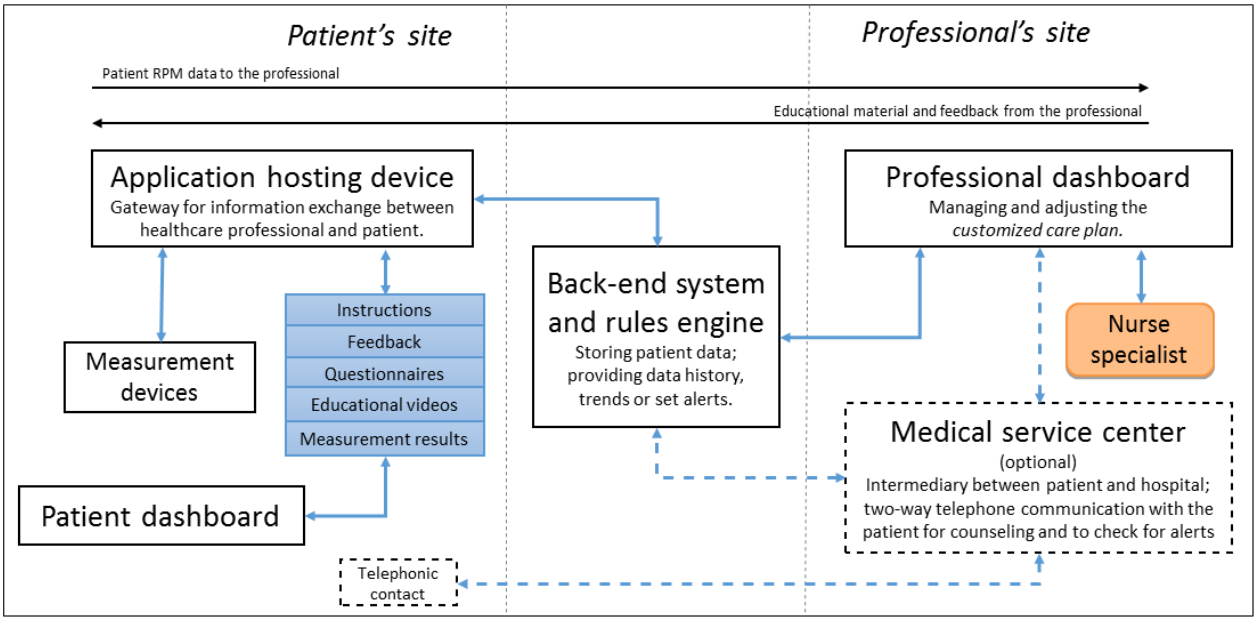

Figure 2: Visualization of the RPM system of S1. The configurational system is shown as an end-to-end infrastructure that connects the patient at home with care providers at their institution. The dashed boxes and arrows imply that these components and linkages are optionally part of the configuration.

A central component of the configuration at the patient's site is the ***application hosting device*** or gateway, which is a set-top box installed at the patient's home and connected to the TV, allowing the patient to interact via a specific health channel on the TV, which is the ***patient dashboard***. Since a few years, S1 also offers the option for patients to connect to the system and interact via an iPad or iPhone instead of the set-top box and TV, thereby offering patients more freedom to travel while being remotely monitored, for instance. Through the gateway, content such as *instructions* on patient's tasks with

[6] Notwithstanding that these three themes are often overlapping, they are treated in separate parts in order to make some distinction in the data obtained on the independent variables.

respect to their remote care process, *feedback* from care providers, digital *questionnaires*, *educational videos* and overviews of *measurement results* is sent to and shown on the patient dashboard. The application hosting device is automatically and wirelessly - via Bluetooth - receiving and storing vital sign data from a set of off-the-shelf ***measurement devices,*** such as weight scale and blood pressure meter, depending on the specific illness and care plan of the patient. Standard educational videos on for instance medication, weight control or nutrition are sent by the care provider on the basis of three-monthly questionnaires filled in by the patient (IN#1, IN#9), and shown on the patient dashboard. As suggested by a heart failure nurse specialist using the system (IN#4), the caregiver can decide to stop offering a certain patient educational content when the patient is deemed able to function without it.

Further, the gateway ensures that the data is send to a ***back-end system*** of S1, which stores all data on patients and transfers relevant content (e.g. alerts) to the ***professional dashboard*** of the care providers that remotely monitor the patient's conditions. The back-end system serves as a ***rules engine*** that uses algorithms and takes the patient's *customized care plan* time with respective intervention rules in order to generate personalized content for the patient or care provider. The customized care plan of individual patients can be adjusted over time, and it includes an individual assessment for every patient when care providers do or do not want to be alerted by the system. Based on the patient's usage of the system and his/her health condition characteristics, as well the customized care plan set by the care provider, the rules engine thus ensures that corresponding alerts are shown on the professional dashboard, and/or new content such as instructions is presented on the patient dashboard. Next to the automatic generation of content by the back-end system, the system can be also queried by authorized care providers to view a patient's history or trends and to set (personalized) alerts.

Additionally, S1 has featured their platform with heart failure ***nurse specialists*** that are educated to remotely manage the patients from the hospital. They do not constantly have to consult the cardiologists, but can figure out themselves what intervention is necessary and they are even authorized to prescribe medicines. Also, S1 always offers their clients (i.e. hospitals) the optional feature of a ***medical service center***. This center then serves as an intermediary station between patients and nurse specialists, and via two-way telephonic communication they filter out the daily errors in alerts such as incorrect measurements detected by the system, and they answer questions on technical problems or lifestyle, for instance. Hence, care providers at the hospital are only alerted if actually poor vital sign data is detected by the system.

As partly follows from the above, the RPM platform is modular and configurational in various ways. For instance, patients can be equipped with different measuring devices, they can be managed with or – at some point – without the personalized provision of educational content, with or without a call center that spares nurse specialists from various responsibilities, and intervention rules can be set to individual patients. As put forward by IN#4, always some interaction between S1 and care providers, as well as between care providers and patients is required, in order to determine what composition of components of the platform best meets the needs of individual users (i.e. care provider or patient) at that time.

As will be addressed in the following part, over the years a variety of changes have been made to the original platform, and as suggested by a director of S1's home healthcare division (IN#9), with their renewed platform S1 believes to better respond to individual needs of both patients and care providers. In the following section will be further elaborated on the contribution of user involvement to the continued development.

4.1.2 User involvement

This section discusses first how S1 has gradually improved their response to the views and interests of end-users, including patients and nurses or nurse specialists, during the continued development of the platform. Second, it is addressed how the feedback of end-users after implementation and their

upstream involvement during continued development has helped S1 to improve their platform. Third, it is addressed that S1 is one of the initiators of a large national pilot project on RPM, and how this project has influenced the continued development of their own platform. Fourth, is discussed that non-use has on the one hand forced S1 to improve their platform, but that successful embedding of the system on the other hand requires better feedback to users and a transformation in healthcare. Lastly, it is discussed what issues have come up in the interviews regarding S1's response to user-specific requirements.

4.1.2.1 Gradually improved response to the views and interests of end-users

The RPM platform of S1 was originally developed in the US, and as suggested by an implementation manager of S1 (IN#1), American universities, hospitals and experts – especially in the medical field – had an important role in the building and validation of basic principles. For the rest, little information is gathered about the specific sources of input during the development of the original platform. It is suggested by IN#1 that after initial development the platform has for a long time remained relatively unchanged, apart from some updates in the dashboard to improve readability, for instance. Furthermore, IN#1 put forward that the perspectives of the actual end-users (i.e. patients and nurse specialists) have long been underexposed in the development, and that S1 has rather taken the perspectives and stakes of decision-makers such as cardiologist and hospital policymakers, who dictate the agreement to implement the system, into account during the initial platform development. As explained by IN#9, this led to a rather clinical application that was largely attributed to the cardiologist, who in fact barely works with the system. Though, as suggested by IN#9, S1 has over the years been increasingly directed by and asked for the views and interests of end-users, including patients, nurses and nurse specialists, and thereby S1 has now migrated to a more individual application, in which more attention is paid to the look and feel of the user interface, to make the system more appealing.

4.1.2.2 Feedback of end-users after implementation and their upstream during continued development

In the following, it is discussed what stimulating influence the feedback provided by actual end-users, including patients and care providers, during early use of the platform, as well their upstream involvement during continued development, has had on the tailoring of the system. Here, it is explained how feedback and complaints of end-users have influenced the continued development and stimulated S1 to allow intervention rules to be more specifically set to individual patients' requirements.

Thus far, hospitals only applied the RPM platform to relatively small groups of patients in a sort of test phases of early implementation, in which S1 and these user organizations together observe the use process and its success. As suggested by IN#9, S1 is aware that they should not only develop their platform for the select group of intelligent and motivated users, but also for people who try to get away from it relatively easily, because the latter is quite a large group. Therefore, during such first user enrollment, S1 does not only involve to the more 'active' patients that are relatively willing to be involved in early use, but also patients who prefer to stay below ground level (IN#9). Based on feedback derived during the use, a variety of changes have been made to the platform. For instance, the intervention rules applied by the rules system of the platform were initially rather fixed, amongst others meaning that it was not possible to adjust the interval at which measurement should be taken by the patient, and that every patient was required to daily measure certain vital signs (IN#1, IN#9). During early use, feedback was provided that more flexibility in these rules was desirable, whereby S1 has adapted these rules over time, and made it possible to measure every other day, for instance, or let the supporting care provider select the days at which the patient is required to take measurements. Furthermore, originally only a limited set of movies was available for patients, but after critic of care providers all movies are practically made available to all patients, depending on the set of videos the professional selects for the individual (IN#4). Also, as put forward by IN#1, during early use S1 received reactions of patients about irritators or annoying factors such as the continuous repeat of the same

questions in questionnaires, such as 'do you smoke?', even when the patient once answered that he/she does not smoke. As IN#9 underpins: *"Those are all obvious things with which you can increase the compliance. If you are only bothering individuals when it is relevant, and when it yields something for the patient, then they remain faithful. But if you […] every time offer the same education and ask the same stupid questions, you lose people."* While acknowledging that this may sound very logical, IN#9 argues that such factors were overlooked during the initial design, but since intervention rules are improved and further specified, it is now easier to tailor the RPM system settings to user-specific requirements (IN#9).

In order to address the flexibility in invention rules, S1 is currently trying divide patients among different personas or profiles based on their individual characteristics, and to connect certain intervention rules to these profiles. IN#9 suggests that each person is unique in his behavior, but that the approach is that you always recognize good profiles that come out of it. Hence, their platform is being programmed in different ways to support care providers with checking on patients, and to easily put down a different 'look and feel' for different patients (IN#1, IN#9). Nonetheless, IN#9 acknowledges that much work still needs to be done in order to customize the platform to individual requirements. Since a huge upscaling in the use of RPM technology in the Netherlands is foreseen, it is desirable to replace the manual process of individually setting intervention rules by automated customization based on algorithms. The use of large amounts of data from patients being stored in a central server or 'cloud' should enable the creation of predicted values, i.e. to make connections between their measurements, medication and lifestyle (IN#1). Although the state of progress of S1 in the development towards a more intelligent system could not be further specified based on the gathered results, IN#1 suggests that S1 aims to link algorithms to patient data, enabling the system to make prognoses that can support the care process as guideline, and show the added value of long-term monitoring at a distance to patients, care providers, and other interested parties. IN#9 poses that if S1 is able to individually vary all parameters on which an algorithm works, the system can be better used at different places, because for instance *"there is almost no cardiologist that treats patients in the same way. They all have their own believes on variables"* (IN#9). This points out that distinguishing individual patients based on different parameters and the application of algorithms may help S1 to automatically tailor their RPM systems to user-specific requirements.

4.1.2.3 Involvement in a large national pilot project on RPM

Together with a major Dutch healthcare insurance company, S1 has initiated a large and still running national pilot project on RPM, in which another RPM platform – i.e. the platform of case 3 – is being used in order to better understand patients' needs regarding RPM technology, amongst others. The pilot project is run by involved organization T (IOT), an independent foundation that is focusing at upscaling the use of RPM services in the Netherlands. In this experimental pilot project, users were for instance involved upstream during evening sessions and interviews with both patients and professionals, in order to let them participate while designing the RPM application used in the pilots – i.e. the RPM platform of case 3 - though indirectly also providing inputs for the design of S1's platform (IN#9). As suggested by IN#9, a director of S1 and board member of IOT, often insights were derived that are odd from a technocratic perspective but plain for a consumer perspective, and that it was found that during design *"you make assumptions that in practice often work out quite different"* (IN#9). For instance, it was generally assumed that people are interested in their own health, whereas for a large part of the patient population this appears not to be true – at least according to the project's results. Therefore, S1 acknowledges that many patients are not busy with or interested in RPM, and that they must in the future be better seduced to participate on a health platform (IN#9). In line, in the optics of an advocate of heart failure patients (IN#6), a shortcoming to RPM systems[7], as well as the way in which they are deployed is that they insufficiently accompany and seduce patients to improve their health, and that

[7] As put forward by IN#6, this actually applies to the platforms of cases 1, 2 and 3, but also to RPM systems in general.

they do not sufficiently focus on actually motivating people to adjust their behavior and achieve better health conditions. IN#6 suggests that it should be better taken into account – by suppliers, as well as care providers - on what aspects in the disease management individual patients are motivated to actively participate. During the evening sessions, patients and care providers could also comment on the RPM application of case 3, and it turned out that *"the patient would prefer to see a simple list, a simple dashboard, and the doctor rather wants a very technical dashboard with many values and different versions. […] The patients only wants to know with a thumbs up or thumbs down whether he is doing well."* (IN#9). Therefore, S1 designed two separate dashboards for professionals and patients, and over time these dashboards are suggested to have been greatly improved (IN#9). Partly based on user knowledge that was derived from the IOT project, S1 is trying to continuously improve the system with a focus on inserting flexibility on both the patient and professional side of the platform, for instance with regard to alerts, reminders, education or questionnaires (IN#9). Though it not explicitly comes forward how much the above described insights have already helped S1 to improve their own RPM platform, the results suggest that the IOT project has been an important source of use knowledge for S1 during the continued development of their original platform into a renewed platform.

4.1.2.4 Addressing non-use and suboptimal use

The following explains that S1 has on the one hand been forced to adapt their platform due to high degrees of non-use - i.e. fall-out - but that they on the other hand also learned that non-use and suboptimal use of their RPM platform should not only be addressed by technological adaptations, but also by a transformation of healthcare routines and better feedback to users.

Over the years, it has turned out that the setting of intervention rules per individual constantly asks for attention, because otherwise users drop out. In fact, as IN#9 argues, a late response of S1 to the need for flexibility in intervention rules has actually been problematic in terms of high degrees of non-use, and as he puts forward: *"That is something that took time, because it takes a while for an application to have so much flexibility. Over the years you find out what bothers one, what makes people stop to look at it, or what makes people want to stop with it. […] Nowadays, it can be done faster, but I have to say, five years ago when I started it was just a horribly slow process. […] Customers can simply vote with their feet for that matter, and they have done that. And we have learned from it. That is a negative way of learning, but you learn from it"* (IN#9). These results suggests that S1 has in that sense learned from non-users - in this case rejecters, who are people that no longer use the technology (Wyatt, 2003) on how to improve the system.

On the other hand, though, other factors than technological adaptations have come up that should address non-use and suboptimal use of S1's platform. S1 has actually become aware that a transformation in the healthcare system and its routines is required for their RPM platform to become successfully embedded into practice and that a good match with users' needs does not only require a robust platform and flexibility of this platform to respond to local practical knowledge, but also changes in of care providers' routines (IN#1, IN#9). Furthermore, they argue that many care providers are still constraint to patient empowerment, and that it is important to *"bring about a transition in the behavior of care providers. They must have the courage to let things go, and become familiar with the system, but also with the different method of caregiving"* (IN#1). Furthermore, during a pilot study with S1's platform in six hospitals, great differences were measured with respect to the effectiveness and efficiency of the RPM system in different hospitals (SD1a, 2014). When looking at the best-in-class hospital of the pilot, it became evident that a RPM process should be shaped with the right competences of actors involved. Moreover, IN#1 and IN#4 argue that efficient RPM is dependent on care providers to understand how such a process works, how they can use the technology, and how it contributes to a transition from reactive to proactive care. As suggested by IN#4, the adequate and efficient setting of customized care plans and respective intervention rules takes learning-by-using and a proactive mindset of care

providers. IN#4 argues that it actually the responsibility of care providers to set the system correctly, and personally, he finds it worth it to invest time into learning how the system works best. However, as he suggests, it can take months or years for care providers to optimally and easily work with the RPM system, and it may be *"a missed chance for S1 to explain people far more in-depth what is possible with the system"* and *"maybe to better use the people that have known the system longer and know how to set it"* (IN#4). With adequate and regular feedback on care providers' use of the system, it could thus be ensured that care providers adapt their routines and thereby accommodate to the system.

4.1.2.5 Issues regarding S1's response to user-specific requirements

Some results were obtained about issues or barriers regarding S1's response to (articulated) user-specific requirements. Firstly, IN#1 suggests that S1's status of being a large international firm may bring along some rigidity and lack of focus on specific local requirements. S1's business unit for RPM products is located in the US and the platform's initial and continued development largely takes place here, amongst others because telehealth is much more an established phenomenon in the US than in the Netherlands. As put forward by IN#4, the platform was initially developed for a diabetes program in the US, which sometimes caused problems for its applicability to Dutch heart failure patients. As IN#4 suggests: "*You notice that on all kinds of upgrades coming. They are all focused on that very tight control of a diabetic patient."* Related thereto, IN#4 also suggests that care providers are sometimes confronted with decisions from S1's global 'think tank' that may be interesting from a technical perspective, but not desirable from a practical perspective. Furthermore, IN#1 poses that a global organization generally has the strength to deliver a solid product, but the downside of it is that several links must be passed before important decisions are made. As he underlines: *"If you see how findings are translated by such a global organization when sitting around the table with the user to evaluate the functionality of the product, and that it still needs to pass some high links before it arrives at one who actually makes the product, then […] it must be very well-formulated in order to finally get comments there one on one. After thirty persons the message has become very different than as sent by the first person. […] Very good things have eventually passed, but the speed at which it should have happened, and the confidence you need from the healthcare profession, there is just one missing link"* (IN#1). Because S1 develops its RPM platform in the US, they sacrifice flexibility to quickly respond to needs expressed in the Netherlands (IN#1).

The rigidity of S1 is acknowledged by IN#9, who suggests*: "we have for some time been so slow that we even lost customers who asked very relevant questions about interconnectivity, functionality, flexibility on the settings and etcetera."* However, according to IN#6 and IN#9 this rigidity can be linked the platform's certification as a medical device, rather than to S1 being a global organization. As explained by IN#9, S1 does not offer their platform - or parts of it, such as the tablet – in an unlocked state, because then other applications could (too) easily be integrated with it, whereby the certificate would void. As he suggests: *"therein we are fairly rigid, but every company that offers certified applications is rigid in that."* Besides, IN#4 suggests that it took many years before the original instructional videos of the platform, which were considered somewhat old-fashioned and pedantic, were adapted. IN#1 and IN#9 explain that the legal risks that could be involved when things are wrongly interpret, for instance, could bring along huge injury claims. From a legal and clinical evidence-based perspective, any adaptation to the system must be validated, which slows down the process of making adjustments.

Concluding remarks

Through feedback from users, the non-use that sometimes results from technological shortcomings, and upstream involvement of users in amongst others a large national pilot project, S1 has been learning about the needs of end-users (i.e. patients and nurse specialists mostly), as well as the required flexibility for tailoring system settings to user-specific requirements. However, it also comes forward that better feedback to users is required, and that a transition is required in the routines and attitudes of care providers towards RPM, in order to successfully implement the RPM technology. Also, the results suggest

that there are also downsides to the entity of a global organization and the medical label of the system to be flexible in their response to (articulated) user-specific requirements.

4.1.3 Generification strategy

Standard technical components are generally installed at the homes of different patients, including a generic application hosting device, such as the set-top box or a tablet, and generic measurement devices that are connected with this gateway. The set of measurement devices always includes a weight scale and blood pressure meter and depending on their conditions, some patient are equipped with a blood sugar meter[8], a pulse oximeter or peak flow meter, or allowed to manually enter data from their own devices (SD1b, 2015). S1 does not change the set of generic devices they offer within configurations because the current set of devices works stable, and because they are part of a certificate (IN#9). Further, the adaptations made to the platform – such as the offering of new generic devices and software improvements regarding the available intervention rules - are adopted into the whole platform, and S1 offers the newest as well as one previous product version of their platform (SD1b, 2015). This means that everyone that purchases and uses the system adopts the last or penultimate improvements. An employee of S1 (IN#8) suggests that if S1 would need to spend a lot of time in customization for each customer, it would cost a lot of money, reducing or negating the added value of the system. Thereby, IN#8 suggests that it is not desirable for S1 to make the platform endlessly configurable, and respond to all the different requirements in the market. S1 only departs from a generic approach if a specific adjustment is considered really necessary (IN#1, IN#8, IN#9). As IN#9 argues: *"not everyone should per definition get his own way, and you need to manage that, which we can do better and better because we know the large common denominators."* Moreover, S1 does not respond to rare or exotic wishes, since they believe that it not necessarily leads to a better result of the RPM process (IN#9).

Nevertheless, as explained in sections 4.1.1 and 4.1.2.2, the platform leaves room for users to select or not to select certain features such as the educational component or the medical service center, as well as flexibility in the setting of intervention rules, and specific offering of educational content, for instance. Although no local adaptations – e.g. in a specific hospital – are made to the platform, some flexibility for tailoring is offered within the generic platform. Moreover, as explained in section 4.1.1.2, S1 is putting efforts into increasing the flexibility for individualization of the settings of the generic platform.

Concluding remarks

S1 delivers a standardized RPM platform which is regularly being updated with supposed improvements, mostly in software. However, within the standardized setting flexibility is offered to select features and system settings and allow care providers to use the system in such a manner that the RPM system can be adapted to their and their patients' needs. Hereby, the potential negative influence of standardization on the tailoring of the RPM systems to user-specific requirements may be somewhat negated.

4.1.4 The use of design standards

As discussed in the following, standards are used and co-developed by S1 and helping them during the (re-)configuring of their RPM system. Besides, flexibility is left within standards to be applied to specific contexts-of-use, and how users are involved in this standardization process, in order to help tailoring standards to these users' requirements. Also, standards help S1 in their aim to gradually make the shift towards integrated care for chronic patients. Lastly, achieving interoperability is not only a question of using standards, but also of S1's willingness to connect with certain components.

4.1.4.1 Use and co-development of standards by S1

S1 builds their platform by taking components from different vendors and integrating these with each other to deliver an entwined service. Importantly, S1 is involved in an international standardization

[8] Chronic heart failure is often accompanied by diabetes type II, for instance, which calls for a broader treatment approach.

alliance (involved organization S, IOS) in which different companies collaborate and make compromises about standards. IOS consists of different taskforces that focus on stimulating the interoperability between different parts of the end-to-end architecture of RPM configurations, among which the system of S1 (IN#8). An employee of S1 and chairman of IOS (IN#8) explains that S1 is dependent on other parties to comply with the same standard guidelines of IOS in order to achieve interoperability with their systems. As IN#8 simply puts it: "*it would help if the other vendors would also implement these standards."* The IOS standard guidelines focus on two different interfaces: the PAN interface and xHRN interface (SD1c, 2015). As explained in Wartena et al., (2009), PAN interfaces describe the connection between devices such as sensors and application hosting devices, and xHRN interfaces describe the connection between back-end services, for instance the back-end server of S1 and information systems or electronic patient records of the user organization, which are often under control of different companies. As IN#8 explains, specific standards are available for each of the interfaces used in the RPM configuration of S1, *"and the work is going on"* because *"more critical care devices are coming into the home […] and that means that a standard needs to be developed for them"* (IN#8). This suggests that the standardization processes continues because new types of devices or subsystems are still being integrated into RPM configurations. Besides, IN#8 argues that *"it would still take time for all vendors in the field to see that everyone is conforming to standards, and to see that there is interoperability"*. No clear expectations were formulated with respect to the time span that is needed before seamless interoperability is reality, and before abundant devices are available in the market.

4.1.4.2 Flexibility of standards and co-creation of context-specific standards with users

The IOS standard guidelines are focusing only on the supposedly necessary aspects to be included, and the standards mostly leave flexibility for vendors to come up with proprietary extensions to the standard, for instance when they want to extend their product with certain features for which no interoperability guidelines are formulated, or if they do not want to declare their extensions publically and keep the advantage from an intellectual property perspective (IN#8). According to IN#8, standards do not seem to lead to any functional limitations with respect to responding to user-specific requirements. The standards being used primarily focus on the data pieces that go from one system to another, and what the message should look like. Basically, how vendors technically work out things internally – within a system, within a device – is not being boarded up (IN#8). IN#8 argues that IOS does *"not say anything about how you process that information"* or *"how you show that information to your user"*, and that standards leave sufficient room for innovation. Importantly, the standardization processes of IOS, as well as those of other standardization organizations are taking place in co-creation with users, as use cases are applied that *"build a bridge between the healthcare sector and the information-technical world"* (Klein Wolterink, 2013, p.7). Use case working groups of IOS assess from the perspectives of different users what their workflow and required interoperability is. Standards and interoperability guidelines are often insufficiently specific to directly derive context-specific standards, whereby use cases are applied in which is being worked together with users – including care providers, patients and or patient representatives – ICT suppliers, and information experts, in order to make concrete agreements about how specific information must be exchanged in specific situations (IN#8; Klein Wolterink, 2013).

4.1.4.3 Contribution to the shift towards integrated chronic care

IN#9 suggests that S1 aims to contribute to the transition in healthcare towards integrated chronic care, and that S1 has learned from the market that people are prepared to transpose the whole care process on one single platform. IN#4 (nurse professional) suggests that close links with the GP and home care are suggested to be important to realize this. Therefore, S1 aims to create one technical environment around the patient by integrating their platform with GP Information Systems and Chain Information Systems (IN#9). Interestingly, this development also responds to a concrete shortcoming of the original

platform about which care providers using the RPM system have been complaining for years, namely the missing integration link between the platform's dashboard and the hospitals information systems (i.e. electronic patient dossiers, EPD) (IN#1, IN#4). Due to the lack of integration, care providers are often forced to work in two different dashboards at the same time – i.e. the RPM system and EPD – and to compare results one on one. This is detriment to the efficiency of the RPM process. S1 is now offering such an integration, and at different sites such integrations are actually being realized (IN#1).

4.1.4.4 The question of willingness to connect components

However, interoperability is not only a question of using standards. In practice, realizing integrations between S1's RPM system and hospitals information systems is often difficult and largely depending on the willingness of the supplier of the other system to open things up, and the willingness of hospital IT departments - who are often overloaded with work - to connect their systems (IN#9). Moreover, information systems of hospitals and GP's are suggested to be often closed system, not designed to be integrated (IN#1, IN#9). Furthermore, regarding the limitations of the RPM system of S1 to be reconfigured with different devices, and in relation to the standardization of their platform as discussed in section 4.1.3.1, interoperability with devices appears not only to be dependent on S1's technical ability to integrate the components in their RPM system, but also on whether the S1 has a policy of allowing or restricting certain brands of devices, and what integrating the device costs. In this line, S1 is still reluctant to integrate their platform with other devices because of anxiety that errors can be occur during data transfer and the associated damage that could possibly be recovered from S1. Therefore, quality and reliability of additional components is a main factor in the decision for S1 to connect their system with these devices (IN#1, IN#8).

Concluding remarks

Standards are important to help achieve interoperability and configurational choice within their RPM platform, thereby helping to tailor the RPM system to user-specific requirements. Moreover, standards help to shift towards an integrated care approach, as they are important for making integrations with existing information systems. However, common standards are not the only condition for achieving interoperability, but different parties must also be willing to integrate their components. Further, S1 contributes to the standardization, which often takes place in co-creation with users, thereby allowing a better fit with their specific requirements.

4.2 CASE 2

4.2.1 Case profile

Supplier 2 (S2) has a web-based platform from which they have developed different online e-coaching programs for a variety of chronic illnesses, including heart failure, COPD, asthma, diabetes type II, inflammatory bowel diseases (IBD), Parkinson's disease and other forms of dementia. Figure 3 displays from what components and associated functionalities the e-coaching programs are built up. This is explained in the following, including how the programs are tailoring to user-specific requirements.

The ***online coach*** is a personalized and secured computer webpage - sometimes offered as mobile application as well - which supports both the patient and care provider in the treatment of the specific chronic disease the program focuses on (SD2a, year.na). At the side of the care providing organization, the coach is being used - generally by nurses or nurse specialists of a back-office in the hospital – separately from their *hospital information system* (IN#3, IN#22). All data gathered and entered into the coach runs through and is stored in the ***central server*** of S2, which exchanges data between the coaches of the patient and the care provider(s). As listed in figure 3, the coach include different modules with different functionalities (SD2a, year.na): first, through *knowledge cures*, personal development of

knowledge and capabilities regarding the disease treatment is offered, by allowing patients to choose which educational modules they want to follow at a specific moment. They are advised on this by their care provider (IN#3). Second, an *individual care plan* aims to provide more insight to patients into their own development and it should lead to more intensive involvement of patients in their entire disease management. Third, patients are asked to update their healthcare conditions through a *periodic health check* with questionnaires, with varying frequencies depending on the specific program. Fourth, an *exacerbation monitoring module* is included; if the patient has more symptoms than normally, then this module enables caregivers to temporarily monitor the patient through weekly gathered signals and complaints regarding their disease (SD2a, year.na). Fifth, patients as well as care providers can remotely ask questions through *e-consults* (text messages). Sixth, patients can set personal goals and *reminders,* for taking medications, for instance. Last, in some programs, for instance for heart failure, it is possible for patients to remotely *monitor vital signs* (IN#13), implying that patients can manually enter vital sign data into the webpage or app, and care providers then remotely check the outcomes. In principle, the remote patient management primarily takes place through the answering of questionnaires and eventual transfer of additional (measuring) data by patients, and the associated response of care providers through the e-consult functionality or by telephone, if necessary (IN#22). As suggested by a board member of S2 (IN#13), every program of S2 can be specifically set to a patient's personal needs. This will be further addressed in section 4.2.2.2.

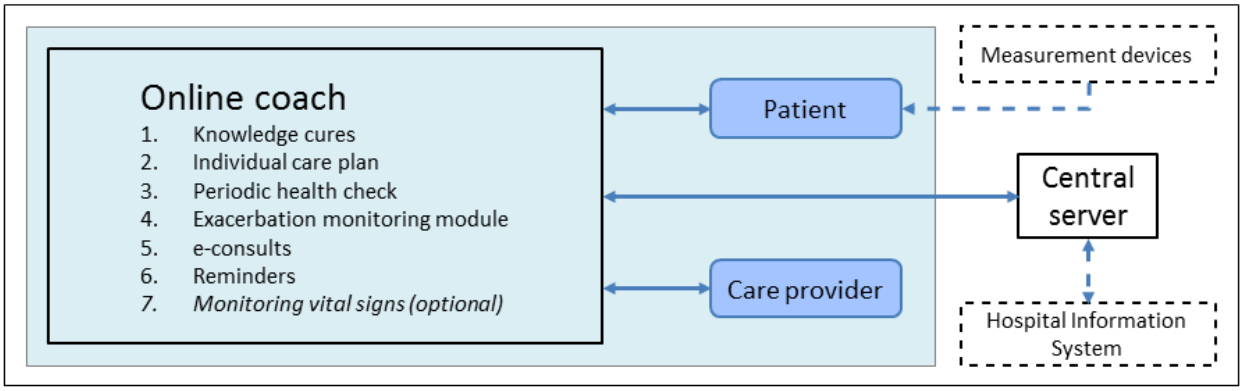

Figure 3: Visualization of the configuration of the e-coaching program including integrations with other components. The dashed boxes and lines imply that components and linkages are not standardly included in the configuration.

Although all e-coaching programs are developed from the same generic platform of S2, not every program is developed in the same manner and especially in content they differ greatly. In the remaining part of this case description, the development processes of two specific programs - i.e. for heart failure and IBD - are addressed as examples and for more in-depth clarification.

4.2.2 User involvement

In this part, it is first discussed how S2 develops and improves the programs in co-creation with the direct end-users of the applications. Second, it is explained how user involvement has contributed to improving the flexibility for the programs to be tailored to user-specific requirements. Third, it is addressed how the feedback of the first users influenced the continued development of the applications. Thereafter, it is shortly discussed how complaints and non-use influence the RPM applications and their fit with user-specific requirements. Lastly, it is argued that S2's attention for supporting the implementation of their programs has increased.

4.2.2.1 Program development and improvement in co-creation with direct end-users

The e-coaching solutions of S2 solutions are demand-driven and developed by teams in which care providers that will finally use the applications take part (IN#3, IN#13, IN#22). S2 develops the programs

in teamwork with care providers, patients and patient associations, and the involvement of patients or their representatives always runs via the specialists and/or specialized nurses. As IN#13 puts forward: *"It is not that we are stepping towards a patient association. It is usually so that when we get involved in something, then one actually works together with patient associations already. And in the development of the coach, also in the tests, the patients are involved again."* Where the main expertise of S2 regards the e-coaching software format and the interplay between different parties during development, the specific medical knowledge required for the development comes from the medical specialists involved (IN#13). Depending on the specific program, a development team can include doctors, physiotherapists, specialist dieticians, patient representatives or patients themselves (IN#13). Talking about this issue, IN#13 remarks that the level of multidisciplinarity within developing teams has increased throughout the years. Involved professionals find each other's discipline increasingly important, and acknowledge that it helps optimizing and fine-tuning the solution. Further, IN#13 claims that user involvement would offer limited benefits if S2 - as a developer - would not show the range of possibilities to the users. IN#13 believes that S2 is the party within the developing team that is most aware of the new technical possibilities, and that it is therefore important to manage the user involvement process through targeted questioning and showing them possibilities. This thought is supported by IN#22, who suggests that S2 has put forward many ideas during the development of the IBD e-coaching program.

Different results suggests that end-users have significantly contributed to the development processes. As suggested by IN#13, the exacerbation monitor module was originally not included in the programs, but this module was developed and integrated after the explicit request by care providers to develop something for the timely tracking of exacerbations (IN#13). In fact, a heart failure nurse professional (IN#3) of user organization 2A (U2A) - who scientifically studies the effectiveness from the solution and helps making improvements accordingly - suggests: *"everything that has changed is done on advice from us."* Further, an IBD specialist (IN#232) of user organization 2B (U2B) that is involved in the development of the IBD e-learning program suggests that when starting the development four years ago, their developing team involved and had meetings with doctors, specialized nurses, patient associations and patients. At the start, the Dutch patient organization for IBD (i.e. Crohn's disease and colitis sclerosis) - which is by IN#22 suggested to be very active and having a large number of members – articulated the requirements that the communication between patient and hospital should be intensified, that the approach should become more personal, and that much more different information about the disease should be provided to the patients, because it is a very heterogeneous disease, and no two patients are alike. Furthermore, the thirty resulting e-learnings (knowledge curses) that are included in the IBD e-coach are mainly written by nurses from U2B, because they are believed to be standing closer to the patients than specialist doctors. Also, a content commission has been set up, consisting of doctors, nurses and patients, and amongst others reviewing the educational content of the platform every two years at least (IN#22).

4.2.2.2 Influence of user involvement on flexibility for tailoring the programs

The results suggest that the programs have been increasingly personalized over time. IN#3 explains that personalization is preferably done at the level of the patient, but that this was not possible for the initial heart failure e-coaching program. In one paper (SD2b, 2011), IN#3 explains that in order to better meet patient-specific requirements, four groups of patients were created that distinguished themselves, and four different programs were designed for these groups with different emphasis on the dialogues about knowledge, compliance and symptoms. Nevertheless, as IN#3 suggests: *"We have continued to ask* (S2) *to further personalize at the level of the patient. And now with the heart failure coach that is possible."* As explained by IN#3, personalization at the level of individual patients is realized by separating the components of monitoring symptoms and offering educational content. As she explains: *"when someone has a lot of complaints, you can start monitor more frequently without necessarily offering him more*

education […] A patient with limited mental capabilities […] gets another offer than someone in such consultations with an college or university education […] and moreover, in the early stages of a patient using a coach, the level of alerts will be higher than after a period of time, because you also have the factor that the patient should get used to e-coaching." (IN#13). Also, based on complaints from patients and care providers, adaptations were also made in the questions asked in the period health checks of the heart failure e-coaching program. Initially patients were asked exactly the same questions every time, no matter what their complaints were, while they are now more often asked questions when they have many complaints and less often when they have few complaints. IN#3 suggests that the heart failure e-coach now automatically adapts its settings to such requirements (IN#3). In line, IN#13 poses that in the near future, S2 aims to realize the development towards a self-learning system through integrating artificial intelligence, allowing more decisions to be left over to the system – also in the alerts, for instance. Lastly, IN#13 explains that the e-coaching program can also be tailored on the side of the care provider: "*a specialist […] has the ability to fine-tune it to his insight. So there is a certain format, which is a main structure with a certain methodology […] but it is fine-tuned to the patient and the practitioner."*

4.2.2.3 Feedback from the first users on the continued development

IN#3 states that feedback from the first users of the heart failure e-coaching applications has primarily been gathered through focus interviews, and that beyond such interviews suggestions for improvements are generally not put forward by separate individuals (IN#3).. As IN#3 argues: *"In principle I think they have been sufficiently involved to express their views and have their say."* However, she adds: "*you should not overestimate the role of the patient in this whole."* This suggests that the influence of patients' feedback is not considered very large, yet they are considered to be sufficiently asked for their views. Besides, the feedback is suggested to be mainly associated with the content of the platform, rather than design aspects. Interestingly, a major issue that came forward was that some patients like some systematic and fixed program, rather than the freedom to make choices themselves. Patients have gained more freedom to choose educational content, but as suggested by IN#3, some patients articulated that they would like to have a fixed program. As IN#3 argues: *"with that they actually say: 'we do not want the freedom we get'."* However, it is acknowledged that the people who gave this feedback were not reflecting the entire target group. Therefore, as a result, both the option for flexibility in the program and the option to run through a fixed program in the first three months are offered (IN#3).

Regarding the IBD e-coaching program development, a small pilot with 30 patient was held in 2013, with positive results regarding patient compliance and high satisfaction scores. Currently, the IBD e-coach is in a phase of quantitatively studying the program's effect on thousand patients supported by four different hospitals (IN#22). It is explained by IN#22 that the developing team aims to broaden their development process by involving a heterogeneous user population. This is firstly realized by applying a randomization tool to this pilot, and stratifying the sample on the basis of gender, type of disease (i.e. Crohn's disease or colitis sclerosis) and the type of medication used. Secondly, this is a multi-center study, and four different hospitals throughout the Netherlands - two academic and two peripheral, regional hospitals which vary in their organizational structure - are joining the pilots. As IN#22 argues: *"We have always thought very well about that it is not going to be an academic trick. […] And I do not want it to be only for very complex patients either, but really for the full scope, so that is why we also involved the peripheral hospitals."* As will be discussed in 4.2.3, this broadening process may contribute to developing an application that is robust among different local settings. Besides, the primary focus of the study on outcomes such as hospital visits, rates of complications, medication adherence, and etcetera, a secondary focus of the study will be to retrieve feedback for improvements (IN#22). Furthermore, IN#22 puts forward that they also want to finally make statements – based on the research – about for what kind of users the program is optimally suitable. This indicates that involvement of end-users during early

use of the application helps to better understand users, and to eventually make improvements accordingly.

4.2.2.4 The influence of complaints or non-use

As suggested by IN#13, complaints of patients and *non-use* are recorded by S2, though few patients that follow the program actually show some form of resistance. As IN#13 states: *"in our experience, people who start working with e-coaching become attached to it. […] at a given time it has become part of his sense of security. I mean, certainly with a rather distressing condition it is pleasant that you have attention, that you are being watched, that strengthens the patient"* (IN#13). Still though, it comes forward that the group of older users remains to be a relatively difficult target group, since they are not used to working with online solutions[9] and a computer, for instance (IN#13). In contrast, a co-developer of the IBD e-coaching program (IN#22) explains that for this particular application young patients are actually more often non-users. As IN#22 puts forward: *"In fact, we thought it was going to be something especially for young people, but the funny thing is that it is mainly something for people in their thirties to sixties-seventies and our twenty-year old [patients] often do not want it. And the reason is that they say: 'yes, but if it goes well, then I do not want to be confronted with my illness."* IN#22 poses that in a later phase probably some effort will be put into stimulating such non-users to use the e-coaching application, but that the focus now is to first optimize it for actual users. Furthermore, some results indicate that non-use is taken seriously, but that it is considered to be sometimes insuperable. As IN#13 explains: *"there are also older people that are done with it after several weeks. And […] you can actually do little about it."* Moreover, IN#3 complements that this is not necessarily a bad thing: *"That is not that people are dissatisfied. But then it is good, they know how it works […] and what is expected from them."* Overall, the results point out that S2 and the developing teams of specific programs are actively considering what factors cause non-use, and if and how this can eventually be addressed.

4.2.2.5 Supporting the implementation process

As suggested by IN#13, the use of the e-coaching programs is perceived to initiate the shift towards a new way of working within healthcare, though these programs must first be gradually introduced next to the old way of working. Therefore, throughout the years, S2 has spent an increasing amount of attention to the implementation of their e-coaching programs (IN#13). IN#13 argues that it is important for users to gradually learn in what way the newly introduced solution delivers the expected or required results, and besides, the old routines of care providers must gradually be adapted accordingly. Also, he suggests that it must be acknowledged that over time, patients following an e-coaching program learn about the possibilities the application offers them – both through the usage itself and through the educational knowledge cures.

Concluding remarks

User involvement has strongly influenced the tailoring of S2's RPM applications to user-specific requirements, since the e-coaching programs are developed in co-creation with amongst others care providers specialized in the specific illnesses that are addressed by the respective programs. In order to keep improving and scale the use of the programs, collaboration continues. Besides, users must gradually adapt their routines to the way of providing care that accompanies the e-coaching programs.

[9] As argued by IN#3 and IN#13, the first e-coaching programs of S2 were offered through a RPM device with four control buttons of an international manufacturer, and thanks to its simplicity and usability, older patients had better compliance with this old option of using a four-button device, than with the current online solutions. However, as suggested by IN#13, major shortcomings of this device came forward during its use, as it did not support all Internet facilities, and many young patients wished to follow a program via devices such as tablets or smartphones. Therefore, over the years, S2 made the transition towards an online platform and the cooperation with the four-button device manufacturer was finally terminated (IN#3, IN#13).

4.2.3 Generification strategy

As follows from the above, the modular nature of the applications and flexibility in their settings enables users - i.e. care providers and patients - to tailor and vary the specific program among different individual patient management processes. Furthermore, S2 delivers demand-driven solutions, which are developed in co-creation with care providers of specific hospitals that will finally use the solution. In this line, an issue regarding the upscaling of the adoption of the e-coaching programs that is put forward by multiple interviewees (IN#3, IN#13, IN#22), and which relates to the customization of the e-coaching programs, is that is many care providers or hospitals do not want to use third party solutions because of their external origins. IN#22, for instance, suggests that it is a very Dutch thing for hospitals to want to invent their own systems. As IN#13 underlines: *"The tendency to keep reinventing the wheel over and over everywhere is very large. […] I still do not understand why all things developed in [city] regarding tele-counseling and e-coaching of heart failure take so much time before taken elsewhere."* Nevertheless, it is also suggested that the solutions are slowly starting to be adopted by other care institutions – i.e. which were not involved during development - as well (IN#3, IN#13, IN#22). In order to stimulate this, the developing teams do not only focus on problems at their hospital, but also on the national problems regarding RPM, because healthcare is not arranged in the same manner everywhere (IN#3). For instance, as addressed in section 4.2.2.3, the IBD e-coaching program is being tested in four hospitals that are differently organized. This points out that through broadening their development process, the developing teams aim to finally develop a solution that is robust among different settings. However, because S2 is a commercial organization, adaptations and improvements to S2's applications are only made when that the involved user organization(s) can pay for the efforts, and as suggested by IN#22, this is sometimes (i.e. when the money runs out) hindering or delaying the improvement process.

Concluding remarks

The flexibility for tailoring the programs to user-specific requirements lies in de modular nature of the standardized applications. Disease-specific programs are currently being developed and somewhat customized to specific user organizations, though the design process is broadened with the aim to finally offer solutions that are robust among different types of user organizations, stressing the applicability of a generification strategy, and its moderating effect on the nature of user involvement.

4.2.4 The use of design standards

Regarding the optional feature of remotely measuring and monitoring vital signs, the set of measuring devices that can optionally be used together with the e-coaching programs is still limited. IN#13 puts forward that an increasing amount of devices is qualified and considered reliable, but that the development of interoperability and associated standards is an ongoing process. Furthermore, as addressed in the following, standards can – in potency - help to realize integrations information systems of user organizations, thereby contributing to the tailoring of the e-coaching programs to user-specific requirements. However, as comes forward, the unwillingness of parties to connect their systems hinders such integrations to be made.

S2 has not integrated their e-coaching programs with other information systems being used by healthcare providers in the hospital. IN#22 suggest that the IBD e-coaching program is currently being used as a 'standalone unit', and that an integration with the hospital information system is deemed desirable, because it requires a lot of discipline of the professionals in the back-office to work with two different systems and to ensure that important data is manually transferred into the systems (IN#22). In fact, as IN#3 suggests, in some use practices (e.g. at U2A), the lack of such integrations strongly hinders the potential of RPM, and *"you do not even get out 5% of the possibilities it has"* (IN#3). IN#3 argues that the only benefit for nurses is that they can daily monitor the patients' health conditions and contact a specialist, if necessary, but because nothing is automatically loaded into the electronic patient dossiers

this leads to a lot of unnecessary work for care providers, as they have to manually enter the data in a hospital registration system. Thereby, the e-coaching solution is in fact being used as an add-on rather than integrated into the healthcare process (IN#3). Importantly though, IN#13 puts forward that lack of standards does not hinder the realization integrations with other systems; *"We have never seen that we could not work together or come to an integration because of the point of a standard. I have not yet experienced that."* As confirmed by IN#3 and IN#22, S2 uses a system that is linkable to hospital information systems without too many efforts. The HL7 (Health Level 7) standards are put forward as an important group of standards for S2 to apply in order to realize such connections. In fact, as IN#22 poses: *"we even know how they calculate the working hours for doing that, and it is the thought that if you have linked once with SAP[10], then that will be easier to do again in the future. And if you have coupled once with Epic, then in the future it will be going easier."* This suggests that in principle, S2 is technically able to integrate their application with information systems.

However, as explained in multiple interviews (IN#3, IN#13, IN#22), a lack of interoperability is an issue of reluctance of hospitals to connect their systems, caused by anxiousness for errors, for instance, rather than lacking availability and use of common standards. IN#13 suggests that it must actually be enforced at ICT-departments of hospitals to put efforts in realizing integrations. Multiple interviewees (IN#3, IN#13, IN#22) argue that interoperability is surely considered important by the care providing organizations, but that this is still an ongoing and laborious process. IN#22 poses: *"you have to negotiate that separately with each hospital, and it is difficult […] because of all the security. The bosses of the IT departments are sitting on top of that."* IN#3 explains that due to the relative novelty of RPM, hospitals have not yet figured out how to solve the interoperability issue, and as she declares: *"I think it is true for all hospitals, but I will speak just for our own hospital […] that the entire telehealth and remote care is relatively new. […] Everything is tremendously secured […] and they now get connections with other systems which may possibly arise data leakages. Those are potential problems over which a hospital […] should determine how to give it hands and feet."* Further, IN#3 puts forward: *"A hospital – and certainly an academic hospital – is just a very viscous institution, and I think I am already trying for three or four years to get that interoperability of the ground. […] It is going to change, I have no doubt. The only question is: how long does all that take?"*

Concluding remarks

Firstly, standardization for interoperability with measuring devices is suggested to be an ongoing process. Secondly, integrations of the e-coaching programs with information systems of user organizations are deemed important for care providers to efficiently use the solution, and due to the lack of these integrations the programs are currently used as an add-on rather than integrated into healthcare. However, the lack of integrations is not caused by lack of standards, but rather by the unwillingness of hospital ICT-departments to connect their systems.

[10] SAP and Epic are two of the major suppliers of Hospital Information Systems in the Netherlands.

4.3 CASE 3

4.3.1 Case profile

The web-based RPM platform of supplier 3A (S3A) is focusing mostly on primary care and designed for RPM of chronic patients with heart failure, COPD and diabetes type II. Figure 4 shows the main components of the platform configuration, including external components of the configuration with which the web-based RPM applications of S3A can be integrated.

A core principle of the platform is that for every patient an *individual care plan* can be set up by the care provider, in which goals are set and associated actions are formulated. As one employee of S3A (IN#5) explains, algorithms that are based on medical and lifestyle parameters are used to realize personalized offering of content to the patient, such as care plans, instructions, latest risk factors, and etcetera. As another employee of S3A (IN#10) puts it: *"the care plan in principle implies that activities of all types are offered in the portal, in a particular sequence, with certain dependency and certain intervals in between. […] And if you meet a number of characteristics, or have condition A or B […] then the system can automatically assign care plans."* In order to ensure that patients can still make some decisions themselves, the pathways that guide patients (and caregivers) can also be adjusted on demand. Patients can access the platform via their online ***patient dashboard***, and care providers – i.e. generally by a GP or a nurse practitioner[11] - access via the online ***professional dashboard***. In between the patient's and care provider's dashboard, a ***back-end server*** ensures that all data is stored, and that it can be retrieved when the user in question has access to this information (IN#5).

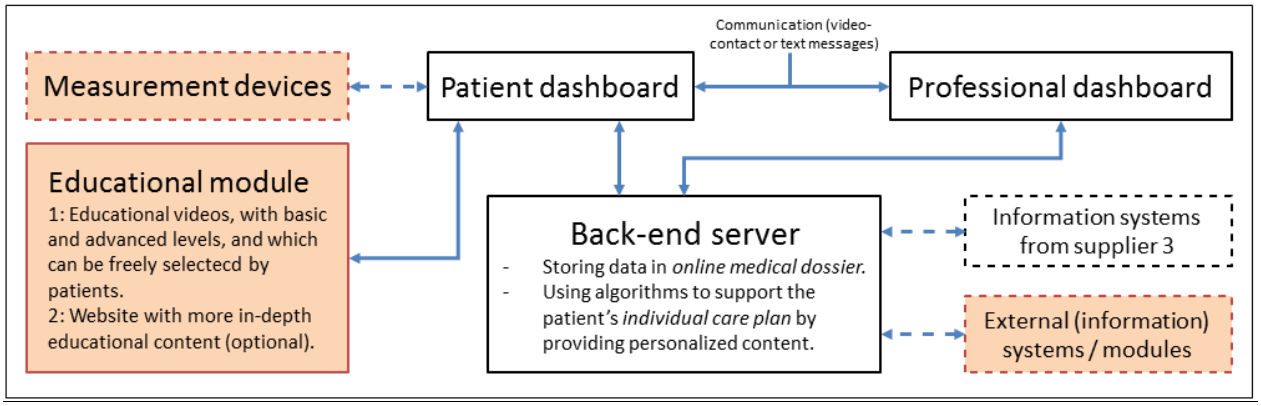

Figure 4: Visualization of the web-based RPM platform configuration of S3A. The dashed boxes and lines are optional components and linkages, and the colored boxes are software or hardware components are not developed by S3A, but (optionally) integrated into the RPM configuration.

The platform offers the following functionalities to be accessed via the user's dashboard (IN#5): firstly, patients and care providers can look into the patient's personal treatment goals, current information on risk factors, medication, lab results and vital signs, and they can update medication lists, submit requests for prescription refills in their *online medical dossier*. Secondly, patients and care providers can have secured communication, initiated by either of the actors, and through video-contact or text messages. Thirdly, S3A offers the option for patients to perform measurements and to enter them -either automatically through connected devices, or manually - into their online medical dossier, in order to enable care providers to remotely monitor the measurements. Patients are - in consultation with the care provider – free to determine which devices they use in combination with the platform, but S3A does not offer technical integrations - that allow automatic transfer of measurements - with many ***measurement devices*** yet. However, as suggested by IN#5, this is strongly upcoming. Lastly, patients can

[11] Nurse practitioners often take over tasks from the GP that are related to chronic care.

enter into an ***education module*** that is integrated with the RPM platform, and developed by supplier 3B (S3B), a supplier of educational material for a variety of diseases. The director of S3B (IN#21) explains that on the educational module, patients can watch a variety of educational videos at the basic or advanced level, or when they are well-advanced in education, they can click a link to a website with more in-depth educational content. The patient's knowledge level is assessed in a short questionnaire. As IN#21 puts it: "*the personalization is not done within the content, but the nurse practitioner actually determines what is important for the patient at that time."* The patient has access to all videos and is free to watch videos according to personal preferences, but they are advised on this by the care provider, and care providers can look into the patients' activity in the educational module.

As explained by IN#5, the platform contains a set of generic components - i.e. modules - from which S3A constructs RPM applications, specifically for their clients. This means that S3A does not separately program RPM applications for different clients, but rather construct client-specific applications from one generic RPM platform (IN#5). Besides, IN#5 suggests that S3A has left much room within the modules for fine-tuning the final solutions to user-specific requirements. This will be more thoroughly addressed in the following sections.

Over the last years, S3A has been improving and further developing their original RPM platform into a renewed platform that will be commercially implemented on the Dutch market in 2015. In the meantime, and since 2009, the platform has been used in a national pilot project initiated by involved organization T (IOT). IOT is an independent foundation and consortium between two main organizations in the healthcare field aimed at upscaling the use of RPM services in the Netherlands, and they have instructed S3A to (re-)build their original platform (version 1.0) with main inputs from IOT, in order for the new platform (version 2.0) to be used in separate pilots for heart failure, COPD and diabetes type II (IN#10, IN#17). In section 4.3.2.2 will be more thoroughly addressed what S3A has specifically learnt from the pilots. S3A has independently continued the development of their platform in parallel (version 3.0), and while the pilot project of IOT is almost to its end, S3A soon starts commercial implementation of their renewed RPM platform (3.0) as a market product (IN#10, IN#17).

4.3.2 User involvement

In this paragraph, it is discussed in what ways users are involved by S3A, IOT and S3B, and it is explained how this influences the tailoring of the system to user-specific requirements. First, it is discussed how S3A involves users during the development and implementation of their solutions. Second, it is discussed that the scientific pilot project initiated by IOT is using the system of S3A to characterize users - patients mostly - and learn about their requirements, and how this project contributes to the development of the RPM platform of S3A. Here, also some limitations are discussed that have come up during the pilot research with respect to user involvement and the possibilities for tailoring the system to user-specific requirements. Third, the user involvement during the (continued) development of the educational module of S3B is addressed. Fourth, it is discussed how S3A, IOT, and S3B are broadening user involvement processes by deliberately involving heterogeneous users, in order to create conclusions that are robust among different settings. Lastly, it is discussed that user involvement is deemed important by S3A to guide users during implementation and help to embed the RPM system in their practices.

4.3.2.1 User involvement by S3A

In the following, the involvement of RPM platform users by S3A will be discussed, including that such user involvement is still in its infancy, but being set up. Also, it is discussed that the perspectives of patients are planned to be increasingly assessed by S3A next to the involvement of care providers.

IN#5 explains that user involvement specifically for the RPM applications is still in its infancy, because the commercial implementation of S3A's RPM platform is starting in 2015. However, as IN#5 suggests, the involvement of users of RPM applications is currently being set up in a similar way as for other product

lines of S3A, e.g. for Chain Information Systems, which are more established. With respect to the other product lines, IN#5 suggests that there is an ongoing process of having meetings with specific clients (i.e. care organizations), involving them in design and development, and taking their inputs into new developments. In fact, IN#10 suggests: *"clients of the Chain Information System are now adding self-management to their service pallet. Those are things that we enter into long-term relationships for."* This implies that (some of the) users of the RPM applications they will involve are existing and already involved users.

Regarding the continuous development of the generic platform, S3A works closely together with for instance, intermediaries such as a Dutch federation for heart doctors are suggested to be providing important inputs as well as inspirations for complementing and adapting the content of the platform (IN#5). Besides, IN#5 and IN#10 claim that the platform is highly configurable, and that for a large part the client decides which tooling is made available within client-specific RPM applications. IN#10 points out that the construction of a client-specific application is a multifactorial process, partly steered by listening to the customer base in roundtable sessions, for instance, but also by S3A's own medical board with experts from the field and by scientific research. Importantly, it is considered essential by S3A to involve users during the development of client-specific applications from the generic platform in order to prevent that an application is *"technically wonderful, but not useful in practice"* (IN#5). Moreover, the technical employees of S3A – except for a few – do not have a background in healthcare (IN#5). During development of client-specific applications, meetings are held with a client, which is usually a (united group of) general medical practice(s). Through the feedback of the involved (first) users, S3A aims to optimize the product before they finally deliver and implement the application for the specific client, in order to prevent shortcomings to the application afterwards. When drastic conversions have to be made after implementation – and this sometimes happens – this namely causes a whole aftermath in the management of the application. Furthermore, IN#10 argues that it is important to have a sense of control and expectation management while involving users and asking their feedback. S3A does generally not stimulate users to come up with whatever specific requirements they may find important. When asking patients what they want, it is deemed important to do some forward thinking and propose ideas and options that are technically feasible, instead of only asking open questions and end up with a too much feedback and many unfeasible wishes and outcomes. Besides, IN#10 suggests that it may be important to prevent that end-users get the impression that all their wishes will be responded to, because it may lead to disappointment whereby S3A may not get them involved anymore later on.

The above results suggests that only care providers are being involved in the development of the client-specific RPM applications and platform, but IN#5 puts forward that the perspectives patients are increasingly taken into account by S3A. The perspectives of caregivers are generally the starting point during developments of S3A, and they generally form the intermediary bridge to patients' perspectives as well. As one employee of S3A states: *"We speak - except in soundboards - relatively little directly with the patient, because we have no formal relationship with them, and the data is not ours. That is all neatly separated."* (IN#5). However, IN#5 suggests that in 2015, it was decided to start using a more structured approach to involve patients - either together with caregivers, or in separate meetings - during the continued development of their applications. Although this process still needs to be shaped, they aim to hold patient panels in the form of meetings, as well as structured tests with respect to the usability, logic, user interaction, design, and etcetera from their perspectives.

4.3.2.2 Scientific pilot project of IOT to characterize users

In the following, it is explained how the project of IOT is amongst others focusing on understanding the requirements and behavior of users – patients mostly – and their requirements, and how this helps improving the RPM platform of S3A. Thereafter, some limitations are shortly discussed regarding the

possibilities for user involvement and the possibilities for tailoring the system to user-specific requirements during the project.

4.3.2.2.1 Understanding the requirements and behavior of users

Since 2009, IOT is running three pilots with S3A's RPM platform (version 2.0) that separately focus on RPM of diabetes, COPD and cardiovascular diseases. Attached to these pilot projects, IOT has launched scientific research at six Dutch universities which for instance investigate how users interact with the software and what information is, or is not, important for them.[12] A researcher (IN#20) in persuasive healthcare technology at one of the involved universities (involved organization W, IOW) explains that their research group is examining how existing RPM applications as well as new ones can be better aligned with the requirements of users (including patients, care providers and other stakeholders), in order to make sure that they will use it on the long term. The research of IOW is amongst others dedicated to the analysis and mapping of trajectories through which different patients move along while using the self-management platform (IN#20). Via periodic questionnaires taken during the pilots they explicitly determine on what characteristics (e.g. age, gender, RPM skills, quality of life, etc.) different users are different or similar to each other. Such information is then linked to log data that is collected about different use aspects – e.g. when they use education and with what frequency (SD3a, 2014; IN#20). In this way, IOW aims to set up a variety of user profiles. Through log file analysis, IOW aims to map 'patient journeys', i.e. the routes and patterns in the use of the platform - e.g. how different functionalities are used together, or when users fall out - in order to determine how the platform can be adapted in order to optimally fit with how users use it, and thus make the platform more persuasive. Most results of the IOT project will be delivered and published in the course of 2016.

4.3.2.2.2 Influence of project IOT on S3A's RPM platform

Importantly, as explained by the director of IOT (IN#17), the project of IOT was initiated from a social perspective and the primary goal is not to help S3A build a new RPM platform. Still, recommendations for S3A have emerged from the project's findings on how to finally optimize their platform for end-users (IN#17). Additionally, IOW has done usability tests in which they presented different use scenarios to potential users of the platform, and on the basis of the gathered feedback, they formulated recommendations for S3A on how to improve the user friendliness of their platform. The findings from the usability tests are sometimes compared to the log data. As IN#20 elaborates: *"when you see in the log data that people often drop out when they start using the education, then you can of course also look in the usability tests for […] what are their thought with that, and why do they drop out there?"* IN#20 suggests that the recommendations are being followed up by S3A in the latest version of their RPM platform, but that they were rather simple in the sense that some components for instance looked like a button to users when they were not. IN#20 suggests that these recommendations are not as major as the findings that will finally be published at the end of the research phases.

4.3.2.2.3 Limitations to project IOT

Two limitations have been put forward regarding the possibilities for user involvement and the possibilities for tailoring the system to user-specific requirements during the project. Firstly, IN#17 and IN#20 argue that it was not possible to easily adjust some settings of the platform (version 2.0) used during the pilots when the adaptations were actually expected to retrieve better compliance of patients with the system. The experience gained through the project is connected to scientific research, and the research inputs are required to be set and stay constant over time. An exemplary restriction is that when patients seemed to have difficulties with following up tasks, it was not possible to bring in simple reminders to better seduce the patient to follow up these tasks. Although S3A has the freedom to make

[12] In this study, primarily the aspects of IOT's project regarding the use and users' needs are addressed, while the scope of this project is somewhat broader and for instance focusing on the assessment of clinical and cost-efficiency of RPM as well.

adjustments to their platform in parallel - which they did - a resulting limitation is that they could not test the adaptations in the pilots. Secondly, patients could not be additionally questioned by the researchers - e.g. of IOW to gain better understanding on use behavior - due to possible affecting of research and/or because patients did not sign a consent to be approached to this end (IN#17, IN#20). This causes difficulties for research teams to approach users for interviews or usability tests, for instance (IN#20). Accordingly, IN#20 suggests that it is very important for future research projects to keep such possible restrictions into account. Besides, as argued by IN#17, these restrictions are highly disadvantageous - also for S3A - because ICT developments and user findings are lately coming up very fast, which requires fast switching with users and constantly improvement of the product in order to be successful. This suggests that scientific pilot research brings along some difficulties regarding the potential of user involvement and improving technology accordingly.

4.3.2.3 User involvement during the (continued) development of the educational module

The director of S3B (IN#21) suggests that the educational software module of S3B - primarily its content - was developed with upstream involvement of nurse practitioners, who will use the system and link it to patients. Also, S3B has learnt much from feedback of patient groups using the module[13], and in an iterative process between development and testing they keep improving their module accordingly (IN#21). Besides, in a comparable manner to the log file analyses done by IOW - as discussed in section 4.3.2.2.1 - S3B also analyzes the behavior of patients in the educational module to learn which elements are often used and which are not (IN#21), and improve the system accordingly. Furthermore, scientific research was not only involved in project IOT, but also focused at the assessment of the use of the educational module. (IN#21) argues that in an independent qualitative research of a Dutch university, patients and nurse practitioners were interviewed in order to assess their experiences with the application of S3B. Outcomes were that the simplicity of information, the manner in which information is transferred, and the extent to which the program can be used on intuition were considered positive factors of the program (SD3b, 2014). The negative feedback gathered is not yet published, but the director of S3B (IN#21) suggest that much useful feedback was derived and used to make improvements, for instance on obstacles in the use such as difficulties with entering passwords. Furthermore, similar outcomes were gathered a six-month pilot study by S3B among nurse practitioners and patients assessing the use of the educational module (SD3c, 2014). Use statistics were calculated and a Technology Acceptance Model of Davis (1986) for empirically testing new end-user information systems was used to assess the perceived usefulness and ease-of-use of the program by patients (SD3c, 2014).

4.3.2.4 Broadening by deliberate involvement of heterogeneous users

Various results are given about the deliberate involvement of heterogeneous users by S3A, in the IOT project, and by S3B, in order to create solutions or make conclusions that are robust among different settings. Firstly, when developing client-specific applications, S3A invites multiple representatives of the client, in order to triangulate between arguments put forward. IN#5 suggests that such triangulation is important, *"because one doctor sometimes says something different than the other. So you cannot rely on one. The group is not that homogeneous."* (IN#5). Besides, regarding the continuous development of the generic platform, IN#5 suggests that deliberation and interaction among different care providers in their nationwide client base is facilitated two or three times per year, and S3A aims to facilitate and take advantage out of the broadening process that occurs when users are questioning one another, correcting each other and together figuring out what the best supported solution is. Patients are not involved here, and as IN#10 prompts: *"whether we put together nurse practitioners, caregivers and patients into one focus group, I doubt that."* In this line, IN#21 suggests that it is not considered very useful by S3B to have interaction between patients and care providers regarding the design and content of the educational

[13] The educational module is also used separately from the RPM platform of S3A.

module, since both user groups have very different stakes; where the care provider's interest is what is important information for the patient, the patient's interest is whether it is understandable.

Secondly, S3A also takes into account that the patient population that potentially uses the platform is heterogeneous. IN#5 explains that patients that are managing their chronic disease extremely well - i.e. *"the tip of the iceberg"* (IN#5) - mainly act as a source of inspiration for S3A, but not leading, since these extreme users are very exceptional and not providing a representative picture of the chronic patient population. Furthermore, S3A also deliberates on reasons for non-use, and IN#10 suggests that fall-out of patients sometimes had very 'banal reasons, such as poor Internet connection, or frustrations with login procedures. Such fall-out is claimed to be always included into evaluations, and sometimes it has been possible to respond to misfits with users' needs and routines by small adaptions such as simplification of the login procedure, or by improving the intuitive usefulness, for instance. Also, it is also suggested by IN#10 that non-use may provisionally occur more often as the current elderly population may be relatively less suited to work with digital RPM applications than somewhat later generations, due to their relatively lower Internet penetration and higher incompetence with digital solutions.

Thirdly, and in this line, during their pilots, IOT intentionally involved patients for whom it was expected that they would not complete the pilots. Thereby, not only were patients included that can do a lot - i.e. the early adapters and frontrunners in the remote management of their chronic illness - it was also deemed important to receive feedback from the laggards regarding RPM.

Lastly, in the six-month pilot study of S3B, a variety of nurse practitioners and patients were involved from both rich and poor areas in the Netherlands, in order to ensure capture some of the heterogeneity among both user groups. Hereby, S3B for example learnt that the educational module works less well in deprived neighborhoods of Amsterdam than in rich villages, because many people there are not speaking Dutch. A consequence for their system is that now also educational videos are developed in English, Turkish and Moroccan, which are commonly spoken in these neighborhoods (IN#21). Through this broadening process, S3B thus learnt how their system must be adapted to work for a more heterogeneous user population.

4.3.2.5 Guidance of users during implementation

User involvement is also deemed important by S3A to guide care groups during implementation and thereby to help to successfully embed the RPM applications into use practices. It is recognized by S3A that many care providers have difficulties with RPM technology and patients empowerment and that they need support with the transition to RPM-integrated care processes (IN#5). As IN#5 argues: for some care providers, RPM *"is very overwhelming, especially for a classically trained care provider who is still in the model of 'I am the one who knows, I am professional, and I will tell you how to do it', because the roles are in fact reversed"* (IN#5). Further, IN#5 explains that if *"a care provider completely takes over the care process and does in fact everything for the patient in order to treat that patient optimally, that stands self-management in the way, actually."* Therefore, he suggests that at the basis of improving the RPM process and respective technical solutions lies a required change in the attitude and behavior of patients and care providers (IN#5).

S3A tries to stimulate such a transformation in Dutch healthcare firstly by interacting with umbrella organizations in healthcare, professional primary healthcare associations, and their clients, in order to emphasize that embedding RPM is *"not just unpacking a box, dropping that thing and getting started. It is rather about the implementation […] of this tooling"* (IN#5). This suggests that S3A is actively trying to stimulate the adoption and successful embedding of RPM systems into healthcare. Secondly, S3A tries to stimulate the gradual embedding of RPM in care practices by offering their platform with a default standards that starts with the common denominators, together with the flexibility to change the system settings, i.e. the system's behavior. Through feedback from care providers, S3A has namely learned that

not all care groups necessarily desire all the freedom that the configurational character of the RPM platform offers. IN#5 suggests that it one time explicitly came forward in a meeting with a care group that care providers look up against the configurational part, that it is a lot of work for them, and that they actually want to approach it rather standardly. With both the default standard and configurational flexibility, care providers can start working with the system, and while building up experience, they automatically discover what works and what does not, and adjust the settings accordingly, yet to have an increasingly individualized RPM solution on the levels of both the care provider and patient (IN#5). Moreover, IN#5 suggests that it is acknowledged by S3A that the configurational nature of their platform also asks for some accompaniment during implementation, which is therefore provided by a consultancy unit of S3A. This reflects the feedback and teaching of users how to use the technology.

In this line, as suggested in an article of a researcher (IN#20) of IOW (SD3d, 2014), it is important to guide care providers in integrating the RPM system in daily routines, and new working routines are - and need to be - established. To this end, it is suggested to be of added value to appoint 'ambassadors': care providers who already successfully use the system in daily practice (SD3d, 2014). Thus, it is recommended that early adapters in RPM among care providers could help other users to successfully adapt their routines to RPM and embed RPM technology in their working practices. Besides, researchers of IOW are putting efforts into learning how to optimally embed RPM in existing contexts-of-use. Namely, the log file data used by IOW - as addressed in section 4.3.2.2.1 - is also complemented with information gathered in focus groups with care providers and aimed at understanding how their existing working processes are arranged, in order to gain understanding about how both the system supplier and care providers can deploy the platform into the existing care practices (IN#20).

Concluding remarks

The results suggest that S3A and S3B are actively deliberating on the perspectives of the users of their systems, and that this provides important inputs for them to improve and tailor their systems to user-specific requirements. While the perspectives of patients are mostly deliberated on via care providers, S3A seems to increasingly involve patients directly. Moreover, S3A's involvement in the scientific pilot project of IOT provides them with important knowledge about users and their requirements, but it seems too early to determine what consequences this will finally have for their RPM platform design. Furthermore, S3A, S3B and IOT broaden the user involvement processes to deliberate on the heterogeneous interests among patients and care providers. Lastly, it is deemed necessary to accompany care providers during implementation of RPM systems, in order for them to gradually learn how to use the system.

4.3.3 Generification strategy

All RPM applications of S3A are built up from one generic platform with generic features that serve as building blocks for all applications (SD3e, 2014). Still, as explained by IN#5, S3A acknowledges that their user populations - i.e. in terms of care organizations, individual care providers, and individual patients - are substantially heterogeneous, and S3A responds to this heterogeneity by providing their generic platform with flexibility to (re-)configure and tailor the client-specific applications' settings. IN#5 explains: *"We deliver it with a default standard, a standard in which we have incorporated the agreed common denominators, and then the care group can […] determine how they want the application to behave itself and what content they do and do not offer to their customers. […] And as a caregiver you can in practice eventually personalize on a patient level. […] you can always put things on and off on patient-level, because you think that a patient is not yet ready […] or for whatever reason"* (IN#5). Thereby, the basis of client-specific RPM applications is generic, but there is customization around it (IN#5). Furthermore, the platform of S3A serves different product lines, including amongst others those for RPM systems and Chain Information Systems. Such systems can also be integrated with each other, in order to offer more complete services when desired by the user. Furthermore, as will be addressed in

4.3.4, S3A is also realizing integrations with systems or modules from other vendors. Accordingly, IN#5 claims: *"I think that there are few configurations exactly the same within our customer bases. There will be some, but […] every customer is unique, and our strength lies in the extent to which we can respond to it."* This points out that individualization of client-specific applications is to some degree possible, despite that S3A uses a generic platform to build up all solutions.

The generic platform of S3A is regularly updated, and one separate division of S3A is focusing on the development of their generic platform by constantly improving and adding components to the platform (IN#5; SD3e, 2014). Furthermore, IN#5 explains that when S3A has a very specific demand from a large client "*it can sometimes be very facilitating to organize a specific user deliberation"* (IN#5) and learn about their specific requirements, but S3A tries to minimize the actual customization - in the sense that adjustments are made to their software - that is only done for one single client, and is not available to other clients. It is namely not desirable to deviate much from the possibilities their generic platform offers. Namely, as IN#5 puts forward: *"we have a many degrees of freedom within the platform, a lot you can simply configure, but the more degrees of freedom, the more complicated and difficult it becomes, so you need to find a balance between manageability and maximum flexibility."* Thus, the downside to a large variation in configurations is that it sometimes brings along some difficulties and extra work on the maintenance side. IN#5 explains that the platform will therefore not be endlessly expanded with relevant functionalities, and that prioritization is necessary in order to keep the generic platform manageable. Besides, as noted in section 4.3.2.1.1, clear expectation management during user involvement is deemed important, and as IN#10 puts it: *"You should not say to people: call whatever you want. You should say to people: you can call whatever you want, but we are tied to a budget, and that means that if you want very special things, we are not going to do it."* S3A actively asks for feedback from end-users to gain inputs on broadly supported user requirements with an expected added value, but due to amongst others budget constraints they cannot respond to all the heterogeneity among users' requirements (IN#10). Moreover, IN#5 puts forward, *"people have often more in common than they themselves think at the first instance"* and *"you also need to help your customers with that, to make it clear. […] And finally it is also better for our clients, because we can maintain it simply at lower rates. […] So I always say: standard where possible, and specific where necessary."* This further emphasizes the potentially hindering effect of a generification strategy on the tailoring to all articulated user-specific requirements.

Concluding remarks

All client-specific RPM applications of S3A are built up from a generic platform which is regularly improved, and S3A aims not to endlessly expand this platform hence to respond to all user-specific requirements. Therefore, a generification strategy may potentially hinder the tailoring to some user-specific requirements. However, S3A believes that their platform offers sufficient flexibility for client-specific applications to be tailored to user-specific requirements, and moreover, it is suggested that users' requirements may be more common than they recognize themselves.

4.3.4 The use of design standards

In the following, it is firstly explained that interoperability with other systems in healthcare is deemed important by S3A, where after it is discussed that standards contribute the realization of integrations with other systems in healthcare. Also, it is suggested that compliance with certain standards may sometimes lead to limitations to respond to user-specific requirements.

4.3.4.1 Importance and realization of interoperability with other systems in healthcare

In order to ensure efficient and reliable communication with systems from other suppliers, a precondition for S3A was to think in open architectures and to connect their applications to existing systems that are already used in healthcare (SD3e, 2014). S3A is aiming to realize increasing integration

between different information systems in healthcare. S3A is intensively integrating their renewed RPM system with their own Chain Information Systems, because they consider the success of implementing a RPM platform to be strongly dependent on the degree of integration between patient and care providers in the chain. However, S3A also offers RPM solutions as 'stand-alone' units that can be coupled to existing information systems of other suppliers, in order to lower the adoption threshold for parties that already make use of other information systems, but still want to start with a RPM system without having to destroy the invested capital and invest in a whole new integrated care information system.

Furthermore, IN#5 explains that S3A's platform is a multi-disease tool unrolled in the width of chronic healthcare, and following the *"development that healthcare is becoming less illness-specific, and that it - also in elderly care - by definition involves multiple disorders"* (IN#5), because chronic illnesses are often provoked by one another, or by the lifestyle that is associated with another illness. Therefore, IN#5 suggests that in the near future, the platform may also be linked to applications from other vendors, for instance digital coaches that can help counteract exacerbations of specific illnesses, based on signs that are individual for patients.[14] Besides, when the RPM platform of S3A is used for heart failure patients, an integration is realized with the platform of case 1, which then serves as medical device when the platform is used for chronic heart failure (IN#5, IN#20).

Regarding the possibilities for integrations of the RPM platform with measurement devices, IN#5 suggests that incentives for S3A are low to realize this, because chances are great that interfaces through which a system can communicate with the devices must later again be adapted, because the industry of measuring devices is changing rapidly. As IN#5 explains, S3A aims to finally offer integrations with different devices, though choices must be made. As he puts it: "*There are hundreds of devices available"* and "*it is almost impossible to connect all of them, so we are searching for the common denominator, and we have taken it up into our roadmap that we want to link these devices"* (IN#5). Further, IN#5 explains that over time, the industry for devices will crystallize, and S3A hopes to make and have made the right choices in the devices with which they connect.

4.3.4.2 Standards' contribution to the realization of integrations with other systems

As suggested by IN#5, S3A always uses specific information-standards for the specific branch in healthcare in which the application must be integrated. Within hospitals often different standards are used when compared to the GP's site, for instance, and S3A tries to select the standard that is most generic, rather than that they try to enforce standards for communication themselves (SD3e, 2014). Within S3A's platform, different integration layers, using different standards, are available. As IN#5 explains: *"If I have an application in the context of primary care, then I will have to invoke my OZIS integration layer. If I have this application in the corner of the hospital world, I will much more have to invoke the HL7 layer."* Regarding the interoperability between the RPM platform and the educational module of S3B, IN#21 suggests that S3B follows standards such as EDIFACT to ensure that the linkage can be made. Moreover, S3B also couples their educational module to RPM systems or Chain Information Systems of other vendors, whereby compliance with certain standards is important (IN#21). IN#5 suggests that standards strongly contribute to the speed and ease with which interoperability with other systems can be realized, and once such integrations have been realized a few times, it becomes relatively easy to effectuate them in other applications with other suppliers of information systems.

4.3.4.3 Limitations to respond to user-specific requirements due to compliance with certain standards.

As IN#5 puts forward, a downside to standards may be that it can also be obstructive in responding to user-specific requirements and even *"kill innovation"*. If the exact way of communicating between parties (e.g. in an integrated care process) is set solid, and a certain 'innovative' care group wants to

[14] An example is the platform discussed in case 2.

reach a specific target group that desires to exchange information in a different way, it is not possible to respond to their needs according to the standards S3A uses. When an integration must be made custom it costs much time and efforts. Besides, maintenance of an integration is much easier and fewer problems turn up after implementation when the integration is achieved with a common standard (IN#5). Yet, IN#5 suggests that when no standards exist, S3A makes integrations custom.

Concluding remarks

S3A aims to integrate their RPM applications with existing systems used in healthcare, as well as with additional component that extend the functionalities of the resulting RPM configuration, allowing the RPM applications to be more efficiently used and better tailored to the specific patients being remotely managed. Common standards contribute to the speed and ease with which S3A can realize such integrations. However, sometimes standards with which S3A complies may obstruct the response to user-specific requirements in terms of preferred ways of data exchange that deviate from a standard.

4.4 CASE 4

4.4.1 Case profile

This case addresses the development and implementation of an approach for the remote management of anticoagulation patients in the Netherlands. Anticoagulation patients take medication based on the measurement of their level of coagulation through the standardized an internationally adopted International Normalized Ratio (INR). All anticoagulation patients in the Netherlands are supported and managed by one of the 58 thrombosis expertise centers (TECs), who all operate as independent care organizations, but are actuated by a national federation of TECs. It is estimated that around 55.000 patients from the approximate 400.000 anticoagulation patients in the Netherlands were self-measuring their INR-values in 2013, and 30.000 of these self-measuring patients were also dosing their own medication, thereby having an even greater responsibility and autonomy in their care process (SD4a, 2013). A remaining share of Dutch anticoagulation patients are managed through the regular method, meaning that patients come by at their TEC where their INR-values are measured through a venipuncture and analyzed in the lab, or through the near-patient measuring method, at which a care provider uses a professional coagulometer, either at a prick station of the TEC, or at the patient's home (IN#7, IN#14, IN#18). Figure 5 visualizes the configuration for remote management of anticoagulation.

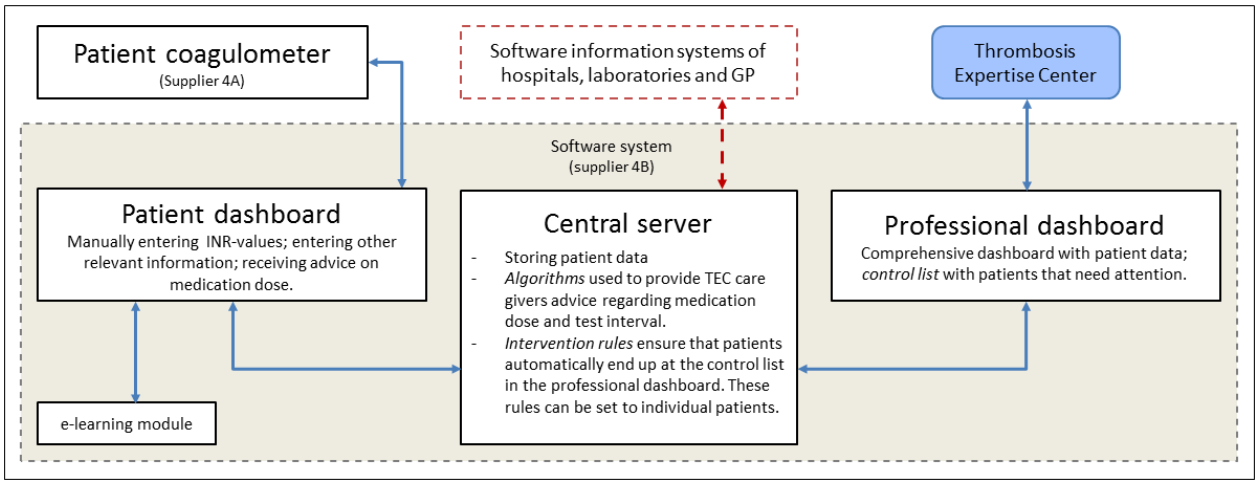

Figure 5: Visualization of the remote anticoagulation patient management configuration with hardware of S4A and software of S4B. The dashed box and line means that this component is optionally connected to the software system of S4B.

The RPM approach includes the INR-measurement by patients with a ***patient coagulometer*** - in this case the coagulometer provided by supplier 4A (S4A)[15] - and the use of a ***software system*** - in this case of supplier 4B (S4B) - by both patient and care provider at the TEC, in order to remotely manage adequate dosing of medication therapy. Every ten days to three weeks, depending on instructions from the TEC, patients need to do a finger prick measurement of their INR with their own patient coagulometer, and enter their values in the ***patient dashboard***, together with other relevant information, e.g. events such as bleedings or plans to travel. Based on norms from the national federation of Dutch TECs, care providers and patients can propose medication dosages. Also, based on the INR-result and the history of INR-values, clinically validated *algorithms* built in S4B's software provide TEC caregivers advice regarding the next dose and test interval.[16] Besides, *intervention rules* ensure that when INR-values fall outside a patient's personal therapeutic ranges (i.e. lower and upper threshold), then the patient automatically ends up at a *control list* on the ***professional dashboard*** of the TEC professionals, which is somewhat more comprehensive dashboards than the patient dashboard (IN#14, IN#18). Further, S4B is realizing options to integrate their software system with other information systems, including *information systems of hospitals, laboratories and general practices,* and S4B also provides an *e-learning module* to teach patients practical skills regarding accurate INR-measurement and, when they also dose medication themselves, to respond adequately to required dosage changes (IN#14).

4.4.2 User involvement

In this part is separately discussed how S4A and S4B have involved users in the development and implementation of the coagulometer and software system respectively. Besides, it is discussed that some degree of non-adoption of the RPM approach is deemed insuperable, though that the adoption of the RPM approach is not purely a choice made by patients, and that many instances of non-adoption may be caused by the attitude of TECs towards self-measuring INR-values by patients, thereby requiring a transformation of TECs and their routines to scale the adoption.

4.4.2.1 Coagulometer development by S4A

S4A is a large international supplier of a variety of diagnostic equipment, and their coagulometers are developed by their global entity. S4A considers quality and reliability to be the most important aspect of the coagulometer, and it is subordinate what the product looks like, for instance (IN#7). Besides, IN#7 suggests that patients do not decide for themselves about the adoption of a patient coagulometer, whereby it is less important to ask their opinions. As IN#7 suggests: *"you can ask a patient 'do you find this color blue more beautiful than that color blue?', but eventually they do not decide themselves. The TEC purchases the meters, and the patients take it on a loan. So in that respect I think that the patient has the trust that the TEC makes the right choice."* Further, as suggested by an employee of S4A's Dutch entity (IN#7), S4A does a large market research every two years, in which they both quantitatively and qualitatively - through interviewing - assess the perspectives of patients on the coagulometer and their self-management process in general (IN#7). However, as IN#7 suggests, notwithstanding the inputs this research may provide for long-term adjustments of their software and hardware, it is primarily focused on creating awareness among users - i.e. patients and professionals - of the possibilities and what they want themselves. These results suggest that there is little involvement by S4A of Dutch patients using the coagulometer to gain inputs for possible improvements.

In line, and in contrast to Faulkner (2008), who suggests that patient advocacy groups in the international field have also been involved in advising manufacturers of coagulometers, the chairman (IN#19) of the Dutch advocacy for and by self-measuring anticoagulation patients (involved organization X, IOX) and self-measuring patient himself, argues that there is only little involvement of IOX by S4A to

[15] S4A also provides a professional coagulometer for near-patient measuring.

[16] This algorithm is not yet offered for self-dosing patients, but only for care providers of the TECs (IN#18).

help improving the patient coagulometer. In fact, as perceived by IN#19: *"the producers of devices […] decide for themselves. They test it, they put it in the market, and that is it."* An explanation for the limited involvement of IOX by S4A, given by an employee of S4A (IN#7), is a limited amount of patients affiliated with IOX, whereby IOX is not considered to be able to efficiently collect and communicate the perspectives of a large number of patients. As IN#7 puts forward: *"that could work out better if you have an advocacy to which all patients are connected. Then you probably get a more realistic picture of all Dutch TEC patients."* IN#19 of IOX, on the other hand, believes that their patient organization, which is run by patients themselves, has sufficient expertise in-house to think along with other organizations, and that they are able to stay close to the actual interests of patients. Although these views contradict, the results suggest that more collaboration may be possible between the Dutch patient advocacy and S4A.

Furthermore, IN#7 explains that the global entity of S4A communicates the latest developments of their organization to the Dutch entity, which is primarily focused on marketing and sales, and which has relatively minor activities in product development. When the Dutch entity receives feedback from their clients, they generally provide this information to the global entity (IN#7). However, as IN#7 argues, the downside of the global organization is that it takes a while before feedback that is passed through to the global entity is finally implemented. For instance, it takes a long time before specific feedback - e.g. on a set-button that is sometimes coincidentally pushed by the patient's forefinger when the device is grasped - is leading to improvements in the device. In this line, IN#19 of IOX complains that it takes too long before improved versions of S4A's coagulometer, which are e.g. handier, less temperature sensitive, and automatically transferring INR-results, are becoming available. As explained by IN#7, it is difficult for S4A to make improvements to - or vary in - their hardware on the short-term, due to the time and investments required for validating the reliability of the product before adjusted version can be implemented (IN#7). As IN#7 explains: "*you have to be careful with certain adjustments because it can affect the quality, and then you need to look again whether the measurement is still as good as from the old meter, whereby you lumber yourself with a lot of time and costs. […] It is mainly quality-driven […] and such a thing as a screen, for example, is than not important."* These results suggest that the global focus of S4A and the medical certification of the coagulometer cause the slow response to locally articulated feedback and slow improvement of the device.

However, IN#7 suggests that although the hardware is outdated, and for instance, the casing has not changed for a long time, the software being used in the coagulometers of S4A is regularly updated and improved. While IN#7 suggests that opportunities for software improvements in the patient coagulometer will increase when the device has additional connectivity features, specific examples of software improvements and connectivity solutions were only mentioned by IN#7 with respect to the professional coagulometer. These developments were based on inputs from the Netherlands, and later tested and implemented here as well (IN#7). This suggests that S4A is sometimes able to respond to locally articulated requirements. Besides, IN#7 states: *"in the software a lot more is possible than in the hardware. And I believe that as long as the quality is good, then in the software […] you can make real efficiency strokes. And that hardware is really subordinate to what they need. So in that regard I think that we have sufficient flexibility."* This suggests that although the hardware is outdated, the software may be sufficiently adaptable to user-specific requirements.

4.4.2.2 Anticoagulation software development by S4B

In the following, it is first shortly addressed that S4A built the anticoagulation software platform in co-creation with a specific TEC. Second, it is addressed how S4B applies a structured procedure for gathering the requirements and feedback of different users groups, in order to set up a prioritized list with improvements to be made. Third, it is discussed how user involvement has finally influenced the continued development of the software platform.

4.4.2.2.1 Co-creation of the software platform with a TEC

As suggested by multiple interviewees (IN#14, IN#18, IN#19), S4B developed their anticoagulation self-management platform in co-creation with a specific TEC. Besides, as an employee of S4B (IN#14) explains, S4B originally only offered software for self-measuring (IN#14). However, at a certain point, TECs that were using their platform figured that they wanted to have one single system in which they could treat both regular and self-measuring patients, rather than their regular patients being managed with a system from another supplier. Therefore, ten years ago, S4B developed an additional part for their platform, specifically for regular lab patients.[17] Now it can easily be looked up in the patient portals whether a patient is remotely measuring itself, or whether he/she is a so-called 'regular' patient that is being measured by a care provider.

4.4.2.2.2 Structured procedure for user involvement and articulating improvements to be made

IN#14 explains that since S4B was established more than ten years ago, the company has been structurally asking for feedback from the users of the anticoagulation platform, including patients and TEC care providers, in order to set up a list with prioritized improvements to be made. Firstly, a patient panel was set up, which consists of a small group of around 10 patients, varying in age - to allow some heterogeneity - with whom they regularly evaluate their software portals (IN#14). Through this panel, S4B not only tries to receive feedback from enthusiastic patients, but also from criticists. IN#14 argues that they *"have had a huge debate over the Internet with a few patients. Then you try to take the sting out of it. Then you say: you are very critical. Don't you like to get into the consumer panel, so you can take part in discussions with your fellow companions?"* Secondly, a professional panel was set up with representatives from all 50 TECs that are client of S4B, and this panel gathers two times per year. IN#14 argues that an agreement was made that every TEC should have a functional application administrator who gathers the wishes of different employees within their TEC, and who makes a judgement about the relevance of these wishes. The functional application administrators communicate with S4B about the new wishes that have come up over the last period, and during meetings it is tried to find the largest common denominators from all their clients.[18] Thirdly, in addition to the patient and professional panels, S4B has its own medical working group, which currently consists of four physicians, and with whom S4B discusses medical content. IN#14 argues that this working group has the responsibility to propose what they believe is medically justified and how this should be processed into the system, and that they propose improvements for better performing dosage algorithms that are used in the software. While IN#19 argues that it is important to include a parameter of the specific type of medication used in future algorithms, it is put forward by IN#14 that this will possibly be part of an algorithm integrated with the platform in the near future. Lastly, the areas for improvement finally articulated by the patient panel, the professional panel and the medical working group are all are registered in a system, and evaluated by a core group of 4 people, which makes a final proposition to S4B for improvements to be made. Together with this core group, S4B prioritizes the improvements under four labels (i.e. medical quality, efficiency, patient safety and usability), and determines how many improvements of each label will be realized in the following half year or platform release (IN#14). Thus, there is constant prioritization of wishes of different user groups to determine what improvements will be made first.

A remark on the user involvement process, as made by IN#14, is that some steering during user involvement by S4B is considered to be important. As he illustrates: *"when you put ten users into a room,*

[17] 30 TECs are now using both functionalities of the software system of S4B, and 20 other TECs only work with the RPM option, while using another software system for their regular patients.

[18] A remark on the professional panel, as made by a former chairman of this user group (IN#18), is that participants in the professional panel do not very actively come up with feedback, that they are badly coordinated, and that they do not seem to be very willing to improve their working processes and integrate it with the software. This relates to the issue of a required transformation of TECs, which will be addressed in 4.4.2.3.

and you are having a discussion about colors, then you receive 100 different opinions. […] So you have to give users a little help by not telling them 'you say it', but by saying 'this is our setup, and let's use that as an agenda to see what direction we should go'" (IN#14). Furthermore, IN#14 puts forward: *"of course the core group sometimes says 'we do not think that is a good idea if the patient wants that because it can lead to mistakes by us, and we do have a medical responsibility'. So that is quite a bit the balance you want between these two extreme groups."* Thus, the core group acts as a certain mediator in the process of broadening during which diverse needs are articulated, and a consensual frame is tried to be established. Overall, the results suggest that S4B triggers and steers user involvement, and that a core group of S4B ultimately strikes a balance between the interests of different users.

4.4.2.2.3 Influence of user involvement on the continued software development

The results suggests that the inputs of users have a significant contribution to improvements that allow to tailor the configuration to user-specific requirements. For instance, an issue on which many patients have articulated their requirements is the need for a mobile anticoagulation management application, which would further facilitate the RPM process. As IN#14 puts it: "*We are beaten to the ears by patients who ask 'when will your mobile app finally come?', because we have simply fallen behind in that. It is clear that this should have been there much earlier"* as *"I see many possibilities to get people more compliant by using an app."* Therefore, S4B is now searching for experienced partners in the development of a mobile application for their anticoagulation clients, and IN#14 suggests that the patient panel will have an important role in defining what the application should contain, and how it should facilitate patients' anticoagulation management (IN#14). This indicates that the consumer panel is not only used to derive feedback on required improvements of the software, but that there also is upstream involvement of a few patients during the realization of improvements.

Furthermore, over the years, S4B has received important feedback from the patient panel regarding the desired simplicity of the dashboard in which they work (IN#14). For instance, the additional information - e.g. events or travel plans - that patients have to report is all coded into the patient's dossier. However, for patients, it appeared much too complex when this information was all displayed on their dashboard. In conversations with patients from their consumer panel, S4B has learned that patients rather have a few simple buttons in which they can fill in some information, and that they prefer to see less information than S4B can actually offer them. Therefore, the TECs have a very extensive dashboard regarding such information, in order to be able to reason based on such information, and the patient dashboard is more simple (IN#14). Over time, when patients become more experienced with the system, they can still ask for more information, or sometimes even their full personal dossier, depending on the respective TEC's decision. However, regarding the release of the full patient dossier on the patient dashboard, the problem was raised by the professional panel that care providers sometimes enter sensitive information that they do not want the patients to see - for instance regarding their expectations of abuse or alcoholism - because it may 'frustrate' the patient (IN#14). IN#14 explains that this issue is currently being discussed with TECs as well as with GPs and some patient advocacies, and that a possible consensus is that there will be a box in which information can be entered by care providers that is not displayed in the patient's dashboard. Thus, after deliberation on the different perspectives, both the needs of patients and care providers may be responded to.

4.4.2.3 Some degree of non-adoption of the RPM approach is deemed insuperable

Although presently not everyone is eligible for self-management of anticoagulation, it is expected that an increasing share of patients will choose for the freedom that self-management brings along (IN#14, IN#19). Nevertheless, as suggested by multiple interviewees (IN#7, IN#14, IN#18), there are plenty of motives for a large amount of these patients to hold on to the regular method; for instance, people do not want the responsibility of self-management, they prefer the real-life interaction with care providers

of the TEC, or they prefer the venipuncture over the finger prick measurement.[19] A certain share of non-use of the RPM approach is deemed insurmountable. In fact, as IN#18 argues: *"it is an illusion to think that everyone finds the finger prick more comfortable than that puncture in the arm."* Moreover, IN#18 hints to technology push of self-measuring technology because *"innovators are saying that everyone can and wants it, but that TECs are not offering it. But then we say: 'nonsense, not everyone simply wants it'."* According to IN#18, the best normative premise is that everyone should get the best method of treatment, and the percentage of self-measurement patients to which that leads is of secondary interest. This indicates that a missing match with user-specific requirements is deemed not always to be possibly solved by technological improvements, and that non-use is sometimes considered insuperable, and not necessarily problematic.

4.4.2.4 Required transformation of TECs to scale adoption

Importantly though, some results suggests that part of the non-adoption of the RPM approach is caused by the attitude of TECs towards the approach, as well as the respective patient empowerment. IN#14 suggests that it may be important for TEC care providers to better acknowledge the potential for many regular patients to manage (part of) their illness themselves, and that ICT solutions can also be of added value for patients that are not remotely measuring their INR. As suggested by IN#14, regular patients could be granted access to the web-based software to online answer standard questions in advance of their visit to a TEC - and thereby spare time at the TEC - or to access information about their management process, allowing them to better assess their risks. For these non-users of the RPM approach, S4B is also constantly aiming to improve their software, and gradually digitizing the methods further in order to achieve greater efficiency (IN#14). Although such developments do not directly lead to the remote management of anticoagulation patients – except if it stimulates the choice for the self-measuring method – the increasing use of online solutions leads to empowerment of patients and more self-control over their illness.

Furthermore, IN#14 puts forward: *"you see that care providers have a little tendency of 'we know it better than the patient, so let us manage everything', whereas I believe that many more people could do self-management than the TEC actually allows."* Accordingly, IN#19 suggests that there is a lack of equality between care providers and patients; *"Medical professionals often determine what is best for a patient"* (IN#19), while patients are actually increasingly empowered - partly through the rise of the Internet - to be more actively involved in their care process. As IN#19 states: "*Self-management is really something that arises from the needs of patients, including older patients. As a TEC, you have to listen very carefully to what the patient wants, and I miss that sometimes."* This is in line with Faulkner (2008), who suggests that *"it is clear that the specialist medical professions, especially those in haematology, are reluctant to cede control over many aspect of their conventional expertise and practice"* (p.151), and that TECs must be more willing to organize their landscape around coagulometers and software portals, in order to allow scaling of self-measuring anticoagulation patients. IN#19 argues: *"for a year of eight they (TECs) have stood with their heels in the sand, because they found it threatening"*, as the RPM approach causes them to require fewer employees. Also, it is put forward by IN#19 that suppliers prioritize the interests of care providers - who decide over the adoption of technology - over the interests of patients. As IN#19 states: *"Technology suppliers such as [S4A] and [S4B] depend on the TECs because they have contracts, and they are reluctant to making adjustments in the interest of patients, rather than in the interest of the TECs."* Thereby, the technology suppliers may have a limited focus on what is actually important for patients.

[19] For instance, some types of musicians such as pianists and violinists, as well as blind people do not want the finger prick method with the patient coagulometer, because they need to use their 'undamaged' fingertips in daily life.

It is argued by IN#19 that important responsibilities are still reserved - also in the future - for care providers from TECs, because (remote) anticoagulation management is eminently an interplay between patients and their TEC rearguard. Remotely managed patients still rely on the monitoring role and expertise of their TEC, in case of any problems such as abnormal blood values or a bleedings. Nevertheless, the results point out that the insufficient acceptance of the RPM possibilities by the established healthcare regime of TECs hinders the upscaling of remote management of anticoagulation, rather than that the offered technological possibilities do not meet patients' requirements. As underpinned by IN#18 and IN#19, many TEC professionals have difficulties and/or are not willing to adapt their working procedures to the introduction of self-measuring technology and practices. They do not sufficiently recognize themselves in a RPM system, and rather find that technical systems must be adjusted to their established working procedures (IN#18, IN#19).

Concluding remarks

S4A is a global venture that is on the one hand suggested to be rather slow in making improvements according to articulated user-specific requirements regarding their coagulometer. On the other hand, software improvements are suggested to be regularly made by S4A, sometimes even based on inputs from the local Dutch needs detected by S4A's Dutch entity. Regarding the coagulometer, there are complaints that improvements are necessary, yet not being made. Further, S4B systematically and periodically involves different groups of users to set up a prioritized list of wishes that they aim to respond to, referring to an important stimulating influence of user involvement in the tailoring process. Non-use of the RPM approach and respective technology of S4A and S4B is not always and necessarily problematic, though it may often undesirably be caused by amongst others the attitude of TECs towards RPM. These organizations may require a transformation to scale the adoption of the RPM approach, rather than that only technological improvements by S4A and S4B are necessary to scale the adoption.

4.4.3 Generification strategy

In this part, it is discussed that a generification strategy applies to S4A and S4B's components and what this entails for the tailoring to user-specific requirements.

A generification strategy applies to the coagulometer because S4A offers the same device to all patients. Although being critical about the currently available patient coagulometer, IN#19 of IOX acknowledges that the act of self-measuring is by protocol the same for everyone, and that a standardized coagulometer is suitable. The difference rather lies in how results are interpreted and followed up by different users, which can be anticipated on in the anticoagulation software system – i.e. of S4B (IN#19). This suggests that it may not be problematic that S4A applies a generification strategy to the patient coagulometer.

Regarding the anticoagulation software of S4B, it is pointed out by IN#14 that it is important for S4B to apply a generification strategy, because all anticoagulation patients in the Netherlands are being treated in exactly the same manner, whereby *"it is important to offer it as much as possible in a standardized manner, and not to modify it per client"* (IN#14). S4B in principle provides only one version of their anticoagulation management platform at the same time, whereby each client has the same product basis. Besides, clients are only being provided with the latest version of their platform, whereby users have the benefit of always being updated with the latest improvements. Though S4B launched their platform with a one-size-fits-all approach, over time they built some parameters into the system which can be set individually by the TEC (IN#14). Thereby, the platform delivers the same final product for each client for 95%, and leaves 5% room for individual settings (IN#14). As IN#14 argues: *"you see an extension in the flexibility regarding the generation or delivery of parameters to a client that they can set themselves. But that does not extend to as far that displays should be built differently. We notice that the more you deliver standardized solutions, the more room is left for new things. If you have parameterized*

everything, you spend a lot of time with management and maintenance in all those different versions." This suggests that a standardized solutions in fact offers S4B the flexibility to improve the generic platform according to the requirements of users.

Regarding the adjustments to the generic anticoagulation platform made over time, S4B recently started working with the new 'scrum-method', whereby they have a functional release every month, because *"five months is of course way to long if something does not function sufficiently"* (IN#14). S4B formerly only had about two or three functional releases of their platform per year, whereby they sometimes 'ran behind the facts', because it generally took very long before adequate adaptations were being made.[20] Through this new method though, S4B aims to respond more quickly to articulated needs and changes in the dynamic healthcare market.

Still, a remark was made by IN#18 that some planned improvements[21] are postponed due to capacity shortage of S4B. As IN#18 puts forward: S4B *"is busy with a migration to another database, and that requires a lot of time now from their technical people. Then you immediately see that wish list grow longer."* Moreover, since S4B needs a sustainable business model, they cannot endlessly hire new developers to respond to all wishes, whereby it is important for them to distinguish between 'nice-to-haves' and 'must-haves', because simply not all nice-to-haves can be addressed (IN#14). IN#14 acknowledges that *"if there is an argumentation of a client, then we should consider that and determine whether we go along with the argumentation of that end-user."* Furthermore, specific requirements are responded to under the condition that S4B also expects this request to be coming from other clients (i.e. TECs) as well, emphasizing that a generification strategy applies and possibly withholds some user-specific requirements to be responded to.

Concluding remarks

Notwithstanding that there are shortcoming to the patient coagulometer of S4A, the offering of a standard measuring device is suggested not to be problematic. Besides, S4B is building increasing flexibility in the settings of their standardized software systems, allowing for tailoring to user-specific requirements, and they regularly update their generic platform according to articulated requirements of users, positive influencing the tailoring process. Nevertheless, due to limitations in capacity, S4B only responds to the needs of a larger group of clients, rather than that they respond to all user-specific requirements. This possibly hinders the tailoring of the software to certain user-specific requirements.

4.4.4 The use of design standards

In the following, it is firstly addressed that an integration lacks between the RPM components of S4A and S4B due to the use of an outdated standard for data exchange by S4A. Secondly, it is addressed that users have little choice for other coagulometers next to the device of S4A, but that this is not caused by a lack of interoperability. Lastly, it is explained that standards help S4B to integrate their anticoagulation software system with other information systems used within healthcare.

4.4.4.1 Lacking integration between S4A's patient coagulometer and S4B's software system

Regarding the format in which information is captured by the coagulometer, IN#7 suggests that a standard protocol (POCT-1A) is used for their devices that is specifically designed for point-of-care devices and internationally used by all firms delivering such devices. Leastwise, as IN#14 puts it: *"I cannot image that there are suppliers that do not follow"* this standard protocol. Unfortunately though, an integration between the patient coagulometer and S4B's software platform is lacking. While S4A and S4B

[20] Of course, extreme bugs – i.e. problems that should be solved directly – are generally directly taken up by the developing team and delivered mostly within a day. But the aim is to minimize the amount of extreme bugs, because it upsets the focus on the regular work.

[21] Here is being referred to the list of improvements to be made - as addressed in section 4.4.2.2.2.

have realized an integration between the professional coagulometer - i.e. for near-patient measuring - and the software portal[22], such an integration is lacking for the patient coagulometer. This is suggested to be undesirable, because it forces patients to manually enter their results into the software portal, while *"manually typed things in this world are enormously error-prone"* (IN#18). Due to the integration of an infrared seeker in the patient coagulometer by S4A, it turned out to be too difficult for S4B to make a successfully working integration with this device (IN#7, IN#14). As suggested by IN#14, S4A may now be working on a new patient coagulometer that uses Bluetooth rather than infrared - which is argued to be an 'old-fashioned' (standard) way for data exchange - to allow a smartphone to capture the INR-values and subsequently sends it to the software portal.

4.4.4.2 Little choice for other coagulometers, though not due to a lack of interoperability

The results suggests that standards do allow tailoring to user-specific requirements through configurational choice between devices. As IN#7 poses, the use of a common standard by different competitors enables consumers *"always to make the choice for the best coagulometer.*" However, there is only little choice between different coagulometer, and S4A has a high market share in the Netherlands. IN#14 explains that it is very unhealthy for the market, because *"this means that prices remain high, and for everyone it would be good if prices of self-measuring devices would go down, because then maybe more self-measurers could be admitted"* (IN#14). User organization 4 (U4), a specific TEC, is one of the few TECs that is intentionally offering patients the choice between two brands of coagulometers, rather than only the coagulometer of S4A. As IN#18, director at U4, explains: *"I found it important to bring in a competitor in this, so I could make better pricing agreements."* This suggests that a lack of choice between different coagulometers is not caused by a lack of interoperability, but rather by a lack of vendors that are delivering high-quality devices, as well as the approach of many TECs - who actually make the choice for the brand of device - to only offer the coagulometer of S4A. Nevertheless, it is worth mentioning that, as suggested by IN#7, it seems as if the trend to point-of-care testing slowly caused the market to break open a little, and allow more vendors to compete with S4A.

4.4.4.2 Standards helping to integrate the software system with other information systems

When S4B launched their self-management software platform, it was firstly being used as a loose system (IN#14). However, through different interfaces and use of different standards - either internationally accepted or nationally defined - they have realized integrations with information systems of hospital, laboratories and general practices. It is argued that standards are simply crucial in order for these systems to work efficiently via integrations between different components, and for these integrations to be made with relatively low investments (IN#14). IN#14 explains that an international standard is generally defined in such a manner that 95% of the standard is set, and 5% room is left for individual completion to ensure alignment with the national and local specifics. Further, realizing integrations with GP Information Systems is suggested to be relatively difficult due to difficulties for suppliers of these systems to adequately follow the required standard or quality differences between the systems of different suppliers. This sometimes increases the required investments in integrations (IN#14). Besides, GP Information Systems are using the relatively old EDIFACT standard protocol, which should actually have been replaced already (IN#14). However - as addressed in the contextual background results - suppliers of these systems are gradually converting to better standards such as HL7. Furthermore, as explained by IN#14, S4B simply aims to hold on to certain standards, in order to prevent that solutions are only customized for a specific user, but not elsewhere. If users come up with needs that do not correspond with a certain standard, S4B tells these users that they should not discuss this with S4B, but rather with the respective standardization commission (IN#14). If a standardization commission finally decides that a certain standard should be extended, S4B will respond with adaptations (IN#14). This

[22] S4B has programmed an interface that automatically requests the INR-results from the professional coagulometer.

suggest that standards may for some users lead to limitations, and that the supplier following the standards considers it to be the responsibility for standardization commissions to ensure that standards comply with users' requirements.

Concluding remarks

A lacking integration between S4A's coagulometer and S4B's software portal - caused by the use of an outdated way for data exchange, i.e. infrared - is undesirable for users. Also, the lack of choice between different coagulometers is not caused by lacking interoperability, but rather by the limited amount of available coagulometers. If more reliable measurement devices emerge, realizing integrations should be relatively easy with standards, and prices would go down. Further, compliance with common standards is important for S4B's software to be integrated with information systems of other parties at low costs, thereby stimulating the tailoring of the configuration to user-specific requirements. However, the use of common standards may for some users lead to limitations, and S4B aims to hold on to the standards as set by the respective standardization commissions, which potentially hinders the tailoring process.

4.5 CASE 5

4.5.1 Case profile

This case study examines the development and implementation of an approach for the remote management of children and adolescents with diabetes type I through integrating a mobile application of supplier 5A (S5A) in their care process. This application is not commercially marketed yet, but rather in phases of research pilots to test, validate and optimize aspects of the application. A first application was used in a first pilot, and currently a second application is being developed. These applications have different main goals; the first application is mainly informative and educative, whereas the second application is focusing on prediction of blood glucose values by means of bringing together different data streams. In essence, the first application is not being used or tested anymore, but the second application development is largely inspired by the first application development (IN#2). Therefore, this case examines the innovation process of both applications. Figure 6 displays what components are part of the configuration in which the second application is integrated.

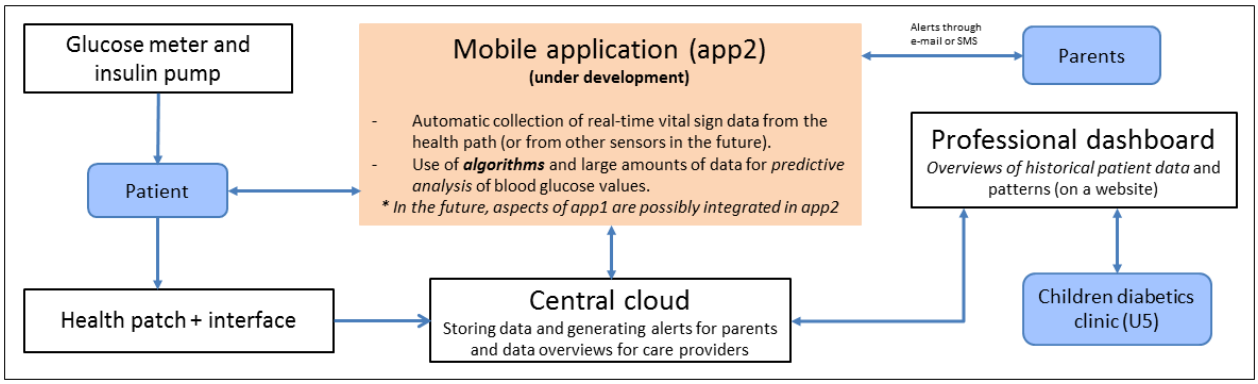

Figure 6: Visualization of the remote diabetes type I management configuration of which the mobile application of S5A will be part when development is finished.

In what follows, it will first be explained what the first application entails, after which the objectives and included components of the configuration of the second application will be discussed, including the uncertainties about the final product that is being envisioned.

4.5.1.1 First application

In 2009, the Dutch entrepreneurial firm S5A, started the development of a first mobile application (*app1*), with the objective to help the planning, the associated follow-up, as well as the digital registration of planned activities regarding the diabetes type I management of children, such as measuring their blood glucose levels, injecting insulin, eating and exercising. The mobile application takes care of the collection and transmission of measurement data from a ***glucose meter*** and ***insulin pump***[23], as well as off-the-shelf wearables (unknown specifics) that automatically collect vital sign data. The patient can also enter other relevant information about activities of the patient, nutrition and medication settings into app1. The data is send to a ***central cloud*** that stores the data and generates overviews of historical patient data, which are shown (e.g. in graphs) on a website for the care provider, i.e. the ***professional dashboard***, for further analyses and evaluation. In case of out-of-range values, or when patients do not - or too late - follow up tasks, the application automatically generates ***alerts*** for the parents, send by email or SMS (SD5a, 2013). As IN#2 puts forward: "*The doctor was deliberately kept out here, because otherwise it raises the expectation that 'the doctor keeps an eye on me', which we have to avoid at all costs."* The patient and parents themselves have the responsibility for the diabetes management, whereas the doctor rather needs to gain insights on daily patterns of patient's values on the long term, in order to adjust their therapy accordingly, if necessary.

The first mobile application has only been used in a half-year pilot research with 24 young patients of a Dutch independent type I diabetes clinic (user organization 5, U5) that manages over 1500 pediatric and young adult patients. From the start of development of app1, the founder and director of S5A (IN#2) has sought for collaboration with U5, and in fact, as will be substantiated in section 4.5.2, U5 inspired the idea of developing the application. Although app1 has not been used after the pilot research, the development and testing of this application - which had positive results (IN#2)[24] - was the basis for the development of a second application being developed by S5A.

4.5.1.2 Second application

In 2013, after being acquired by a US venture capitalist group, S5A[25] started developing a second mobile application (***app2***) that will be mainly focused at making ***predictive analyses*** about patients' personal blood glucose values through ***algorithms***. S5A decided that app1 was not sufficiently distinctive compared to other mobile diabetes management applications, and that personalized predictive analyses are a valuable addition to app1. Therefore, S5A is now aiming to develop algorithms for such analyses and integrate them into app2. This application is still in early phases of development, and S5A is currently running new pilots – with 20 patient subjects of U5 – to gather patient data and perform a study to find correlations between data on different bio-parameters and blood glucose values measured by a glucose meter. As the project leader of the pilots with app2 (IN#16, U5) suggests, the study will be addressed more quantitatively and better focused at specific correlations in subsequent steps. The bio-parameters are gathered by an off-the-shelf CE-certified and FDA-approved ***health patch*** – and transferred to the cloud via an health patch *interface* from supplier 5B (S5B) The health patch includes sensors that automatically collect real-time vital signs such as heart rate, heart rhythm variability, ECG, movement of the patient, respiration rate, skin temperature, sleep, stress, fall detection and etcetera, and it is developed by a US manufacturer, but delivered to S5A via S5B, a partner of the manufacturer that is located in the Netherlands.

[23] U5 itself already equipped all its patients with a glucose meter and insulin pump, and the measured values of these devices needs to be manually entered into app1.

[24] The demonstrated results of the first pilot show an improvement in the HbA1c values – an important parameter in following diabetes patients – by about 10%, as well as a reduction in secondary care costs, including absenteeism of parents (IN#2).

[25] The acquired organization continued under a different name, but this research still refers to S5A.

The development of the application is not nearing its end yet, and major components, such as the algorithms, are yet to be developed and validated. IN#2 claims that S5A is thus far able to connect predictions with a very small standard deviation to the collected data, but as IN#11 puts forward: *"if you have a prediction that is not 100% reliable, then you are basically still very far away from the patient."* Further, IN#2 suggests that after developing predictive algorithms, a next step for S5A will be to integrate aspects such as communication with the care provider, provision of information (e.g. education or social media discussions) and motivation into their application, and that aspects of app1 could be useful here. Besides, the interviewees posed several other ideas about the final shape of an application in which the predictive analyses could be integrated, and it comes forward that the algorithms may not only be useful in a mobile application, but that it could potentially be integrated in automatic insulin pumps – which are still being improved - or the emerging artificial pancreas (IN#11, IN#12, IN#16). In fact, the director of S5B (IN#12) suggests: *"What I understand from [IN#2] is that they are not even necessarily positioning in terms of making a final app, but that they rather see the added value of the algorithms, and perhaps would be able to ultimately offer that as a building block for other solutions."* In this line, IN#11 poses, that if S5A succeeds in developing good predictive algorithms, "*they will one day be acquired by a major party."* Based on the results though, no unequivocal and definitive view is given about the final shape of the application.

4.5.2 User involvement

In this part, it is first explained that S5A is working together with U5, a care institution that is very upfront in leveraging new technological possibilities, and that the development cannot be realized without U5, as they are the enabler of user involvement. Thereafter, it is discussed how the involvement of the children diabetics of U5 can be seen as some form of first user enrollment, aiming to eventually reach a larger part of the niche market of children diabetics, or even more types of diabetic patients.

4.5.2.1 The children diabetics clinic as co-originator of the idea and enabler of user involvement

As suggested by IN#2, the care providers from U5 are an important source of inspiration and enabler of the application development (IN#2). U5 moves beyond the model of infrequent visits to a clinic a few times a year, and provides near-real-time, personalized care, as patients' glucose and insulin data are tracked remotely and feedback is given to patients more quickly (SD5b, 2015). The clinic has a custom developed information system that allows patients to easily upload their own data, and allows care providers to monitor this data and identify those patients who need help (SD5b, 2015). Importantly, U5 is a care institution that is very upfront in leveraging new technological possibilities, as well as transparence about outcome measures of their treatments (IN#16; SD5b, 2015). In fact, U5 is one of the first European Centers of Reference in diabetes care, meaning that they have proven to be actually working on changing and improving care, conducting research and introduction of technological innovations (SD5c, 2015), and multiple interviewees (IN#2, IN#11, IN#16) suggest that U5 is often seen as a benchmark for other organizations. This may be advantageous for S5A with respect to creating awareness about the possibilities of their technology among other potential users.[26] Together with S5A, U5 now aims to realize a new form of remote collection of personal data by patients that moves beyond glucose and insulin values.

The idea for the application development emerged during meetings and discussions between the founder of S5A (IN#2) and U5, during which it was discussed that different bio-parameters could have a

[26] It is worth mentioning that in 2015, U5 was acquired by a large international manufacturer of insulin pumps and glucose meters (SD5b, 2015), hinting to the interest of the industry in their way of managing diabetes. A side effect, as suggested by IN#2, is that the independence of U5's care providers is now scrutinized, but the Dutch Minister of Health officially expressed her approval of this acquisition and explains that the joining of forces between the two parties should lead to improved patient outcomes and reduced healthcare costs (SD5d, 2015).

great influence on a patient's glucose level. As IN#2 explains: *"The doctors with whom I spoke said: 'We have a strong suspicion that parameters such as heart rate, stress, temperature, and movement actually have much more impact on glucose levels than what is actually published […] In fact, it may be an announcement of what will happen with your glucose. Would it not be nice if we could do some research to that?' Glucose is a resultant of everything that happens before […] yet those things were never monitored."* The idea resulted in the development of app1 - in co-creation with professional users of the application – which was used in a first observational pilot with 24 young patients managed by U5.

IN#2 believes S5A to be quite distinctive in having involved physicians from the beginning as co-creators or *"architects"* of the system, rather than that they are only being asked for feedback after the application has already been partly developed. IN#2 believes that their immediate upstream involvement may have made an important difference regarding their commitment to contribute to the ongoing development process, and to overcome the common 'not-invented-here syndrome'. As IN#2 argues: "*The key thing is that medical teams are involved from the start, and that they mainly see the data in a way that they know and understand."* Moreover, IN#2 suggest that S5A and U5 are mutually dependent in improving the remote diabetes management of children. Whereas the doctors of U5 lack the expertise for handling large amounts of data with statistics, as well as time to develop an application themselves, S5A lacks the authority to test their application on real patients which is necessary to develop algorithms and gather feedback on the application.

The second round of pilots, which was initiated in 2015, is dominantly focusing on data collection for the development of algorithms to make predictive analyses that can be eventually integrated into app2, and less on the gathering of feedback on the application, as was the case in the first application development (IN#2, IN#16). In fact, as suggested by IN#11, the development process is too far away from the final product to consider it from the user perspective. Further, some aspects of the application - e.g. the specific parameters measured - are still uncertain and it is possible that they will later be adjusted. As IN#2 underpins: *"it may well be possible that we need to take new parameters that have more or a more direct influence […]. The trends that I see at a number of patients point out that I am in the right direction, but I still need to prove that for the large group of users."* In order to developed and finally validate the resulting algorithms, S5A must involve a large number of patients and see which parameters need to be included. However, it must be denoted that, as suggested by IN#16, it is still uncertain whether S5A has sufficient corporate power to fully realize the development of a robust predictive model independently. As IN#16 puts forward: *"I think that especially the power to robustness of your prediction models is very important. And I do not know if a very small company with limited amount of data could sufficiently arrange that."* On the other hand, the acquisition of S5A by the US venture group may be beneficial for accessing resources to realize the development.

Next to the collection of measurement data during both the first and second pilots, IN#2 could ask patients and parents questions when joining consults with U5. Doctors of U5 were - and still are - the station for S5A to learn from patients as well as the doctors themselves what obstacles they encounter during the diabetes management process, how they prefer the data to be presented in the application, or to derive other feedback on the application. In app1, data was visualized purely by plotting the data on different parameters over each other. Since this results in graphs that are quite complex for many people, S5A now tries to learn - together with patients and parents, and via U5 - what kind of data users prefer to see. The first important lesson learned and associated follow-up regarding the visualization of data was to put all measured data and activities in one display, as this was suggested to be very important for the involved patients and parents (IN#2). Further, an example of a shortcoming of app1 that came forward from feedback is that it is annoying for users – i.e. patients or parents - that they need to insert the tasks or activities regarding the diabetes management in a separate agenda, next to the patient's school agenda, for instance. Although it is uncertain whether S5A will be technically able to

solve this shortcoming[27], IN#2 argues that the company at least aims to respond to this articulated requirement of users, and that it is S5A's challenge and responsibility to solve this.

In addition to the involvement of U5, IN#2 (S5A) sometimes also consults IN#11, who is both patient and expert in diabetes, and digital publisher on diabetes information. With respect to this interaction, IN#11 suggests: "*I think that it is useful for [IN#2] to get confirmation on how the patient deals with things. What I probably influenced in the mathematical models that they use is that when it comes to managing my own diabetes, then I occasionally try to push the limit and do things differently from the usual. Thus I would at least give ideas to look differently at algorithms."* This points out that IN#2 is also involving a diabetes expert who provides inspirations for the algorithm development and how to characterize diabetics. Further, IN#2 and IN#11 were introduced via U5, further emphasizing the importance of U5's involvement by S5A.

4.5.2.2 First user enrollment, aiming to eventually reach the broader children diabetics niche market

S5A considers the current users of their application - i.e. in the pilots - as the first users, who pave the way for a future, larger user population, in two ways (IN#2). Firstly, S5A has chosen to focus their mobile application development on a niche market - i.e. young diabetics - in which they perceive the management of diabetes to be the most difficult, and who have often yet to learn how to manage their disease. Hence, IN#2 puts forward that this is a pragmatic approach, because specific problematic issues regarding diabetes management can be addressed within this niche. If the application proves to be successful in this niche, upscaling to a wider diabetic patient population is expected to be relatively easy. Secondly, IN#2 suggests that the young patients involved in the pilot phases are not representative for the whole young diabetic patient population. The patients of U5 are standardly equipped with glucose meters and insulin pumps, and additionally provided with a health patch, whereas this does not apply to all diabetic children in the Netherlands or US, for instance. Besides, IN#11 argues that compared to regular hospitals, U5 is *"very far in guiding the children in the sense that their computer and algorithms largely already telling what should happen."* This suggests that the diabetes care model of U5 is not representative for the general population of diabetics.

However, as IN#2 and IN#16 explain, the limited representativeness of the users that are involved at this stage is not considered problematic, because the developments are mainly focused on determining the minimum amount of parameters on which data should be gathered by the patient, either automatically or manually, in order to do reliable predictive analyses on the patient's blood glucose values. In fact, to this end, S5A thus far only involves people that are willing to voluntarily join the search to find an application that can help them manage their disease and plan daily activities in advance (IN#2, IN#16). As IN#16 elaborates: "*It are often people that are already excited about a technology who go into these kinds of phases. But for this research issue that is good, because we want as much data as possible about glucose values and from [S5A]'s plaster, so that you get a large body of data. In that sense […] the type of patient does not make much difference yet."* Still, it is acknowledged that at a certain point account must be taken of what is a feasible amount of data to be collected by the more 'general patient' (IN#2, IN#16). Thus, although S5A currently only involves the relatively early adapters, it seems that in the future they aim to take the interests of more general diabetic patients into account.

Concluding remarks

The development of the two applications of S5A is primarily guided by the upstream involvement of the acclaimed specialist doctors of U5, and S5A has been strongly dependent on the cooperation and involvement of U5 and their patients as source of knowledge about these users and feedback on the mobile application. The involvement of users hereby stimulates the tailoring of the application to these

[27] IN#2 explains that in order to solve this, the new application could be integrated with an existing agenda – e.g. Google or Apple Calendar – which however, do generally not offer the possibility to make an interface to the parents to set alerts.

users' specific requirements. It is expected that in later development phases, S5A will broaden their perspectives towards the more general (potential) users of the application, rather than only involving the 'technological frontrunners' of U5.

4.5.3 Generification strategy

According to the results, S5A aims to offer one final application, though with flexibility within the settings of their mobile application in order for users to choose the functionalities they want to use, or the specific information they want to see. As IN#2 puts it: "*I want that people can configure what they do and do not want to be included in the application. [...] I can imagine that for many people it is yet too much, and certainly when you apply it for diabetes type II. They only need part of it."* Furthermore, S5A aims to develop their algorithms in such a manner that the predictive analyses are highly personalized and responsive to personal lifestyle and dependence on certain parameters (IN#2). As IN#2 argues: "*What patients want to hear is that they really are extremely unique." […] So it is indeed that I have to prove and confirm that what you see here is your personal model based on your data, based on what we have learned from you […] and that is not simply transferable to another patient, whom has a different lifestyle."* Accordingly, IN#2 notes that the option that multiple algorithms will be developed is not excluded, and that S5A is eventually prepared to offer different specific algorithms for different users, when necessary. In line, IN#11 states: "*I think that in 80% of the cases it simply is a mathematical algorithm. If it works for one patients, then it works with the other patient as well. Only we have 20% of patients where other factors are going on that cross the mathematical algorithm. […] What is a factor, for instance: people that have had diabetes for a long time can suffer from delayed gastric emptying. So when the stomach does not start working immediately after eating, but it rather takes one and a half hour […] then you make the rules different, because that one and a half hours is not in that algorithm."* Therefore, it seems that S5A may have to deviate from offering one single solution. Besides, with respect to the full RPM configuration in which the mobile application will be part, S5A aims to allow users to choose with which specific measurement devices they connect the mobile application, as addressed in section 4.5.4.

Concluding remarks

Although one application will probably be offered to all users, the aim is to offer flexibility in choosing specific functionalities and ways of data display, as well as measurement devices to be connected. Moreover, the algorithm development is specifically focused on making an adequate distinction in the predictive analyses of individuals' blood glucose values. Thereby, the potentially negative influence of offering a single solution on the tailoring to user-specific requirements may be somewhat negated.

4.5.4 The use of design standards

In the following, it is first discussed that S5A aims to automate as many aspects of their future application as possible, and to offer flexibility with the future application for users to choose themselves what measurement devices they connect to the application. Thereafter, it is explained that the set of available devices that can finally be integrated with the mobile application gradually increases, and that design standards facilitate to realize integrations with these devices.

4.5.4.1 Aim for automation of measurements

IN#2 suggests that S5A aims to automate as many aspects as possible within the RPM process supported by the mobile application. As IN#11 explains, everything that goes wrong in the diabetes management process is what patients should do themselves, and such errors can be prevented by automation. Therefore, IN#11 argues: "*if making something for people with diabetes you should make sure that it is all automated. So automating and making it simple, that is the only way in which you get compliance from people"* (IN#11). This points out that automation of aspects in the remote diabetes management

process and the required interoperability between measurement devices and the mobile application of S5A to facilitate automated transfer of data are important for users

4.5.4.2 Aim to offer flexibility to select measurement devices

During the second pilots of S5A and U5, a health patch is used for the gathering of bio-parameter data, next to the standard data gathering by a glucose meter and insulin pump. Although there are some downsides to the health patch - i.e. short shelf life and stickiness - the device is chosen because it is one of the few available medically certificated devices (IN#2, IN#16). As IN#2 argues, wearables are "*becoming more reliable, but for me it was an alternative that had far less quality than the plaster."* By all means though, IN#2 suggests that the idea of S5A's final mobile application is that different sources - preferably smartwatches and fitness trackers - can be used as inputs for data on which the predictive analyses will be based. As he puts it: *"I definitely prefer consumer electronics or normal wearables that can be used without irritations such as the stickiness of those things. […] My preference is that eventually the consumer, the patient himself chooses what wearable he uses. […] We can say: well fine, give us that data, we will process it and give it back in our app."* Recently, S5A already realized interfaces with a wireless heart rate and activity wristband, as well as a smartwatch for tracking fitness and sleep (IN#2). When S5A has gained more insight on the types and amount of data that are required for reliable predictive outcomes of their application, they can eventually set up a list with the types of wearables that can be used in combination with the mobile application. Additionally, IN#2 states that it will be important here to do some recommendations to users on what kind of measurement devices are reliable. Thus, although S5A has not yet reached this phase of laying connections with a variety of measurement devices, the results suggest that they will finally offer configurational flexibility to this end, if possible.

4.5.4.3 Standards as facilitator to integrate measurement devices with the application

Some standardized ways for data transfer by wearables have come up in the interviews. Most wearable measurement devices use Bluetooth Low Energy for transferring data, which as in fact become a de facto standard way regarding realization of connectivity (IN#2, IN#12). However, no general information-standard is available yet for the way in which the data is presented and transferred, and although existing standards such as HL7 offer little help for transferring the kind of data concerned in these devices, the standardization of measurement data is suggested to be addressed at the moment (IN#2). Furthermore, IN#2 and IN#12 point to a trend towards the creation of ecosystems or containers, such as Apple HealthKit and Google Fit, in which large amounts of measurement data can be stored, and to which different devices can easily transfer their data. It is expected that such ecosystems can facilitate the transfer of data from measurement devices to mobile applications, and serve as an intermediary station with standards for data exchange. As IN#12 explains: *"at some point some party just bashes through and creates the de facto standard, and the chance that that will be an Apple or a Google is very likely, of course."* As IN#2 states: "*that makes it much easier for me to get that data. Then you can choose yourself what kind of wearable or application you use."* This development may be important for IN#2 to finally offer freedom with the mobile application for users to determine themselves how to collect data.

Concluding remarks

S5A aims to offer their final mobile application with some flexibility for users to choose which measurement devices they use together with the application. Using standards for data transfer is important to make integrations with different measurement devices, and allow to tailor the RPM configuration to user-specific requirements. Emerging ecosystems with standards for data exchange may become important intermediary stations that can lay the connection between measurement devices and the mobile application.

4.6 CONTEXTUAL BACKGROUND

In this section, additional results regarding the research phenomenon are discussed which go beyond the scope of the specific cases under investigation, but which provide relevant information that help answering the research question. First, it is discussed that the quality improvement and upscaling of standardized RPM platforms is being stimulated on a national level through the independent assessment and optional approval of different platforms. Then, additional results are given about the importance of design standards for tailoring RPM configurations to user-specific requirements, and about the progress in both their development and adoption.

4.6.1 Stimulating quality improvement and upscaling of standardized RPM platforms

In the following, it is first explained that involved organization V (IOV) is a Dutch initiative that aims to provide better insight and create transparence about the quality and the choice between different RPM platforms that are available, and that this development is expected to stimulate a shift towards a consumer market in which suppliers are forced to listen to users. Also, it is explained how the objectives of IOV are may increase the incentives for third parties to connect their products to standardized platforms, thereby extending the functionalities of the platforms.

4.6.1.1 Objectives of IOV; independent assessment of RPM platforms

IOV is an independent foundation for the assessment of remote care platforms in the Netherlands.[28] IN#17 explains that IOV aims to stimulate the tailoring of RPM systems to the needs of end-users, by providing better insight and creating transparence about the quality and choice between different RPM platforms that are available. As IN#17 explains: *"there were seventeen platforms who said they were doing something with self-management. […] That means that you should create clarity and transparence, and that is must clearly come up what is, and what is not effective. Well, we are very busy doing that. […] We have brought up all kinds of rules, tools and things that are good to the surface […] and put them together in an implementation toolkit. But we have also said: 'what is really crucial for a patient and a caregiver?' and we have put down the minimum basic requirements for that."* IOV thus defined what should at a minimum be included in a RPM platform with respect to aspects such as security and functionalities (SDCa, 2014). Platforms that apply for approval are being assessed by an audit commission - independently from IOV - and the resulting platforms that comply with these basic criteria are put on a list (SDCb, 2015).[29] Crucially, healthcare insurers will ultimately pay reimbursement only for the approved platforms that are put on this list. This implies that compliance with the basic criteria by suppliers and adopters is partially enforced, and that user organizations in the Netherlands will finally be allowed - or at least financially stimulated - to choose to adopt a platform from this list. As IN#17 argues: *"If they all meet with these requirements, then I am happy. But on the other hand there is the question whether there is room for so many platforms, because they should also be paid for. You assume that you must have a certain scale, because you do have done some investments."* Thereby, it is expected by IN#17 that this list will eventually grow to around five platforms.

Further underpinning the importance of transparence about what different platforms offer, IN#17 states: *"It must be clear for users which ones are, and which ones are not effective, which do not meet certain standards, and what do others think of it?"* Thereby, it will become easier for care organizations

[28] As addressed in cases 1 and 3, the pilot project of involved organization T (IOT) assessed the needs of a large variety of patients and user organizations in Dutch healthcare regarding remote management of chronic illnesses. While the activities of IOT arrive at their final in the end of 2015, a large part of IOT is merging into IOV, as suggested by the director of both IOT and IOV (IN#17). In contrast to IOT, which is a consortium between two large commercial organizations, IOV is joining forces between representatives of patients, care providers and health insurance companies, who actually decide over the adoption of RPM platforms and/or are using them (IN#17).

[29] This list currently contains three platforms, including those of case 3 and 4.

to choose the platform that best match with their specific requirements. Besides, IN#17 explains that RPM market – and healthcare more broadly – is making the transition towards a consumer market in which users have an important influence on the technological design, and in which suppliers are forced to listen to users. The transparency in the choice between different systems and the enforcing of certain requirements – as formulated in the basic criteria – stimulates suppliers to deliberate on the interests of (potential) RPM technology users, in order for their RPM systems or components to become adopted. In fact, IN#17 argues: *"The ones that are best listening to their customers will be most commonly used. And then you get a very different market than we are normally used to in healthcare, because then you get a consumer market. We are not there yet, but that is where we want to go."* As suggested by IN#17, it is preferred that users can themselves decide which (approved) platform and additional components best fit their needs. Although usability of the platforms, for instance, is not included in the basic criteria of IOV, it is deemed important for IOV to facilitate the disclosure of information about this in reviews, for instance, and that then the best products will survive through market forces (IN#17). Thus, the expectations are that platforms that best meet the needs of users will ultimately survive.

4.6.1.2 Potential increase in incentives for third parties to innovate on standardized RPM platforms.

Interestingly, IN#17 explains that because a relatively small set of platforms is expected to be good enough to qualify for approval by the independent audit commission, platform suppliers have the opportunity to obtain a large market share, which may actually stimulate third parties to innovate on these platforms (IN#17). This is mutually beneficial for the platform suppliers and third parties, because *"the more you put on it, the more attractive it becomes for that platform"* (IN#17). Hence, an important requirement for the platforms is that *"things need to communicate with others, and that does not only mean sharing information, but it also means that you should be able to put applications and devices from third parties on a particular platform"* (IN#17). Accordingly, the aim of IOV is that additional components - e.g. mobile applications, measuring devices, or e-learning or e-coaching modules such as the one addressed in case 2 - can also be integrated in these platforms, to extend the RPM configurations with additional functionalities, if required (IN#17), and allow the configurations to be better tailored to user-specific requirements.

4.6.2 The importance of using design standards and progress in their development and adoption

Building upon the above, it is suggested that when products of third parties are not easily linkable to a platform, consumers will rather tend to adopt other products in their configurations (IN#17). IN#17 suggests that in order for different components to be easily linkable to standardized platforms, it is important that single design standards emerge for certain types of technologies - e.g. mobile applications, measuring devices, information systems, etc. - to be integrated with the RPM platforms. In the following, it is explained what results are found on the progress in the development and adoption of standards.

Regarding the development of standards, IN#17 suggests that IOV still needs to define them and include them in their implementation toolkit. Further, IN#17 suggests that standards are still lacking with respect to aspects of e-health such as the individual care plan, but that such issues are being addressed by, amongst others, involved organization Z (IOZ), which is a Dutch expertise center in the development of Healthcare ICT. As a program manager of IOZ (IN#15) explains: *"We are working hard to ensure that everyone is using the same language. […] you just use one language, because different care providers need to understand each other when they exchange information. It is very hard work to get that aligned. We see that it really takes a lot of years to really match that well with each other."* This points out that more efforts need to be, and will be put into the further development of standards, and that it takes time for interoperability to be achieved among many instances.

IN#15 suggest that much work still needs to be done on the fine-tuning of standards to specific use practices. As IN#15 explains: *"for many things there are a lot of basic standards, but many of those standards must constantly be made custom to the users. It is not like 'well, here is the standard, plug and play'. […] You should really make agreements about that standard in the Netherlands like 'what do we mean with this, what do we mean by that?', because otherwise it will just not work."* On the other hand though, IN#15 suggests that it is also important for IOZ to follow international developments on standards, for instance on the HL7 standards, because around forty countries are making agreements on the exchange of data, thereby creating a large mass of parties that is compliant with these standards. Furthermore, IN#15 argues that some commonly used standards, such as EDIFACT, are sometimes no longer suitable and leading to limitations regarding the response to certain user requirements. As IN#15 explains: *"The world today demands solutions à la smartphone, so you also want to include pictures or photos, you want to send along ECGs, you name it. Then you surely need to have a slightly different standard in order to transport that kind of data."* In fact, as found in the basic criteria document of IOV (SDCa, 2014), it is strongly recommended to convert to HL7 standards during the maintenance of integrations with EDIFACT. Thus, such 'outdated' standards are gradually being replaced by newer, improved standards such as HL7 (IN#15), gradually allowing systems to better meet users' needs (IN#15).

Regarding the adoption of common standards, IN#17 suggests that some users and suppliers may in the first instance oppose the standards that emerge, because up until now, everyone has been storing data in a different way (IN#17). However, as he points out: "*standards should actually lead - at least the ones we define here - to greater flexibility, more possibilities, and not that you have one solid design. […] I think that for the users it will much better in the end, but it has a turning point"* (IN#17). This point out that it is expected to be a matter of time before interoperability and compliance with the finally dominant standards is realized among many care practices and suppliers of RPM system components.

Concluding remarks

The additional results point out that - on a national level - the IOV initiative stimulates the compliance with basic requirements by RPM platform suppliers, and the transparency about the quality and choice of these different platforms. Hereby, the healthcare market may be in a transition towards a more transparent consumer market, in which users can better determine what configured system best meets their needs, and in which RPM technology suppliers are forced to listen to their clients in order to tailor their products. Further, the use of design standards is important for different technologies – including third party products - to be easily connected to the platforms and thereby extend the overall functionalities of the platforms and increase the configurational choice for users. In turn, this may lead to more flexibility to tailor RPM configurations to user-specific requirements. Also, it is suggested to be important to follow international developments in standards and to adapt the more broadly defined standards to specific local requirements. The additional results are taken up into the overall analysis of case results in order to help answering how the independent variables influence the dependent variable.

5 ANALYSIS

This chapter addresses the main findings regarding the influences of the three independent variables on the dependent variable that emerged during coding and analysis of the empirical data. A cross-case analysis is given, in which the results of cases and contextual background are taken altogether and compared with literature according to the division made in the theoretical background, in order to discuss a number of cross-cutting themes and analyze how the independent variables ultimately influence the dependent variable. Parallel to the case profiles given in chapter 4, section 5.1 discusses the dependent variable in terms of the ways in which RPM systems can be tailored to user-specific requirements, in order to better understand the dependent variable and how it can be influenced by the independent variables. Thereafter, sections 5.2, 5.3 and 5.4 provide separate analyses on the several patterns and concepts that emerged about the influence of user involvement, generification strategies and the use of design standards on the tailoring of RPM systems to user-specific requirements during development and implementation. Some of the similarities and differences among the cases regarding these findings are explicitly discussed.

5.1 THE TAILORING OF RPM CONFIGURATIONS

The case results show that the RPM systems consist of multiple technical and human components that can be integrated and arranged in different ways, according to specific needs of different use practices. Figure 7 visualizes how the RPM configurations are generally built up.

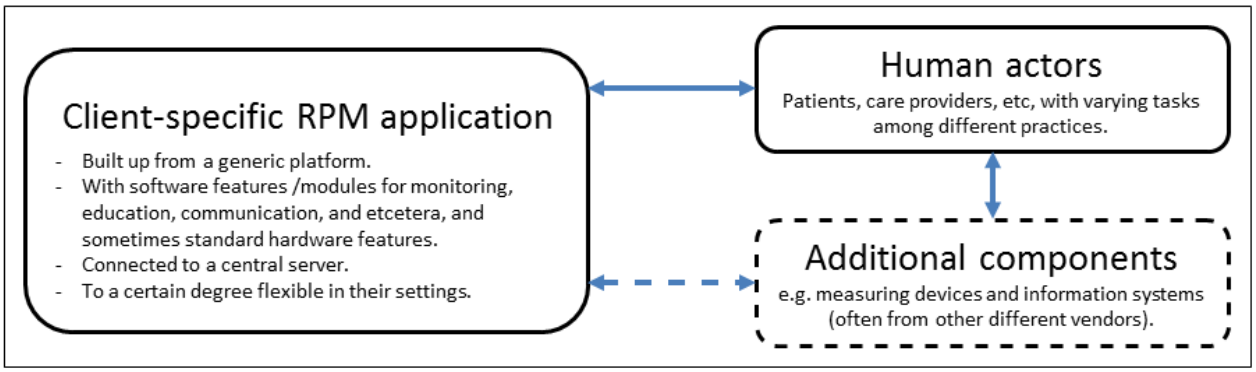

Figure 7: Visualization of the components from which the RPM configurations are generally build up. The dashed box and arrow represent components and connections that are optionally part of the configuration.

The configurations are primarily built up from generic platforms that contain the building blocks for client-specific RPM applications, including features or modules for monitoring vital signs, education and communication, for instance. The client-specific RPM applications, which are used by a specific care group and their patients, are connected to the supplier's central server, which stores data, eventually analyzes data, and exchanges data between different parts of the RPM application - e.g. between a patient dashboard and a professional dashboard - or additional components such as information systems from the care institution. Some generic platforms offered by suppliers only contain software components (e.g. cases 2, 3, 4 and 5), while other platforms also contain standard hardware devices, such as a set-top box and measurement devices, with integrated software (e.g. case 1). The platform applications are generally stabilized into more generic structures, because most features of the generic platforms are standardly part of the client-specific applications. However, as explained in the following, in three ways room is left for tailoring the RPM configurations to user-specific requirements.

Firstly, the client-specific RPM applications built up from the generic platforms are part of a larger RPM configuration; human actors including patients and care providers, and in many cases components such

as measuring devices and other information systems, are also part of, and eventually integrated into the configuration. Thereby, it applies to all cases under study that the RPM configurations consist of various subsystems that complement each other, and which are provided by different suppliers. There is substantial variety in the additional components - i.e. used together with the RPM platform application - that are part of client-specific RPM configurations used among different practices. For instance, care groups adopting the RPM platform applications are often already working with established information systems from a variety of vendors, and different types of measuring devices may be required among patients. Such local contingencies must be taken into account by the RPM system builders, in order to better tailor the system to user-specific requirements. Complementing platform-based RPM applications with additional RPM technologies thus ensures part of the tailoring of RPM configurations to user-specific requirements. Importantly, the case results show that sometimes, and preferably, the subsystems are connected to each other in order to increase efficiency and ease-of-use, as they prevent the need for users to work in two different systems at the same time or to manually enter data.

Secondly, on a patient-specific level, the tailoring of RPM systems is partly realized within the technical components by offering content specifically selected for the individual patient. By taking personal characteristics of patients into account, and tracking them over time, if dynamic, the RPM platform applications can offer personalized content in its various forms – i.e. education, instructions, feedback, questionnaires, and etcetera. As addressed in section 5.2, the involvement of users by suppliers and interactions between care providers and patients are crucial in determining the settings of the configuration. Importantly, it is often tried to develop more generic solutions that fit with certain patient profiles which can be distinguished. Also, in all five cases, the platform suppliers have added and/or are adding some form intelligence to the system, by integrating algorithms for making decisions regarding the offering of content, for instance. Hereby, they aim to realize that some of the tailoring work is automatically done by the system.

Thirdly, human actors such as patients and care providers are also part of the configurations, and their assigned tasks, responsibilities and routines regarding RPM can vary among different use practices. These are also local contingencies to be taken into account in order to successfully implement the RPM systems, and as discussed in section 5.2.4, this is not only a responsibility for suppliers, but also for users themselves in terms of adapting their routines.

To conclude, it emerges in all five cases that the tailoring of RPM systems to user-specific requirements is one the one hand realized on the architectural level by (re-)arranging pre-existing components, such as measurement devices and information systems. On the other hand, much room for tailoring RPM systems lies within the components – i.e. in the content - offered.

5.2 THE INFLUENCE OF USER INVOLVEMENT

Table 1 provides the main findings regarding the influence of user involvement that have emerged from the analysis, including four main categories that constitute the nature of user involvement by RPM technology suppliers and its influence on the tailoring process, together with subcategories. Firstly, it is found that end-users of RPM systems are increasingly involved upstream and providing suppliers with feedback during the continued development of RPM systems. Secondly, suppliers are broadening the design process to deliberate on heterogeneous user perspectives. Thirdly, explicating the characteristics of the heterogeneous users is providing a means for tailoring system settings to user-specific requirements, and fourthly, it is important that suppliers interact with users to encourage them and teach them how to use the system. In the following, it is discussed what these categories and subcategories tell about the influence of user involvement on the tailoring of RPM systems to user-specific requirements.

Table 1: Main findings about the influence of user involvement, and the parts of results in which they emerged (case numbers and cb=contextual background). Each finding listed here is highlighted (bold and italic) in the following part.

Main findings (user involvement)	1	2	3	4	5	cb
1 Upstream involvement and feedback from end-users during continued development						
Suppliers are structurally and actively involving end-users during the initial and continued development	x	x	x	x	x	
User involvement is deemed necessary during development to build systems that will be adopted and successfully used		x	x			x
Feedback from users after implementation of major importance for improvements	x	x		x		
Increasing deliberation on the views of the actual end-users	x		x			
The interests of care providers may sometimes be prioritized over the interests of patients				x		
The gathering of feedback during organized user involvement is directed by designers		x	x	x	x	
2 Explicating the characteristics of heterogeneous users as a means for tailoring system settings						
Situated use in pilot projects (important to understand and articulate needs)	x	x	x		x	
Explicating patient characteristics and the associated creation of patient profiles	x	x	x			
Fine-tuning the system settings, together with the user, though increasingly being automated	x	x	x	x		
3 Broadening the design process to deliberate on heterogeneous user perspectives						
Broadening the design process by involving a variety of patients and multiple care groups		x	x	x		
Not always deemed important by suppliers to stimulate mutual understanding of interests between patients and care providers			x	x		
Awareness about the limited representativeness of early adapters among the first involved or enrolled users for the whole targeted user population	x	x	x	x	x	
Complaints and non-use are taken seriously or even forcing suppliers to improve their systems	x	x	x	x		
Non-use is found to be sometimes insuperable		x	x	x		
4 Required interaction with users to encourage them and teach them how to use the system						
Required feedback to users after implementation; teaching them how to optimally use the system	x	x	x			
Healthcare practices and the routines of care providers require a transformation	x	x	x	x		

5.2.1 Increasing upstream involvement and feedback from end-users during continued development

As found in all cases, ***suppliers are structurally and actively involving end-users (i.e. patients and care providers) during the initial and continued development*** of their systems; for instance by having part in a grand national pilot study that amongst others focuses on gaining understanding about the requirements and behavior of different users of RPM technology (cases 1 and 3), by developing and improving RPM solutions to a greater or lesser extent in co-creation with end-users and intermediary patient organizations (cases 2, 3, 4 and 5), or by applying a structured procedure for gathering the requirements of different users groups through feedback, in order to set up a prioritized list with planned improvements (case 4). In fact, as comes forward in cases 2 and 3, as well as the contextual background results, ***user involvement is deemed necessary during development to build systems that***

will be adopted or successfully used, in order to prevent that RPM solutions are only developed from a technical perspective, but not (optimally) useful in practice. The contextual background results suggest that it is currently being stimulated on a national level to improve transparency about the features and quality of RPM platforms and additional components (i.e. third party applications), hence to enable (potential) users of RPM systems to optimally determine what technologies best match with their specific needs. In this way, it is aimed to make the RPM industry - and healthcare more broadly - more of a consumer market, in which suppliers are forced to listen to their customers in order to come up with desirable products.

Further, it emerges from cases 1, 2 and 4 that ***feedback from users after implementation has been of major importance*** in terms of further demand articulation and for suppliers to improve their systems accordingly. This finding does not emerge in cases 3 and 5, because these systems are not yet commercially implemented, but rather used in pilot projects. This finding particularly applies to case 1; the RPM system was implemented relatively early compared to the other cases, and - at least in the Netherlands - the system supplier ran into a laborious implementation process, partly due to limited available knowledge within and beyond the organization about what is relevant to end-users, i.e. patients and care providers. Over time, this supplier has extensively learned from the use of their platform and respective feedback from users on how to improve it. Largely based on feedback from care providers, intervention rules determining under which circumstances care providers are alerted by the system have been adapted, for instance. Related thereto, as emerges in cases 1 and 3, there appears to be ***increasing deliberation on the views of the actual end-users*** of RPM systems when compared to formerly when RPM was an even newer phenomenon. The original system of case 1 was largely designed based on the perspectives of actors that decide about the adoption of RPM technology, such as specialists and hospital policymakers, but who are barely or not working with the system. As a result, the system did not fit well with the needs of the actual end-users, i.e. patients and nurses or nurse specialists, causing difficulties during and after implementation. Therefore, the respective supplier has been increasingly directed by the perspectives of these end-users during the development of their renewed platform. An explanation why especially this supplier rain against this problem may be that at the time of the initial development of this system, the role of RPM in healthcare and the associated roles and responsibilities of different actors were less apparent than at present. Further, this pattern also applies to case 3, because the respective platform supplier since recently aims to actively involve patients in soundboards that evaluate and help improve their platform, next to the already extensively involved care groups. In turn, this indicates that the perspectives of care providers and patients may be considered more equally important by suppliers than in the past. In contrast though, it also emerges in case 4 that ***the interests of care providers may sometimes be prioritized over the interests of patients***, because care providers actually decide about the technology adoption, for instance. Also, the perspectives of patients are often accessed by suppliers via care providers, as explicitly found in cases 3 and 5, though it is not clear whether and how this influences the tailoring of RPM systems to patient-specific requirements.

As found in cases 2, 3, 4 and 5, ***the gathering of feedback during organized user involvement is directed by designers***, meaning that that suppliers actively seek for specific feedback and determine the aspects on which specific feedback is asked, rather than that users are asked to give all kinds of feedback. As specifically found in cases 3 and 4, it is deemed important to have some steering by the supplier in order to gather useful feedback, ensure efficiency of user involvement processes, and prevent users to expect that all their wishes can or will be responded to. This does not imply that no feedback is obtained by suppliers outside of these boundaries, as users can still come up with other feedback from their own initiative, though it does imply that it is not stimulated by suppliers that users come up with any kind of feedback they consider important. However, based on the gathered results, it cannot be determined

whether or not the steering of user involvement processes by suppliers withholds important feedback to be gathered and thereby hinders the tailoring of RPM systems to user-specific requirements.

Further, though only found in case 1, a shortcoming in the involvement of users is that the respective supplier sometimes comes up with undesired adaptations without sufficient deliberation on users' views. While some adaptations may seem logic and useful from a technical perspective, they may appear not to be desirable from a practical perspective. An explanation that this shortcoming is found for case 1 could be that the decision about the adaptation was made on a global level where local contingencies and preferences are not always taken into account. As comes forward in cases 1 and 4, large international suppliers - especially those of certificated hardware devices, as discussed in section 5.3.3 - are sometimes rather rigid in responding to the articulated needs of users - especially those articulated locally - despite their strength to take the lead in extensive development processes, extensively involve users, and deliver a solid product, because of the many links that must generally be passed within large international firms to communicate user insights and before important decisions are made.

5.2.2 Explicating the characteristics of heterogeneous users as a means for tailoring system settings

The results of cases 1, 2, 3 and 5 indicate that the ***situated use of the systems in pilot projects*** has been important for users to understand and articulate their needs, hence for suppliers to make improvements to their technology. In case 3, for instance, a former version of the platform is extensively used in pilot studies in order to map trajectories that different patients follow during the RPM process, and thereby better understand how to optimally set up the system. These user trajectories reflect the result of a process of ***explicating patient characteristics and the associated creation of patient profiles*** that takes place in cases 1, 2, and 3. The resulting patient profiles direct care groups in assigning specific care pathways supported by the RPM systems to individual patients. Results on this process of explicating user characteristics were also found in case 5, although here no distinction is (yet) made between different user profiles within user groups (i.e. patients and parents). As found in cases 1, 2, 3 and 4, an important task during implementation that is dependent on the adequate explication of user characteristics, and for which patient profiles can be used, is the tailoring of RPM systems in terms of ***fine-tuning the system settings, together with users***. Though ***increasingly automated***, this is done in conjunction with users, meaning firstly that suppliers interact with care groups in order to determine how to tune RPM systems specifically to their practice. Secondly, on a more specific level, care providers tailor the RPM process and associated use of the RPM system to the individual requirements of patients, which can be done in cooperation with these patients or based on insights on their characteristics and health status. The fine-tuning seems to be increasingly automated by integrating some form of intelligence (i.e. algorithms) into the systems, which direct the systems in the content they deliver to individual users - e.g. education, instructions, feedback, questionnaires, and etcetera. Thereby, the task of adequately tuning the system settings according to user-specific requirements seems to be partially shifting more towards suppliers and the development phase.

5.2.3 Broadening the design process to deliberate on heterogeneous user perspectives

The suppliers seem to acknowledge that their user populations are likely to be very heterogeneous, and the results indicate that they are ***broadening the design process by involving a variety of patients and multiple care groups*** in order to understand heterogeneous user needs, and because they acknowledge that they cannot rely on the views of individuals (cases 2, 3 and 4). By involving patients with varying characteristics in terms of age, gender, education, and etcetera, as well as multiple healthcare institutions with possibly differing methods and routines, suppliers try to learn about the heterogeneity among and within these user groups, and gather insights about the more common denominators among different users, hence to set a platform that is robust among different settings. Regarding the involvement of different healthcare institutions, in case 2 it is found to be acknowledged by the developing team that different care institutions - e.g. peripheral versus academic hospitals - and their

care providers can be very different from each other. Moreover, as comes forward in cases 2 and 5, care institutions often tend to apply the not-invented-here principle, and they keep reinventing the wheel in order to make sure that solutions are specifically customized to their practices, which reduces the chance of adoption and upscaling of a system developed elsewhere. As put forward in case 2, the involvement of different types of care groups or care institutions during development may help to overcome this principle, because care institutions perhaps earlier tend to adopt a technological solutions when it is being developed in co-creation with a care institution with similar practices and routines. By all means, this finding suggests that user involvement is here indeed part of a generification strategy to develop RPM systems that are robust across a variety of use practices.

An interesting finding regarding broadening that comes forward in cases 3 and 4 is that it is ***not always deemed important by suppliers to stimulate mutual understanding of interests between patients and care providers*** by simultaneously engaging them during the design process. In these two cases, these two end-user groups are mostly involved separately to deliberate on their interests regarding the RPM technology design. In case 4, it was even suggested that the supplier is the actual link in the development process that connects the perspectives of different user groups to establish a consensual frame. Related thereto, it applies to all cases is that the needs of patients and care providers are separately being responded to in RPM systems, for instance in the sense that separate dashboards with different degrees of data complexity are provided to both user groups. This may be one explanation why some suppliers do not consider it necessary to engage these different user groups simultaneously.

Furthermore, in all cases, suppliers are found to have some ***awareness about the limited representativeness of early adapters among the first involved or enrolled users for the whole targeted user population***.[30] Suppliers acknowledge that a substantial share of the first users may be relatively easily adapting to the introduction of RPM technology, since these types of users (i.e. early adapters) are generally more willing to participate in pilots or early phases of implementation. Besides, in all cases except case 5, suppliers have not only involved the users that are relatively easily adapting to the introduction of RPM technology and more willing to participate, but also the more slowly adapting and critical patients in pilot research and patient panels, for instance. The concerning suppliers namely aim to develop and improve their platform to such an end that it becomes robust for the broad user population among which many people are found to be having difficulties to adapt and use the technology. The reason why the system supplier in case 5 - in contrast - does actually only involve the relatively early adapters is their current focus on gathering measuring data for algorithm development, which is easier with users that are enthusiast and willing to gather this data, rather than gathering the perspectives of a variety of users on the technology.

Though, the above finding that suppliers aim to deliberate on the perspectives of the broad user population does not imply that they also aim to always respond to the requirements of users and potential users that have difficulties and dissatisfactions with their systems. On the one hand, suppliers claim that ***complaints and non-use are taken seriously*** (cases 1, 2, 3 and 4), and if possible improvements are made accordingly. In fact, as in case 1, non-use can even be problematic because too many users stop using the technology, thereby ***forcing suppliers to improve their system***. Non-users - in this case specifically people who are no longer users (i.e. rejecters) - of the technology can thus have a positive influence on the tailoring of the system to user-specific requirements. On the other hand, though, it is found that not all user-specific requirements can be responded to, and ***non-use is found to be sometimes insuperable*** (cases 2, 3 and 4) because some patients simply do not want - or are not able

[30] The five RPM platforms under study are still being used in pilot projects or in relatively early phases of implementation and their use scale is still limited, whereby it can be stated that there is first user enrollment, and suppliers aim to improve their platforms according to the use insights derived from these first users.

- to be remotely managed on their illness (anymore).[31] Moreover, complaints and non-use are not only deemed to be caused by technological shortcomings, but also by a poor approach at the implementation side, which will be discussed in the following.

5.2.4 Required interaction with users to encourage them and teach them how to use the system

As suggested in section 5.1, the assigned tasks, responsibilities and routines of users regarding RPM can vary greatly among different use practices. In this line, some results point out that tailoring RPM systems to user-specific requirements is not only an issue of designing and redesigning the systems by suppliers, but also of encouraging users to use the system and teaching them how to use the system. As follows below, this is not only a responsibility of suppliers, but also of users themselves.

The results show that not only among patients, but also among care providers, a distinction can be made between early adapters and later or non-adapters, in terms of ability and willingness to work with RPM systems. This firstly points to the ***required feedback to users after implementation to teach them how to optimally use the RPM system*** (cases 1, 2 and 3). As comes forward in case 1, there may be room for improvement regarding the in-depth explanation by the supplier to users about what is possible with the system, hence to achieve a better fit between their routines and the technology. As emerges in cases 1 and 3, the provision of such feedback is the responsibility of both suppliers and the early adapters among users who already successfully work with the system.[32] Besides, as put forward in case 1, a shortcoming to existing RPM systems and the way in which they are enrolled may be that they do not sufficiently seduce patients to actively participate in the RPM process, as they do not focus on the care aspects that are deemed important by individual patients themselves.

Secondly, many results indicate that in order to sufficiently adapt to the introduction of RPM, ***healthcare practices and the routines of care providers require a transformation*** to better fit with the RPM process (cases 1, 2, 3 and 4). In order to improve the efficiency and quality of care, it is deemed important for these actors to be less constraint to the use of RPM technology and patient empowerment, and in fact, they should adapt their responsibilities and routines to the RPM process. In this way, RPM systems may better fit with the 'supposed' requirements of users. In case 3, it explicitly comes forward that the RPM system supplier aims to stimulate the transition towards RPM-integrated care processes.

Conclusion

The analysis suggests that while RPM systems have initially ran - and still do run - against problems during implementation due to a misfit of technological design with user-specific requirements and a lack of flexibility to tune system settings to individual preferences, interactions with heterogeneous users have provided suppliers with valuable insights that helped tailoring of RPM systems to user-specific requirements during initial and continued development, as well as during implementation when deploying the systems. Both initial and continued development processes have increasingly taken place in conjunction with the actual end-users, namely care providers such as nurse specialists and patients, although the interests of the care providers may sometimes be prioritized over the interests of patients, causing RPM systems to be potentially less well tailored to patients' requirements. Also, although sometimes deemed insuperable, non-use and dissatisfaction are taken seriously by suppliers, and sometimes even enforcing certain improvements to be made. Furthermore, it is important for suppliers and successful professional users to provide other users with feedback and teach them how to use RPM technology, and room may be left for better utilization of this way of user involvement. Besides, it is important to stimulate the adaptation of healthcare practices and routines to - or in fact a cultural change towards - the remote management of chronic illnesses, in order to allow RPM systems to fit with

[31] Thus, this applies to both voluntary and involuntary non-use, as distinguished by Wyatt (2003).

[32] In cases 1 and 3, only the necessity of such feedback to care providers comes explicitly forward, but adequate feedback may also be important for patients.

users' supposed needs and preferences. On the other hand though, user involvement may not always be a means to respond to all user-specific requirements, and even hindering the tailoring of RPM systems to all user-specific requirements. The nature of user involvement is namely found to be sometimes moderated by generification strategies of suppliers, causing suppliers to broaden their design process by being critical about the perspectives of individual users and deliberating on heterogeneous user perspectives, hence to gather insights about the common denominators and build standardized platforms that are robust across different healthcare practices and among a broad patient population. It is therefore concluded that user involvement may simultaneously stimulate and hinder the tailoring of RPM systems to user-specific requirements.

5.3 THE INFLUENCE OF GENERIFICATION STRATEGIES

Table 2 provides the main findings regarding the influence of generification strategies of suppliers that have emerged from the analysis, including three main categories that constitute the nature of generification strategies by suppliers and how they influence the tailoring process, together with subcategories. Firstly, suppliers are using their own generic platforms to build up client-specific RPM applications. Secondly, suppliers regularly adapt the generic platforms and thereby try to better respond to users' requirements. Thirdly, suppliers offer possibilities to integrate different components into the configurations. In the following, it is discussed what these categories and subcategories tell about the influence of generification strategies on the tailoring of RPM systems to user-specific requirements.

Table 2: Main findings about the influence of generification strategies, and the parts of results in which they emerged (case numbers and cb=contextual background). Each finding listed here is highlighted (bold and italic) in the following part.

Main findings (generification strategies)	1	2	3	4	5	cb
1 Use of generic platforms to build up client-specific RPM applications						
Generic, modular platforms from which the different client-specific RPM systems are built up	x	x	x	x	x	x
System with a focus on the common denominators, together with the option for individual fine-tuning of settings by users		x	x			
2 Regular adaptations to the generic platforms to better respond to user requirements						
Supposed improvements to the platform apply to all users (i.e. care providers)	x	x	x	x	x	
Prioritization of adaptations; not the aim/possible to respond to all user-specific requirements	x	x	x	x		
Users believed to be more common than they recognize themselves	x		x			
Limiting individual customization	x		x	x	x	
Better manageability of standardized solutions allows suppliers to focus their efforts on generic improvements			x	x		
The level of generification strategies is higher for RPM systems used in pilot projects in than for commercially implemented platforms	x		x		x	
3 Possibilities for integrating different components into configurations						
Flexibility for making adaptations or variation lies in software, rather than in hardware	x			x		
Some system builders generally remain to offer same set of components	x					
Some system builders aim to offer some freedom of choice for end-users to select generic measuring devices to be integrated in the configuration		x	x	x	x	
Standardization of RPM platforms on a national level may actually increase the configurational options						x

5.3.1 Use of generic platforms to build up client-specific RPM applications

The suppliers of the RPM platform applications - which constitute a primary component of the RPM configurations under study, as discussed in section 5.1 - all have their own ***generic, modular platforms from which the different client-specific RPM systems are built up***. The platforms consist of different subcomponents, including features or modules for monitoring vital signs, education, one- or two-way communication, and etcetera. These subcomponents serve as the building blocks of the different applications delivered to different care groups, meaning that they can be separately included in the client-specific applications. Yet, most features or modules are standardly included in a client-specific RPM application. Nevertheless, the whole RPM configurations vary significantly among different use practices, and the client-specific applications are only part of the configuration. Besides, as explained in section 5.1, the client-specific platform applications entail flexibility within their system settings that allows them to change their behavior, i.e. the content they offer. Suppliers acknowledge that for some care providers it is desirable to have some freedom in tuning the settings or choosing content on the basis of their knowledge about patient-specific requirements. Interestingly though, indications are also found that many users (i.e. patients and caregivers) do not necessarily or immediately want this freedom, and that they rather prefer that suppliers determine some of the behavior of the application, at least during early use (cases 2 and 3). Therefore, as comes forward in cases 2 and 3, some suppliers deliver the ***system with a focus on the common denominators, together with the option for individual fine-tuning of the settings by users*** (i.e. in principle by the care provider), after having discovered what settings work best for the specific situation. This points out that suppliers do deliver the system as a standardized solutions, but that they simultaneously provide these systems with the flexibility and option for professional users to change the system's behavior at their own discretion.

5.3.2 Regular adaptations to the generic platforms to better respond to user requirements

Albeit with different frequencies, the generic platforms of the suppliers from which different RPM applications are built up are regularly updated - largely based on feedback and articulated user requirements, as discussed in section 5.1 - in order to better meet the requirements of users, which can moreover be dynamic. For all cases applies that the improvements made by suppliers are adopted into the generic platform, whereby in principle the ***supposed improvements made to the platform apply to all users***. In fact, all clients are perceived to be taking advantage from the adaptations. Importantly, as comes forward in cases 1, 2, 3 and 4, the adaptations taken up into updates are ***prioritized, because it is not the aim or possible for suppliers to respond to all user-specific requirements***. As explicitly comes forward in cases 2 and 4, firms - especially smaller ones - need to distinguish between the must-haves and nice-to-haves, as they only have limited capacity and budgets for making adjustments to their products. Moreover, while suppliers aim to reach a broad spectrum of users with one configurational platform, they also ***believe that users are actually more common than they recognize themselves*** (cases 1 and 3), decreasing the perceived necessity to respond to the full variety of user-specific requirements.

In line with the above, it emerges from cases 1, 3, 4 and 5 that suppliers try to actively ***limit individual customization*** of their products, meaning that generally no local adaptations - e.g. for a specific healthcare institution - are made to the system. When a specific client articulates user-specific requirements that are not offered by the generic platform, suppliers in principle only respond to these requirements when the concerning adaptations are deemed sufficiently relevant and useful to be made for a larger set of clients, and thus to the generic platform. In first instance, the supplier of case 2 seems to deviate from this pattern, since they deliver solutions that are quite narrowly customized and developed in co-creation with the care institutions that will finally use the solution. However, the aim here is to eventually scale the RPM solutions and set a robust product that will also be adopted by other healthcare institutions, as discussed in section 5.2.3. By all means, the aim of suppliers is to keep offering their solutions with a standardized base where possible, and specific customization where necessary

(cases 1 and 3). As emerges in case 3, a large variety in configurations, which is expensive in terms of development and maintenance, may otherwise be the result. Though more degrees of freedom within configurations may lead to better tailoring of solutions, it affects the manageability of the solutions for the supplier. As emphasized in cases 3 and 4, the offering of standardized solutions prevents that suppliers have to spend much time and money on the extensive development, management and maintenance of various product versions, whereby it spares suppliers some resources that can rather be spend in improving the platform. This points out that the ***better manageability of standardized solutions actually allows suppliers to focus their efforts on generic improvements*** of RPM systems according to user-specific requirements. In this way, a generification strategy of suppliers may actually be positively stimulating suppliers to invest more in the tailoring of RPM systems to user-specific requirements. Importantly though, the case results do not give a clear indication whether the advantage of saving resources - i.e. through limiting the required efforts put into maintenance - is actually (and consciously) exploited by suppliers to better focus their efforts on improving the generic platform.

Interestingly, it emerges from cases 1, 3 and 5 that ***the level of generification strategies is higher for RPM systems used in pilot projects in than for commercially implemented platforms***. Within pilot projects that are connected to scientific research often exactly the same RPM solutions are offered over time and among different users in the pilot, in order to keep research conditions constant over time and have a substantial amount of objects on which the same study is done. On the other hand, suppliers that are commercially implementing RPM systems seem to offer more flexibility to make variation in the RPM systems user among different practices. In case 3, for instance, no adaptations were made to the platform used during pilot studies. The platform supplier made adaptations to another version of their platform in parallel, yet without the option to test the adjustments in the running pilots.

5.3.3 Possibilities for integrating different components into configurations

As explained in section 5.1, client-specific RPM applications built up from generic platforms can often be integrated with other components, such as measuring devices and information systems. Whereas information systems are often specifically built for user organizations by the respective vendors, measuring devices are generally offered as generic products (cases 1 and 4). In this line, it is important to highlight that ***flexibility for making adaptations or variations lies in software, rather than in hardware***, as emerged in cases 1 and 4. Generification strategies apply to a greater extent to hardware applications, which are often offered in one version, than to software applications, which are to a certain degree configurable in their settings and the way in which their subcomponents are arranged. As found in cases 1 and 4, this can at least for a part be explained by the certification that is often linked to hardware, and the associated time and investments needed before adaptations are validated and approved. This potentially locks these RPM components in to specific standardized designs that are not quickly redesigned, as the high required investments reduce the incentives or possibilities for the suppliers to frequently release improved product versions that are better tailored to user-specific requirements.

Regarding the aim of suppliers to offer flexibility to (re-)configure the RPM platform applications with other components, two contradicting findings were gathered among the cases. On the one hand, as in case 1, ***some system builders generally remain to offer the same set of components***, such as measuring and communication devices, and they do only deviate from this set when deemed necessary - e.g. when pressure from the market is high, due to measuring errors that occur with a certain amount of users. This can be explained by the supplier's satisfaction with the reliability of the equipment, or by the medical certification attached to the platform, whereby adaptations to the configuration cannot be made quickly and cheaply. On the other hand, as found in cases 2, 3, 4 and 5, some system builders rather aim to offer ***some freedom of choice for end-users to select generic measurement devices to be integrated in the configuration***. However, an important consideration on this finding is the lack of evidence that such configurational flexibility is actually realized. The case results point out that the concerning suppliers aim

to offer this flexibility, but have not actually realized it yet. As comes forward in case 3, this can for instance be explained by the fact that the industry of measurement devices is changing rapidly, and system builders are reluctant to the risk of fruitless investments in the realization of integrations with device suppliers that finally do not become successful. Further, in case 4, the software and measuring device of the concerning two suppliers often work together within a configuration, yet this does not imply that these suppliers exclude other vendors from integrating with their applications. Rather, both suppliers have a robust product in a market with few other vendors for their partner to connect with.

Further, the contextual background results point out that a certain Dutch initiative (involved organization V) is on a national level stimulating the setting of standardized RPM platforms for a large user population according to basic and independently established criteria. In this way, standardization is being enforced by the initiative, and the corresponding approval for reimbursement is being earned by platform suppliers that meet the basic criteria.[33] Interestingly, the results suggests that via increasing returns to adoption that can be achieved via reimbursement, incentives for third parties to connect their RPM components to the platforms are expected to increase.[34] This implies that ***standardization of RPM platforms on a national level may actually increase the configurational options offered by a certain platform***, and thereby the flexibility for tailoring RPM systems to user-specific requirements through the opportunity to choose from more different components that can be integrated into the configurations, and to extend the set of available functionalities of the platforms.

Conclusion

Generification strategies are applied by suppliers of client-specific RPM applications to the level that they build up their solutions from single generic platforms that are being adapted – and improved - on a regular basis. Hardware components such as measuring devices are often offered as generic products - which can, at least partly, be attributed to their medical certificate. Regarding the improvements made, platform suppliers prioritize the adaptations they make, because not all user-specific requirements can be responded to. Moreover, some suppliers are found to be believing that users are actually more common than they recognize themselves. Thereby, the application of generification strategies by suppliers may be hindering the tailoring of RPM systems to the full variety of user-specific requirements. However, it appears that the different RPM configurations that are primarily built up from single platforms vary significantly among different practices, firstly because the offered software generally entails some flexibility for adaptations or variations in system settings and respective behavior - i.e. delivered content - of different client-specific RPM applications. Secondly, the platform-based applications can often be integrated with other components, such as measurement devices or information systems from other vendors. Thereby, the basic ingredients of every RPM system supplied by a certain vendor are generic, but there is customization around them. Accordingly, generification strategies of suppliers in the sense that generic platform form the basis for all their RPM solutions may not necessarily withhold the tailoring of the configuration to user-specific requirements. In fact, it emerges that the use of generic platforms may actually save efforts in the maintained of the RPM applications, and – in potency - stimulate suppliers to better focus their efforts on improving the generic platform according to user-specific requirements. Moreover, standardization of RPM platforms on a national level is facilitating the possibility and increasing the incentives - through increasing returns to adoption - for third parties to connect their applications to RPM platforms, thereby increasing the configurational options within RPM systems and the respective opportunities for tailoring to user-specific requirements. It is therefore concluded that applying a generification strategy can in potency

[33] Although this finding does not necessarily reflect the application of a generification strategy by single suppliers, this does in some way reflect a generification strategy on a national level, since standard conditions are formulated that platforms must meet in order to be qualified for reimbursement.

[34] Throughout the cases, some possible connections between examined RPM systems came across.

stimulate the tailoring of RPM systems to user-specific requirements, provided that suppliers offering relatively standardized components provide sufficient flexibility within the system settings and allow to integrate their product with other components, if needed, and since it may allow suppliers to better focus their efforts on improving the generic platform according to the requirements of users.

5.4 THE INFLUENCE OF USING DESIGN STANDARDS

Table 3 provides the main findings regarding the influence of the use of design standards by suppliers that have emerged from the analysis, including four main categories that constitute how the use of design standards influences the tailoring process, together with subcategories. Firstly, standards in practice facilitate the integration between different components or subsystems in a configuration, and secondly, it is found that there is improvement in standards themselves, as well as in their use. Thirdly, some flexibility is left within standards to be tailored to user-specific requirements. Fourth, interoperability is also a question of willingness to connect different components, and not only dependent on compliance with common standards by the different parties involved. In the following, it is discussed what these categories and subcategories tell about the influence of using design standards on the tailoring of RPM systems to user-specific requirements.

Table 3: Main findings about the influence of design standards, and the parts of results in which they emerged (case numbers and cb=contextual background). Each finding listed here is highlighted (bold and italic) in the following part.

Main findings (design standards)	1	2	3	4	5	cb
1 Standards facilitating the integration between different components in a configuration						
Compliance with common standards increases the ease of integrating components	x	x	x	x	x	x
Creation of integrated care systems connected with the help of standards improves the fit with professional users' requirements	x	x	x	x		
Large data ecosystems are emerging, in which de facto standards are set for exchanging data from a variety of measuring devices					x	
2 Gradual improvement in standards and their use						
Use of outdated standards, but gradual conversion of suppliers to better standards			x	x		x
It still takes time before there is wide compliance with common standards and associated interoperability	x				x	x
Information-standards developed in co-creation with users	x					
3 Flexibility within standards for tailoring to user-specific requirements						
Room is left within standards for fine-tuning to local contexts				x		x
Use of standards may entail limitations regarding the response to deviating needs			x	x		
4 Interoperability is also a question of willingness to connect components						
Lack of interoperability cannot necessarily be attributed to a lack of standards, but also to unwillingness to connect their systems	x	x	x			

5.4.1 Standards facilitating the integration between different components in a configuration

Firstly, in all cases as well as the contextual background, it is found that ***compliance with common standards increases the ease of integrating components*** in a RPM configuration, for instance the integration of measurement devices or information systems with client-specific RPM platform applications. In fact, as suggested in case 3, it becomes relatively easy to lay connection with other applications, once integrations with standards have been realized a few times. Standards define how data pieces should be constructed when they go from one system to another, and without the

compliance with common standards by different parties, the realization of interoperability can be difficult and requiring significant engineering investments. As in case 1, some suppliers actively take part in the process of setting standards and making agreements with others firms about how to connect their systems in order to exchange data. This may be especially important for RPM system builders, such as the supplier in case 1, who are very much dependent on common standards, as they take different components from multiple vendors and integrate these with each other to deliver an entwined RPM service.

Besides, an important trend in healthcare that emerges in cases 1, 2, 3 and 4 is the ***creation of integrated care systems connected with the help of standards***. For instance standards for the structure in which messages are being exchanged, such as the HL7 standards and the more outdated EDIFACT-standard, are important in order to realize these integrations. The current creation of connected technical environments around a patient's care process enables care providers at different levels and organizations to communicate and exchange data with each other through integrated information systems. This is an important development that ***improves the fit with professional users' requirements***, as it helps them to work more efficiently. Better integration with other information systems lowers the necessity for care provider to enter data manually and work in different systems (or dashboards) at the same time, since data transfer between these systems is then facilitated or partially automated. Moreover, it allows to more easily exchange data with other care providers. Still, notwithstanding the importance of standards to achieve interoperability between different systems with which care providers are working, the common lack of interoperability between such is not only an issue of standards, as will be addressed in section 5.4.4.

Further, from the results of case 5, it comes forward that ***large data ecosystems*** - so-called 'containers' - such as Apple HealthKit and GoogleFit, ***are emerging, in which de facto standards are set for exchanging data from a variety of measuring devices***. These open ecosystems can serve as intermediary stations through which big amounts of data can be exchanged between a variety of measurement devices and mobile applications, for instance. Via the establishment and use of common standards to exchange data, such ecosystems can connect with a wide variety of measurement devices, leaving flexibility for users to choose the devices with which they measure their vital signs that they finally enter into their mobile RPM application. This finding only comes forward in case 5, which can be explained by the fact that this case concerns the development of a mobile RPM application, for which this way of exchanging data might be especially useful.

5.4.2 Gradual improvement in standards and their use

As emerges in cases 3 and 4, as well as the contextual background results, ***some standards are considered to be outdated*** (e.g. the EDIFACT standard) and sometimes leading to limitations in data exchange, though fortunately, ***suppliers are gradually converting to better standards*** for these specific purposes. However, this is not to say that everyone eminently agrees with the standards that emerge, and that standards directly fit with everyone's supposed needs. Based on cases 1 and 5 and the contextual background results, it can be suggested that ***it still takes time before there is wide compliance with common standards and associated interoperability*** between different components that are potentially part of an RPM configuration. As comes forward in the contextual background and case 1, standards are still under development, and it will take time before the majority of parties complies with common standards and before the benefits of standards - in terms of interoperability and more configurational options - are thus actually dropped. As comes forward in the contextual background results, it is expected that for many actors there will at some point be a turning point from (partially) working their own way and disagreeing with the common standards to complying with the common standards and exploiting the associated advantages of interoperability and configurational choice. In the meantime, the suppliers from the RPM systems under study aim to follow the supposedly

best standards (cases 2, 3, 4 and 5) or eventually contribute to the setting of common standards themselves (e.g. case 1).

Some standards are relatively undisputed; for instance, technical standards such as Bluetooth Low Energy (BLE) are common for data exchange between measurement devices and other systems (cases 1 and 5). Though, for many other types of standards, such as information-standards, the development and adoption is still in full progress. Moreover, in contrast to the BLE-standard, for instance, some standards are only of added value if they are developed according to the specific context in which they are used. Therefore, as comes forward in case 1, standardization organizations (e.g. involved organization S) apply use cases in which a variety of care providers, patients and/or patient representatives and ICT- and information experts work together to make concrete agreements about which information is captured and exchanged in a concrete situation, and by whom. This suggests that these ***information-standards are developed in co-creation with users***, and that if suppliers comply with the correct standards, this does stimulate the tailoring of their RPM solutions to these users' specific requirements.

5.4.3 Flexibility within standards for tailoring to user-specific requirements

Integrating RPM components through the use of standards is not just plug and play. To some extent, standards need to be made custom to the specific local situation or integration for which they are used. However, the fact that that information-standards are being developed according to use cases concerning specific contexts-of-use does not imply that very different 'standards' should necessarily be used among different local practices. The results of case 4 and the contextual background suggest that many standards - especially internationally accepted standards such as HL7 - are broadly defined, and that ***room is left within standards for fine-tuning to local contexts***. A relevant remark on this that emerges in case 4 is that differences between parties' interpretation of the same standard - for instance because they operate in different regions or countries - or difficulties for certain parties to adequately apply the required standard can sometimes cause difficulties during integrating, thereby increasing the required investments to integrate. Still, without standards for data exchange, efforts to connect systems may be even greater.

On the one hand, the results seem to suggest that the use of design standards does not cause a standard design to emerge on the system level, because they do not define how information is shown to the user by a certain application, but only how data pieces should be constructed in order for them to be easily transferred to other systems. Furthermore, as comes forward in case 1, vendors sometimes come up with proprietary extensions to certain standards, for instance when the standard does apply to certain features with which these vendors want to extend their product. Thereby, it seems that the compliance with standards does not result in functional shortcomings and limitations in responding to user-specific requirements (cases 1, 3 and cb), except when the applied standards are outdated.

On the other hand, it emerges in cases 3 and 4 that the ***use of standards may entail limitations regarding the response to deviating needs***. The results of case 3 suggests that when certain ways of communication between two systems are being desired by a specific user (i.e. care group) but not supported by the specific standards that are generally applied to achieve such an integration, this may lead to difficulties for suppliers in terms of the required efforts and investments in realization of the integration. In case 3, it is suggested that the supplier is then prepared to make an integration custom. In contrast though, the software supplier in case 4 aims to hold on to certain standards to ensure that their products are and remain robust among a variety of settings, and they consider it to be the responsibility for standardization commissions to ensure that standards comply with user-specific requirements. This implies that user-specific requirements that do not correspond with a certain standard are not being responded to. However, since no results were gathered about whether and how often standards are actually limiting for some users, it cannot be substantiated whether and when the use of design

standards actually has a hindering influence on the tailoring of RPM systems to certain user-specific requirements.

5.4.4 Interoperability is also a question of willingness to connect components

Different findings emerged that point out that a ***lack of interoperability*** between different components that are potentially part of an RPM configuration ***cannot necessarily be attributed to a lack of standards, but also to unwillingness of certain parties to connect their systems*** (cases 1, 2 and 3). Firstly, it is found in cases 1 and 2 that often connections lack between RPM systems and the general information systems of care organizations, such as hospitals. While the RPM system suppliers are actually able and willing to integrate, hospitals and the suppliers of their information systems are reluctant to integrate their systems due to anxiety of errors that can occur during data transfer, and the associated damage and liability issues. Fortunately, according to results of cases 1 and 2, this matter is currently being addressed, though no results were gathered about possible solutions for this issue. Secondly, as comes forward in case 1, this issue also applies to the integration with measurement devices, for instance. Namely, next to compliance with common standards, system builders also must have the policy of allowing the specific devices to be integrated into the RPM configuration, which amongst others depends on their supposed reliability. Thirdly, as shortly put forward in section 5.3, the results of case 3 also suggest that a lack of integration between RPM systems and certain measurement devices should not necessarily be attributed to a lack of standards that facilitate to connect, but rather to uncertainty about the fruitfulness of integrations, because the industry of measuring devices - especially wearables - is changing rapidly (cases 3 and 5), leaving much uncertainty as to whether certain devices will still be (sufficiently) used in the future. As comes forward in case 3, and as can be expected according to the Product life cycle theory described in Utterback and Suárez (1993), there will be a shake-out of players when this industry becomes more mature, resulting in a more compact - and definite - list of reliable components that can be integrated with RPM applications. This may increase the incentive for RPM system suppliers to realize interoperability with these devices. These findings indicate that standards can indeed help to realize integrations and thereby allow to better tailor the configuration to users-specific requirements, but both parties involved in an integration must be willing to connect their systems.

Conclusion

The use of standards during the design of RPM systems or components is on the one hand found to be an important facilitator during the realization of interoperability with other technical components when building and improving RPM systems. Common standards help suppliers to respond to the needs of both care providers and patients, in terms of interoperability and its associated increase in efficiency and configurational choice between different additional RPM components. While specific standards are often needed in specific contexts-of-use, the results suggest that standards generally leave sufficient room to be adapted accordingly. However, it is not obvious for everyone to directly agree and comply with the common standards, and it will take time before there is wide compliance to common standards. Notably, a lack of interoperability cannot always be attributed to a lack of standards; the unwillingness of some parties to connect their systems - for instance due to anxiety of errors or uncertainty about the fruitfulness of integrations - is an important obstacle for interoperability to be achieved. Further, in contrast to the positive effect of using design standards on the tailoring to user-specific requirements, some results suggest that standards may for some users have limitations in terms of not complying with their preferred way of data exchange. However, the results do not indicate whether and how often this actually occurs, and contrasting results were gathered about suppliers' response. Suppliers are then found to either make integrations custom or to hold on the standard, whereby they do not respond to the user-specific requirements.

6 CONCLUSIONS

This research investigates the efforts that are taken by technology suppliers to tailor of remote patient management (RPM) solutions to user-specific requirements. RPM provides an important means for increasing efficiency in chronic care and the quality of life of chronic patients. However, due to a frequent mismatch between the offered RPM services and the requirements of specific use practices, including individual patients and care providers, the adoption of these services is only slowly increasing. To that end, it is important to deliberate on the heterogeneous perspectives of users during design and implementation, and to use design standards to achieve interoperability between different subsystems to increase efficiency, as well as configurational choice within RPM systems. Simultaneously though, standardization or generification strategies of suppliers may withhold the systems to be specifically tailored to the requirements of different contexts-of-use. Aiming to provide better understanding about how these three factors in practice influence the match between the offered RPM systems and specific needs of users, the question is raised:

How do user involvement, generification strategies, and the use of design standards influence the tailoring of remote patient management systems to user-specific requirements?

In a multiple case study using 22 interviews complemented by documents, the development and implementation processes of five RPM systems in the Netherlands were examined. The notion of configurations was adopted to better understand and analyze how RPM systems are tailored to user-specific requirements, both at the architectural level and at the level of individual components. This research shows that in order for RPM configurations to be tuned to individual requirements, flexibility is offered in the system settings of the applications, in possibilities to integrate the applications with other components such as measuring devices and established information systems, and in the tasks and responsibilities given to patients and care providers. Alongside, theoretical insights about the three independent variables have provided guidance in approaching and analyzing the empirical instances.

Finally, the analysis and comparison of the different cases leads to various conclusions, as presented in figure 8. As shown in the figure, all three independent variables can both positively and negatively influence the dependent variable, i.e. the tailoring of RPM systems to user-specific requirements. For user involvement and generification strategies this depends on their nature in terms of how and why they are applied. The influences as indicated by arrows 1 to 6 (and M) are addressed in the following.

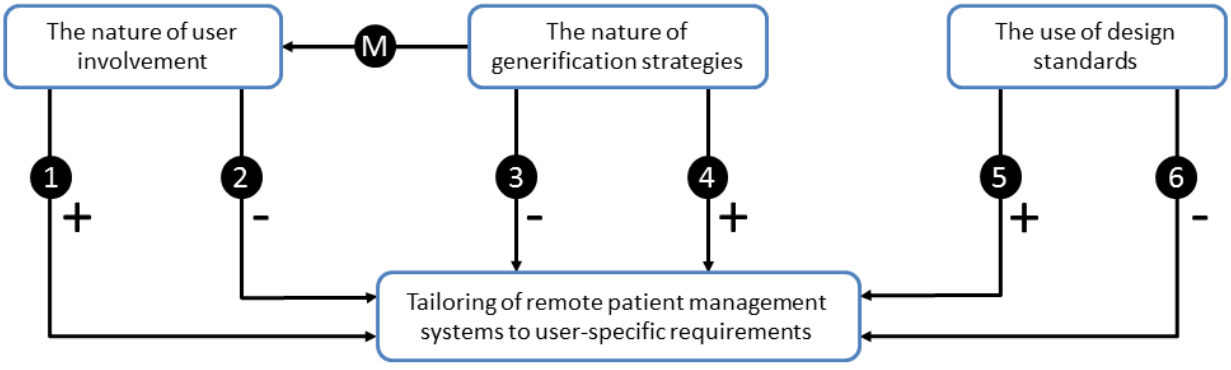

Figure 8: Conclusions about the independent variables' influences on the dependent variable. The numbers of the arrows are referred to in the following conclusions.

(1) Users are often actively involved by suppliers to develop and tailor RPM systems…

Notwithstanding that areas for improvement have come forward in the results, user involvement by suppliers is on the one hand found to be stimulating the tailoring of RPM systems to user-specific requirements, as it may be aimed at learning about the heterogeneous needs of users, and how to serve the needs in the design. Users have been involved upstream during early and continued development hence to articulate their demands and give feedback, they have been involved in pilot projects to examine the situated use of technology and improve the RPM systems or their deployment accordingly, and suppliers explicate the characteristics of the variety of users and involve users during implementation to determine how the system must be tuned per user (e.g. care group). Also, the current study found that suppliers are consciously dealing with the given fact that some involved patients adapt relatively easily to the introduction of RPM technology. In order to make sure that the involved group of patients provides more representative insights about the targeted user population, they also involve critical users and slow adapter during pilot projects or in focus groups, for instance. Besides, complaints of users and reasons for non-use are taken seriously by suppliers and sometimes even force suppliers to improve their systems. Importantly, user involvement is not only essential during development to steer the designing and redesigning of systems, but also during implementation to help users adapt their routines to the use of RPM systems. To this end, users require feedback - either from suppliers, or from early adapters - on how to optimally use the RPM system. Also, adoption and successful implementation may ask for a cultural change and different attitudes of some care providers towards the use of RPM technology and patients empowerment in chronic care.

(2)…though user involvement can also hinder the tailoring to the variety of user-specific requirements

However, user involvement may not necessarily and exclusively be a means for suppliers to learn how RPM systems can be tailored to user-specific requirements. On the other hand, user involvement may also negatively influence the tailoring of RPM systems to the variety of user-specific requirements, as it provides a way for suppliers to learn about a broader user population, hence to develop relatively standardized solutions that are robust among this user population. Generification strategies can have a moderating effect (arrow M) on the nature of user involvement, meaning that it may stimulate certain ways of user involvement, such as broadening of the design process by involving multiple care groups and patients, which facilitate the development of robust standardized products.

(3) Somewhat standardized RPM solutions are being offered, potentially hindering the tailoring...

Secondly, the application of generification strategies by suppliers is on the one hand potentially hindering the tailoring of RPM systems to user-specific requirements. Generification strategies are to some level applied by RPM technology suppliers, who build up client-specific RPM applications from generic platforms, and who do not aim to respond to the full variety of user-specific requirements, but generally respond to articulated user-specific requirements only when respective adaptations are deemed relevant for a larger amount of clients. Nevertheless, such generification strategies do not necessarily hinder the tailoring of RPM systems to user-specific requirements. While hardware components, such as measuring devices are often offered as generic products, generic software platforms generally entail some flexibility for adaptations or variations between client-specific applications that are built up from the generic platforms. The flexibility in the system settings and respective behavior of the application, as well as options for integrations with other components offered by generic platforms allow for the contextualization of the RPM configuration, thereby counteracting - at least part of - the negative influence of applying generification strategies.

(4)…though in some way applying generification strategies may actually stimulate the tailoring

In fact, generification strategies of suppliers may even stimulate the tailoring of RPM systems to user-specific requirements, as it allows suppliers to focus their efforts on generic platform improvements according to the needs of users, rather than on maintaining many different products. With a more

homogeneous set of configurations to be maintained, suppliers can better focus their efforts on improving the functionalities offered within their generic platform according to user-specific requirements. Besides, standardization of RPM platforms and high use scales may stimulate third parties to connect their applications to the platform, in order to extend the functionalities of the system and thereby provide better options for tailoring the configuration to user-specific requirements.

(5) The use of design standards is an increasingly important facilitator for achieving interoperability…

Thirdly, the use of common design standards is on the one hand found to already have an important stimulating influence on RPM systems to be tailored to user-specific requirements. Although the reluctance of some parties to connect their systems is a rather important obstacle for achieving interoperability, standards help to realize integrations between different RPM components, at least if parties are willing to connect their components, and provided that they use the same standard. Hereby, standards stimulate the match between RPM configurations and user-specific requirements, in terms of increased efficiency in users' RPM tasks, as well as in terms of configurational choice between different components such as measurement devices. Also, further efforts are put into the continued development of standards and compliance of different parties with these standards, whereby the stimulating effect is likely to become greater in the coming years. Finally, it is expected that standards will allow technology suppliers and care organizations to build integrated care systems through which different care providers in the chain are connected and efficiently exchanging data.

(6)…though it also potentially hinders the tailoring to certain user-specific requirements

On the other hand, indications are found that the use of design standards may potentially hinder the tailoring of RPM systems to certain user-specific requirements. Certain design standards may sometimes be obstructive in responding to user-specific requirements - in terms of not complying with these users' preferred way of data exchange - leaving suppliers with the decision between making integrations custom or holding on to the standard and not responding to the user-specific requirements. This research leaves room for further investigation about how different suppliers then respond to this issue.

7 DISCUSSION

This final chapter reflects on the research process and its outcomes. The quality and limitations of the applied research design and methods, theoretical implications, some possible directions for further research, and policy implications of this research are addressed here.

QUALITY AND LIMITATIONS OF THE RESEARCH

It should be emphasized that this has been an explorative study based on rich and contextual qualitative data with the intention to understand and highlight the influences of user involvement, generification strategies, and the use of design standards on the tailoring RPM systems to user-specific requirements. In the following, some points are made about the reliability and validity, in order to briefly address the quality and wider potential of the research efforts.

Internal reliability

Throughout the research, it is tried to remain transparent regarding decisions made while analyzing the data. Also, quotes were extracted from the interviews to support claims made in this research. Though no other researchers were involved in the process of collecting and analyzing data - reducing the internal reliability of the present study - accurate transcripts and recordings of all interviews can be obtained from the researcher to prove the consistency of research efforts.

External reliability

It is attempted to make the research steps as transparent as possible, in order to make the research as replicable as possible (Bryman, 2008). The interview structure as given in appendix II provides a useful tool for other researchers to gather or check data in a similar fashion. It cannot be guaranteed that the respondents will recall exactly the same information and perceived 'truth', but there are no obvious reasons to assume that the interviewees will change their perceptions or cover up information. Nonetheless, as for qualitative studies in general, this research is difficult to be replicated precisely by other researchers, as the social settings studied are highly dynamic and subject to continuous change.

Internal validity

The internal validity of findings was safeguarded by constant comparisons between the empirical data and the emerging theoretical constructs (Bryman, 2008). In the initial analyses and description of empirical results, it was attempted to stay as close to the raw data as possible, in order to prevent making arbitrary and unreliable inferences. Also, interviewees were sent the results of respective cases (chapter 4) to determine whether the raw data were rightly interpreted by the researcher and prevent the researcher to code his own interpretation instead of the observation. This improves the validity of the findings in this research. Further, the current study was dependent on the perceived 'truth' of the situation by the respondents, rather than on real observations of the development and implementation processes of the RPM systems, whereby it could not be evaluated by the researcher himself how user involvement has taken place, for instance, and influenced the systems to be tailored to user-specific requirements. Besides, the interviewees were questioned about both real-time and retrospective events and processes during the development and implementation processes of RPM systems. The retrospective focus possibly caused some difficulties for interviewees to reproduce certain information and to give examples. Furthermore, subsequent interviewees were sometimes able to explicitly corroborate initial findings, which allows for triangulation and reduces biases like socially desirable or politically correct answers. However, data triangulation in terms of validating findings with two or more sources was not possible for all results, because individual perspectives are considered from a variety of respondents with different roles within and information about the development and implementation processes of the RPM systems under study. Therefore, these results should be interpreted with care. It is

worth mentioning here that when certain findings do not emerge in a certain case, this does not necessarily imply that the finding does not apply here, but rather that it did not come forward in the gathered results. Some of the main findings only emerged during analysis of specific case results and were not expected on beforehand and actively searched for via the interview questions. This may have limited possibilities for some findings to be corroborated by interviewees in other cases, suggesting that there may be room for improvement in the iteration between data collection and analysis.

A strength of this research is the deliberation on the perspectives of a variety of respondents that have their own objectives and interpretation of a situation. This enabled the development of a wider critical gaze than would otherwise have been possible. However, note must be taken that many respondents in this study were frontrunners in the development and adoption of RPM systems, i.e. representatives of suppliers, the rather early adapters among users, and stimulators of upscaling of RPM. Future research could involve other actors that are relevant for the development and implementation of RPM systems.

External validity

The selected cases under study were quite different from each other with respect to the types of RPM solutions and technologies used, the types of diseases remotely managed, and the types of users, for instance. Triangulation in the sense that multiple cases are under investigation gives more valid insights on the influence of the independent variables on the dependent variable in this field. In the course of the analyses, the researcher has distinguished between information that is relevant to all cases, in contrast to aspects that are unique to particular cases (Polit & Beck, 2010). Although the aim was not to make conclusive statements about the effect of the chosen factors during the development and implementation of other RPM systems, this research warrants a degree of analytic generalizability through the richness and depth of the data from the different cases. Rather than only contributing to abstract theory building, this allows some generalization of the findings to other concrete situations based on the relevance of similar theoretical concepts (Polit & Beck, 2010; Yin, 2003). In order to facilitate extrapolations to other innovation processes of RPM systems - or ICT-integrated healthcare innovations more broadly - within and beyond the Netherlands, this report provides a substantial amount of descriptive detail in the form of case profiles, interview quotes and explicit relations between the independent variables and dependent variable, making it easier to compare the results with other empirical instances.

THEORETICAL IMPLICATIONS

As discussed in the following, this research has contributed several insights to the theoretical perspectives on user involvement, generification strategies and the use of design standards.

User involvement

This study refined the insights into the interaction of RPM technology suppliers with the healthcare context, and the seven types of user-producer interactions (UPI) distinguished by Nahuis et al. (2012) provided a useful operationalization for approaching user involvement in an explorative manner.[35] Some extensions or clarifications to the UPI operationalization of Nahuis et al. (2012) follow from the current study. Firstly, related to the UPI broadening, some suppliers of RPM technology broaden the design processes by involving heterogeneous of users, including patients and care groups, in order to gather insights that help to develop solutions that are robust across a variety of local circumstances. In accordance with Peine & Moors (2015), this indicates that user involvement - and the process of

[35] Note that from this distinction, only downstream innovation did not emerge as a UPI that takes place in this field. A possible explanation for that is the lacking opportunity for users to make technological adaptations to the RPM systems. Further, the UPI of constructing linkages was not explicitly mentioned when it applied, but obviously this UPI is important for any other UPI to occur.

broadening specifically - can be understood as part of suppliers' generification strategies. Secondly, the UPI user characterization appears important in the context of this research, in the sense that explicating the characteristics of a variety of users - for instance during pilot studies - helps suppliers, as well as users themselves, to better understand how RPM systems and their settings should be specifically configured and tailored for different users, in order to adequately respond to their needs. Eventually, the manual way of tailoring RPM systems may be gradually replaced some forms of intelligence - i.e. algorithms - being built into the systems, which automatically - though still based on the characteristics of individual users - determine part of the system settings. Thirdly, though it may not sufficiently be provided, the feedback to users to encourage and teach them how to use the technology turns out to be especially important in this specific context, because the introduction of RPM technology into care practices delegates different and new responsibilities to both care providers and patients, sometimes asking for more active accompaniment during implementation and early use. This is in line with Elwyn et al. (2012), who argue that the roles and accountabilities of different actors that change due to the introduction of RPM services are important to be articulated, understood, and adapted in order to successfully integrate the RPM system into existing practices. As found in this study, the provision of such feedback is not necessarily and exclusively an interaction between users and producers, since it may also be provided by other, successful users - i.e. early adapters - thereby potentially being a user-user interaction. Fourthly, this research shows that complaints of dissatisfied users and non-users that reject a technology, as well as the active deliberation of their perspectives by suppliers are important UPI that helps improving technology and its acceptance. In fact, non-users are not only considered a relevant social group in design processes because they may have good reason not to use a technology (Wyatt, 2003) - high degrees of non-use may actually be problematic for suppliers, whereby non-users may even force suppliers to make improvements, to offer less generic solutions, and to better respond to the need for flexibility in system settings, for instance, in order to better meet their specific requirements. This way of user involvement could be grouped under feedback or (non-)user characterization, as suppliers actively aim to learn what these (non-)users want and what aspects of technology need to be changed for these users to be satisfied and persuaded to use the technology.

Generification strategies

An important implication that follows from this study is that the aim of RPM platform suppliers to tailor RPM configurations to specific practical context may actually be accompanied by a moderate level of a generification strategy of these suppliers in terms of offering somewhat standardized solutions that are built from one generic platform, provided that the generic platform and the resulting applications must be sufficiently flexible in their settings and configurational options to be integrated with a variety of other components, such as measuring devices and information systems. Additionally, the specific socio-technical arrangements between users and technology may vary among different practices, further contextualizing the RPM configuration and its behavior. This necessity for flexibility is in line with the notion of 'methodological insecurity' put forward by Kiran (2012). This notion implies that the design of RPM technology should enable users to take responsibility to shape their own relationship to the technology, rather than locking them to specific ways of appropriating the technologies. Put differently, it means that that designers should anticipate how needs and demands differ among practices, and that they must leave some flexibility in how the technology can be implemented into the care practice. The current study suggests that methodological insecurity is to some degree reflected in RPM systems' flexibility to individually tune system settings, their configurational options to be integrated with additional components, and in the flexibility regarding socio-technical arrangements. The original lack of flexibility to tailor RPM systems to user-specific requirements, as reported by Tesanovic et al. (2009), for instance, may potentially be assigned to the novelty of RPM, rather than purely to a generification strategy of suppliers. This reason for a lack of flexibility for personalization is also put forward by Boyne

& Vrijhoef (2013). Further, this research contributes to the notion of methodological insecurity by suggesting that user involvement, design standards, and in some way maybe even generification strategies of suppliers may be contributing to the increasing applicability of this notion to RPM systems.

The use of design standards

The current study confirms that the use of design standards already allows better matches between different technologies in terms of interoperability, and thereby stimulates the tailoring of RPM configurations to user-specific requirements, provided that concerned parties are actually willing to connect their components. However, it was found that it still takes time before design standards fully bear their fruit, and before the majority of parties agrees with common standards. Further, it is important to denote that this research regards and examined the concepts of generification strategies of suppliers and the use of design standards as two separate factors that may differently influence the tailoring of RPM systems to user-specific requirements. However, to some degree, these variables could interfere with each other, since the standardization of ways for data exchange between different technologies and the use of resulting design standards is also a way of generification by suppliers, leading to (a set of) standardized options for users in which data is captured and exchanged with other actors in the RPM chain. Yet, in this research it was chosen and considered valuable to analyze the influence of these factors separately, as the lack of interoperability that can lead to inefficient care processes and limited configurational flexibility is a substantially different issue than the lack of personalization of RPM systems that may be caused by generification strategies of suppliers.

FUTURE RESEARCH

In the following, some recommendations are done for further research regarding the influence of the independent variables on the tailoring process, as well as regarding contextual factors that may influence the tailoring process, but which were somewhat underexposed in this research.

User involvement

The current study was guided by only one possible operationalization of user involvement, and future studies could use a different operationalization - for instance, based on the classification scheme for UPI developed by Moors et al. (2008) - and determine whether this yields similar results regarding the ways in which users are involved during development and implementation of RPM systems, and regarding their influence on the tailoring of RPM systems. Furthermore, this research focused on user involvement by suppliers only, whereas it could be interesting to investigate the involvement of patients by care providers, for instance, and determine how this influences the tailoring of RPM systems to the specific requirements of individual patients.[36] Also, rather than examining the influence of user-producer interactions between certain actors directly involved in the development and implementation of a specific RPM system on the tailoring process - as done in the current study - it may be useful to investigate how the discussion and deliberation on user perspectives occurs within a broader societal debate, and how this affects the match between the design of RPM systems and the heterogeneous needs of users. This way of broader deliberation on the perspectives of (potential) users relates to the recent trend of doing responsible innovation. Responsible innovation is an upcoming concept in the governance of science and technology development, founded on the idea that present modes of innovating insufficiently take societal needs and values into account (van Oudheusden, 2014). It could be useful to analyze and deduct methods applied for doing responsible innovation from specific practical contexts such as innovation in RPM technology, and to that end, insights from the current study may be useful.

[36] The interaction between care providers and patients could for instance be helpful regarding the need - as found in case 1 - to better focus on aspects in RPM that are important for individual patients, to better seduce them to actively participate in RPM.

Generification strategies

Rather than that the approaches of generification and tailoring to user-specific requirements are purely in conflict, the current study found that a generification strategy may in fact even stimulate the tailoring to user-specific requirements, firstly because it may provide suppliers with the opportunity to better focus on improvements of the generic platform. The standardization of products could save efforts that would otherwise have needed to be put into the development and maintenance of a variety of customized and heterogeneous products. It could be useful for future studies to reveal whether the advantage of saving time and costs in development and maintenance for suppliers that use generic platforms to build different solutions is actually stimulating them to put more efforts into generic improvement of their platforms, and whether this stimulates the tailoring of end solutions to the variety of user-specific requirements. Secondly, generification strategies may positively stimulate the tailoring process, by increasing the configurational options of standardized platforms through increased incentives for third parties to connect their products to the platforms. Future research could further explore whether this trend actually occurs. Furthermore, it is found that the level of generification is likely to be greater for products that are not - or to a lower degree - of a configurational nature (e.g. hardware components such as measurement devices). It could be useful to examine whether and when this is actually disadvantageous in terms of responding to user-specific requirements, because it is possible that these kind of technologies have lesser need for personal customization.

The use of design standards

According to the gathered results, the use of design standards does not seem to cause RPM systems to be rigidly designed and thereby being unable to respond to different of user-specific requirements, as they offer the possibilities for local adaptation of standards as well as for suppliers to work around these standards with proprietary extensions. However, the current study did not determine whether this applies to all standards used during the design of RPM systems or other types of ICT-integrated healthcare systems. Rather than focusing on the influence of specific standards, this research provides better understanding about the general contribution of using design standards to the tailoring of RPM systems to user-specific requirements. It could be useful for future studies to use a more refined operationalization of this variable - for instance by distinguishing between different standards as given in Nictiz (2012) - in order to determine more specifically how the use of different types of design standards does or does not contribute to the tailoring of RPM systems. Furthermore, room is left for further investigation regarding the possibly hindering influence of certain standards in responding to some user-specific requirements. This research does not indicate whether and which standards may actually be deviating from some users' preferred ways of data exchange. Also, it remains unclear how different suppliers address this issue, though two different responses were found, i.e. either holding on to the standard, or making an integration custom. It is useful to gain better understanding on this issue, since it helps understanding whether the use of certain standards may actually hinder the tailoring process. Lastly, it could be useful to examine in what other ways - except for the compliance with standards when developing RPM technology - interoperability between different technologies is ensured and stimulating the tailoring of RPM configurations to user-specific requirements. For instance, it could be useful to investigate what efforts are being taken by different parties to make agreements about connecting their systems. Also, it could be interesting to examine whether and how integration components that are placed between two applications in order to allow for data exchange, or initiatives such as the Dutch LSP (Landelijk Schakelpunt) - i.e. a national exchange point that facilitates communications between different healthcare providers (VZVZ, 2015) - actually help to lay connections and exchange data between different components that are (potentially) part of RPM configurations. Design standards also have a role within such technological solutions, but it may be valuable to specifically examine the usefulness or potential of such technical solutions.

Other contextual factors

This study applied some selection criteria to ensure some variety among the cases regarding their context, which provides some clarifications for the influence of the three independent variables on the tailoring process. However, the focus was not to examine how different contextual factors may explain - and moderate - these influences, or how they directly influence the tailoring of RPM systems to user-specific requirements. Various directions are possible for future studies to further investigate the influence of these other contextual factors on the tailoring process. To name some of them: it may firstly be useful to analyze the influence of the size of firms on their response to user-specific requirements, and how it for example differs how user involvement has a role in this tailoring process. Janssen & Moors (2013), argue that entrepreneurial firms - who are generally small - are able to develop innovations in close interaction with the healthcare context, possibly implying that they may also be better able to respond the more local user-specific requirements, when compared to larger and more internationally oriented companies. Secondly, it seems plausible that the phase of development of a technology influences the degree to which a technology is tailored to user-specific requirements, as later phases of development may entail a higher degree of learning about the specific requirements of different users, for instance through insights from pilot research or a longer period of upstream involvement. It may be useful to examine how the tailoring process evolves throughout the innovation process, and in which phases certain bottlenecks may arise. In this line, this study found that the degree of tailoring to user-specific requirements may be different for RPM systems used in pilot projects when compared to already commercialized RPM systems, though this difference may be attributed to the research efforts being involved in some pilot studies, which require research conditions to be the same for different study objects (i.e. patients). Thirdly, the match between RPM systems and the specific requirements of users may be different for the variety of chronic illnesses that are managed by the various systems, and it may be different for single systems that can manage multiple chronic diseases when compared to systems focused on the remote management of a single chronic illness. Lastly, the influence of the nature of the technology on the degree of tailoring to user-specific requirements has slightly come forward in the findings of the current study, with the finding that software generally leaves more flexibility to be tailored to user-specific requirements than hardware. It could be useful to more explicitly investigate this difference, or even to examine more specifically for the variety of technical components, including data portals, coaching programs, mobile applications or measurement devices, how they entail differences in their possibilities to be tailored to user-specific requirements.

POLICY IMPLICATIONS

Given that RPM systems are built up from different components that can be integrated and arranged in different ways, they may leave, to a greater or lesser extent, room to be adapted to user-specific requirements. Besides, although still offering somewhat standardized platforms, a trend towards better customization of client-specific RPM systems seems to take place, since suppliers aim to keep learning about the requirements of different users, to build in more flexibility for tuning the settings of their systems, and to realize integrations with additional components such as measurement devices and established information systems. Different actors in the supply chain of RPM configurations should support the common and supposedly best standards or contribute to the standardization themselves, in order to integrate their components and thereby increase the efficiency during use and the amount of options for different components to be integrated into the configuration. This allows for a better response to the local requirements of different use practices, which could help to achieve more optimal use and higher adoption rates of RPM systems, contributing to the sustainability of healthcare.

An important implication for suppliers is that standardized RPM platforms can potentially serve a wider population of patients and care institutions with heterogeneous user-specific requirements, under the

condition that they entail flexibility in their system settings and respective behavior and offered content, as well as options to connect with additional components. It could be valuable for some vendors to develop RPM applications that focus on the requirements of a specific group of users - i.e. a niche market - and to make sure that their applications can be coupled to the more generic RPM platforms used on a larger scale. Put differently, third party vendors focusing on niche markets could ensure that relatively standardized RPM systems can be configured in such a way that certain user-specific requirements are being responded to. Hence, in order to stimulate a desirable balance between individualization and standardization of RPM solutions and ensure that the provision of healthcare is sustainable, it is important for viable policies to stimulate the development of third party applications that focus on certain unserved niche markets. Also, it could be helpful for policies to stimulate the continued development and adoption of the relatively generic RPM platforms, since larger use scales of platforms may increase the incentives for third parties to innovate on the platforms.

Further, it should be recognized that different care institutions, care providers and patients are unique types of actors, and attention must be paid to the optimal configuring of RPM systems to their specific requirements and routines, implying that the tailoring process must take place at these different user levels. During both development and implementation, suppliers and the different types of end-users must work together to determine how the RPM system must be configured, and it is important for users to be properly supervised in determining and learning-by-trying how system settings should be tuned for their specific practice, as well as how they must adapt their own routines in order to successfully use the system. In this line, the suboptimal embedding and non-use of RPM technology is not always in the hands of technology suppliers, as it cannot always and exclusively be attributed to technological shortcomings or insufficient feedback to users. Remote patient management is still a relatively new phenomenon and many users of RPM technology are not yet willing and/or well-arranged to adequately apply it, potentially causing them to become non-users or unsuccessful adapters after all. Therefore, scaling the adoption and successful embedding of RPM technology also requires a cultural change within healthcare, meaning that it would be helpful if care providers - and eventually patients - allow more aspects of the chronic care process to be left over to technology and patients, and adapt their routines in order to create a better match with RPM technology. Better socio-technical arrangements between the heterogeneous assemblies of human actors and RPM systems may ensure better compliance of both care providers and patients with RPM technology, which could result in better efficiency of RPM processes and quality of life of chronic patients. It may be helpful for policy makers to create better awareness among suppliers, healthcare organizations and other relevant parties in the field about this barrier to the upscaling of RPM in chronic care.

This study has looked at configurational systems for the remote management of chronic patients, with the aim to provide better understanding about how technology suppliers cope with the tension between heterogeneity and homogeneity in the offered technology. An adequate balance is necessary to respond to the specific requirements of different use practices, and simultaneously ensure the sustainability of healthcare systems.

APPENDIX I: ANONYMIZED LIST OF INTERVIEWEES

In table 4 below, the anonymized list with interviewees is given. As shown, some of the interviewees occupy several positions in various organizations that are relevant to mention. This public version of the report does not include names of the systems, interviewees and organizations.

*Table 4: List of interviews; IN#=interview number; Translation (abbreviated) codes: S = system supplier, U = user organization, IO = involved (user) organization, *Interview used for two results sections.*

Case nr.	IN#	Function	Type of organization	Code	Date
1	1	Implementation Manager	Platform supplier	S1	04-02-15
	4	Heart Failure Nurse Specialist	Hospital and user organization	U1	10-03-15
	6	Policymaker Patient Advocacy	Heart failure patient organization	IOU	02-04-15
	8	Employee + Chairman	Platform supplier + International standardization alliance	S1 + IOS	10-04-15
	9	Director Home Healthcare + Board member	Platform supplier + Foundation remote care	S1 + IOT	10-04-15
2	3	Heart Failure Nurse Specialist	Hospital and user organization	U2A	09-03-15
	13	Board member	System supplier	S2	22-04-15
	22	Gastro-enterologist	Hospital and user organization	U2B	04-06-15
3	5	Manager eHealth	Platform supplier	S3A	17-03-15
	10	Senior Product Manager Self-management	Platform supplier	S3A	16-04-15
	17*	Director + Director	Foundation remote care + Foundation for the assessment of remote care platforms	IOT + IOV	01-05-15
	20	Researcher in persuasive healthcare technology	University (user research)	IOW	27-05-15
	21	Physician and director	Education module supplier	S3B	28-05-15
4	7	Product Manager Diagnostics	Coagulometer supplier	S4A	03-04-15
	14	Manager Anticoagulation	Software system supplier	S4B	23-04-15
	18	Director	Thrombosis expertise center	U4	08-05-15
	19	Chairman Patient Advocacy	Dutch advocacy by and for self-managing anticoagulation patients	IOX	11-05-15
5	2	Founder & director	Mobile application developer	S5A	25-02-15
	11	Diabetes patient and expert	Digital publisher in diabetes and partner of S5A	IOY	20-04-15
	12	Director	Health patch interface supplier	S5B	21-04-15
	16	Pediatric endocrinologist & project leader pilot study	National diabetes center for children and youth	U5	29-04-15
Contextual background	15	Program Manager	National expertise center in the development of Healthcare ICT	IOZ	28-04-15
	17*	Director + Director	Foundation remote care + Foundation for the assessment of remote care platforms	IOT + IOV	01-05-15

APPENDIX II: INTERVIEW STRUCTURE

Below, the interview questions are presented that were used to guide the semi-structured interviews. One interview was conducted in English, since the respondent was not from the Netherlands. As discussed in section 3.3.1, the interview structure is used in a flexible way as a checklist to discuss certain topics. The researcher has intuitively addressed interesting observations and anecdotes when they appeared. As some general information about a case was sometimes known through previous interviews or background research, the researcher may sometimes have decided to pay less attention to this aspects of the script. As shown a few times in the structure, slight variation is made between the questions asked to parties on the supplier side compared to the users of the respective RPM system.

Dit interview staat in het teken van mijn afstudeeronderzoek voor het tweejarige master programma Innovation Sciences aan de Universiteit Utrecht. Dit onderzoek richt zich op het vraagstuk hoe er wordt geprobeerd een goede aansluiting te creëren tussen telehealth toepassingen en de specifieke behoeften van de gebruikerscontext. Door de relatieve nieuwigheid van telehealth worden vaak gestandaardiseerde systemen aangeboden, terwijl een oplossing op maat gewenst is. Daarom probeer ik beter een beter beeld te krijgen van het besluitvormingsproces over hoe een telehealth oplossing wordt ingericht, en ik richt me daarbij op de rol van (1) de betrokkenheid van verschillende gebruikers (zorgprofessionals, patiënten etc.) tijdens de ontwikkeling en implementatie en (2) het gebruik van design standaarden. Met andere woorden, ik onderzoek in welke mate deze factoren zorgen dat specifieke gebruikersbehoeften daadwerkelijk tegemoet worden gekomen. Ik neem [applicatie] mee als één van de casus in dit onderzoek.

Het is begrijpelijk als u slechts over een deel van de ontwikkeling en/of implementatie iets kunt vertellen. Het zou fijn zijn als u antwoorden kunt geven met betrekking tot de processen waar u zelf kennis van heeft, of waar u verwijzingen naar kunt geven. Het kan voorkomen dat gevraagde feitelijke informatie ook in [documenten] beschikbaar is – toch is het voor dit onderzoek belangrijk juist over uw ervaringen te horen. Vooraf zou ik u nog willen vragen:

- Gaat u akkoord met opname van dit interview?
- Heeft u zelf op voorhand nog vragen?

Algemene informatie

1. Kunt u iets vertellen over uzelf, uw organisatie, en uw functie?
2. Kunt u wat vertellen over [applicatie], en hoe deze wordt gebruikt? Door wie wordt deze gebruikt?
3. Kunt u iets vertellen over de geschiedenis van [applicatie]?
    - Wanneer is het eerste idee gekomen?
    - Wat waren de uitgangspunten bij de ontwikkeling?
    - Wat is de ontwikkeltijd geweest?
    - Wat is de huidige status? Is [applicatie] een succes?
    - Wat zijn belangrijke obstakels waar uw organisatie tegen aan is gelopen, en hoe zijn deze opgepakt?
4. Kunt u wat vertellen over het aandeel van uw organisatie in de ontwikkeling en/of implementatie van [applicatie]?

Aanpassing aan specifieke gebruikersbehoeften

5. Wordt [applicatie] als een standaard product aangeboden en (precies hetzelfde) ingezet bij iedere situatie? Of wordt hierin gevarieerd om in verschillende gebruikersbehoeften te voorzien, en zo ja, hoe? (Denk bijvoorbeeld aan kleine verschillen in functionaliteit of user interface, de mogelijkheid om [applicatie] te koppelen aan verschillende soorten meetapparatuur, of de mogelijkheid om [applicatie] ook te gebruiken op reis.)
6. Heeft u voorbeelden van gebruikers(groepen) waarbij [applicatie] op een andere manier is gebruikt of waarvoor [applicatie] zelfs is aangepast?
7. In hoeverre is er volgens u verbetering nodig en mogelijk in het afstemmen van [toepassing] op specifieke gebruikersbehoeften?
8. Zijn er volgens u ook dingen die [applicatie] mist of die niet goed werken? Zo ja, wat voor mogelijkheden zijn er om hier iets aan te doen?

Betrokkenheid van gebruikers bij ontwikkeling en implementatie

9. a) Wat voor samenwerking en communicatie vindt er plaats en heeft er plaatsgevonden tussen [uw organisatie/leverancier] en gebruikers van [applicatie] zoals zorgprofessionals en patienten, om inzicht te verkrijgen over hun behoeften?
    - Welke gebruikersgroepen?
    - Wanneer? Is/was dit tijdens het design proces of tijdens implementatie en gebruik?
    - Eventueel doorvagen op omvang van de interactie.

    Vraag 9a kan worden bevraagd a.d.h.v. verschillende typen interacties die kunnen plaatsvinden:

    - Gebaseerd op wat voor informatie (en van wie) is door uw organisatie een beeld geschetst van potentiële gebruikers en hun behoeften?
    - Zijn hierbij experts of mediators betrokken geweest?
    - Is er interactie geweest met en tussen gebruikersgroepen om te leren hoe [applicatie] impact heeft op henzelf en anderen? (bijvoorbeeld interactie tussen patiënt en zorgprofessional om elkaars belangen te begrijpen)
    - Zijn gebruikers actief betrokken bij de ontwikkeling en het vormgeven van [applicatie]?
    - Hoe zijn de eerste gebruikers van [applicatie] geselecteerd?
    - Op wat voor manieren is feedback verkregen over [applicatie]?
    - Zijn er ook gebruikers die zelf aanpassingen hebben gemaakt aan [applicatie]?
    - Is er ook geleerd over gebruikersbehoeften via inzichten van of samenwerking met andere organisaties?
    - Zijn mensen die bewust geen gebruik maken van [applicatie] of hier mee zijn gestopt ook geraadpleegd?

    b) Wat voor inzichten over gebruikersbehoeften- en voorkeuren waren hier uit verkregen?

    c) Zijn er op basis van de inzichten bepaalde keuzes gemaakt over het design van [applicatie] of de manier waarop deze wordt toegepast?

10. Ziet u ook mogelijke verbeterpunten met betrekking tot het raadplegen van gebruikers van [applicatie] om beter inzicht te verschaffen in hun specifieke behoeften?

11. Zijn er nog andere soorten gebruikers of stakeholders waar we het nog niet over hebben gehad, maar waar ook goed rekening mee moet worden gehouden in het design?

Design standaarden

Naast de samenwerking met gebruikers onderzoek ik ook hoe het gebruik van standaarden voor het design van telehealth bijdraagt aan een betere aansluiting van technologie op de behoeften van de gebruikerscontext. Het gebrek aan standaarden voor bijvoorbeeld informatie-uitwisseling kan namelijk zorgen voor slechte aansluiting van telehealth oplossingen aan bestaande systemen waar gebruikers mee werken (zoals het patiëntendossier). Ook beperkt het de opties waaruit gebruikers kunnen kiezen, omdat veranderingen in een telehealth systeem, bijvoorbeeld integratie met een beter/nieuwer meetapparaat, grote kosten met zich mee kunnen brengen. Door gebruik te maken van design standaarden kunnen leveranciers verschillende apparatuur of systemen met elkaar integreren, wat wellicht leidt tot meer flexibiliteit om de juiste (samengestelde) oplossing te creëren voor gebruikers.

12. Kunt u iets vertellen over de interoperabiliteit van [applicatie] met andere apparatuur of systemen waar binnen het zorgproces gebruik van wordt maakt?
    Met andere woorden, hoe goed sluit [applicatie] aan op het zorgproces, bijvoorbeeld op verschillende meetapparatuur, communicatiemiddelen, of bestaande informatiesystemen waar mee wordt gewerkt?
13. Hoe is er door [uw organisatie/leverancier] rekening gehouden met interoperabiliteit tussen applicatie] en andere technologieën die worden gebruikt? Wat voor rol hebben standaarden hierbij?
14. (indien van toepassing) Heeft het gebruik van standaarden bijgedragen aan flexibiliteit om de juiste oplossing aan te bieden voor specifieke gebruikers?
    Met andere woorden, is het hierdoor makkelijker om een oplossing op maat aan te bieden voor specifieke gebruikers?
15. Leidt het gebruik van standaarden ook tot beperkingen in wat er mogelijk is binnen de [applicatie] productgroep, en met betrekking tot de behoeften van bepaalde gebruikers?
16. In hoeverre zijn er volgens u verbeteringen mogelijk in het gebruik van standaarden door [uw organisatie/ leverancier]?
17. Zijn er volgens u voldoende huidige standaarden beschikbaar voor het ontwikkelen van telehealth?

Oplossing op maat

Tot slot wil ik u nog enkele vragen stellen – die wellicht al gedeeltelijk beantwoord zijn - over hoe er volgens u wordt omgegaan met heterogeniteit in gebruikersbehoeften:

18. Is er in uw optiek veel heterogeniteit in de behoeften en/of voorkeuren van verschillende gebruikers?
19. En hoe goed wordt hier bij [applicatie] rekening mee gehouden?
    Met andere woorden, worden er binnen de [applicatie] productgroep voldoende flexibiliteit geboden om [applicatie] zodanig in te richten zodat deze aansluit op de behoeften van verschillende gebruikers of verschillende situaties?

Afsluiting interview en bespreken vervolgafspraken.

APPENDIX III: ANONYMIZED SECONDARY DATA SOURCES

This appendix is not included in this public version of the report.

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