

From Research Prototypes to a Marketable eHealth System

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Abstract. This paper presents three distinct challenges to research and development (R&D) of marketable eHealth systems and suggests strategies to mitigate them. The eHealth system in question is designed to improve self-care and collaboration between remotely monitored heart failure patients and clinicians. By way of introspection and reflection on a current and a previous project, the authors propose solutions for mitigating the central challenges.

Keywords. Methods, research and development, eHealth, regulatory requirements, mitigation

Introduction

Patient-centered eHealth is expected to improve health outcomes. For more than a decade it has been a cornerstone in eHealth research to engage patients in their own treatment and care. Many studies in Health Informatics and HCI show promising potentials of self-management and remote collaboration between clinicians and patients [1, 4, 6, 12]. Yet few prototypes leave the research lab to become marketable systems. Moreover, contradictory to the overly positive potentials, stands the evaluation of collaborative eHealth systems that are currently available and in use by patients and clinicians. A critical review of telemonitoring systems, for example, shows the lack of high quality evidence for improved outcomes or cost-effectiveness [7], while others reveal unintended consequences e.g. complicate the patient-physician relation [8, 9].

We address the multi-edged challenge in R&D of marketable eHealth that hold commercial value, support patient self-management, and improve remote collaboration between clinicians and patients. We describe challenges in running large-scale experiments, and at the same time, mobilizing a transition from research prototypes into a regulatory approved implementation process that ends with a marketable eHealth system. By introspection and critical reflection, we analyse the problems encountered in a previous project (CITH) and propose the mitigation strategies that we try out in a newly started project (SCAUT). We use the concept of ‘context’ to highlight the gaps that exist when moving between the contexts of design and use and between research- and commercially-oriented contexts. We have experienced three challenges in bridging these gaps due to only partly overlapping experiences, concerns, and rationales.

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1. New Contexts: From CITH to SCAUT

We are an interdisciplinary group of cardiologists, public health and computer scientists. In our prior work [see 1, 2], we discuss challenges and opportunities as to features and affordances of eHealth systems to support self-care and collaboration between patients and clinicians. Instead, here we address methodological issues related to making the transition and move research and development (R&D) prototypes to a market that has high regulatory demands. We base our reflections and recommendation on two projects that deal with remotely monitored patients with implantable cardiac devices (ICDs and pacemakers).

The purpose of the CITH-project (2008-13) was to explore the solution space and develop concepts and prototypes. In the SCAUT project (2014-18) we have teamed up with a software company and a medical device manufacturer to further explore the solution space and to transform prototypes into products. The combined purpose of SCAUT is to bring an eHealth system to the market, while still delivering traditional research in the form of papers and theses. The overall R&D approach is presented below. First, however, we describe how the contexts of the two projects are similar and how they differ. In section 2 we discuss the challenges induced by these differences and the mitigation strategies that we propose.

1.1. Use Contexts

Firstly, the use context is shared by the two projects, and it has three main elements: patients' homes and two clinical settings. Patients and clinicians live and work in different contexts and they hold different views on disease, treatment and care [2, 5]. The ways in which patients relate to their disease vary according to where they are in their trajectory. Partly therefore, they have developed a diverse set of strategies for handling the different types of information they collect or receive related to their disease, and they use different media for that purpose. In the two clinical settings decisions are taken whether or not to change the treatment. At the university hospital any alteration of the treatment is primarily based on interpretation of data from the cardiac device. However, at the local hospital or at the general practitioner's office the patients overall situation and the medication are the main issues.

1.2. Project Contexts

Secondly, there are the project contexts, where the design, development and implementation take place and where the two projects are clearly different. We strive for design, development and implementation to be more intertwined than indicated below, but for clarity we distinguish between three project contexts: (a) the IT-researchers' habitat that mainly includes patients' homes, clinical settings, the university and the two companies; (b) the software company, which holds the primary responsibility for the development and implementation; and (c) the medical device manufacturer that employs its own R&D departments in the US and in Europe, and will licence the software, if we are successful.

As also pointed out in Eng [15] there exist some tensions between academic institutions and commercial companies: researchers' primarily strive to produce new knowledge, while companies are in the project to explore new market opportunities. However, SCAUT participants acknowledge, that both parties are critical for academic

as well as commercial success.

1.3. Overall R&D Approach for Both Projects

The diverse use contexts motivate that we start out with ethnographic techniques to explore existing practices in patients' homes and in clinics. We used prototyping to experiment with versions of a Personal Health Record and with a set of (re-)designed tools and services supporting the work of clinicians, patients, and relatives. Based on such experiments, we iteratively adjust the prototype, the tasks, and the roles, but we also learn about new issues in the current practices, which then inform the next round of design activities. Initially, the experiments are conducted in isolation from the daily practices, but as the prototype matures we intervene to cautiously try out the prototype, the tasks, and the roles as part of real life practices. This takes place within an overall participatory approach for users to have a say and to foster mutual learning [3]. Clinicians, patients and relatives participate actively in defining the aim of the project as well as in analyses, design, and evaluation. A final element in the methodological approach is theoretical reflections on the use of evolving prototypes based on medical phenomenology [5] and studies of other researchers [see e.g. 10, 11].

2. Bringing Health Informatics to the Market: Three Challenges

We have experienced three challenges in bridging the gaps between the contexts of design and use and between research- and commercially-oriented contexts. Below we argue that these challenges are rooted in the only partly overlapping experiences, concerns, and rationales of the researchers and industrial partners, who have joined forces for the purpose of developing a marketable eHealth system. An overview of the challenges, their potential consequences and suggested mitigation strategies are listed in table 1, and they are argued for below.

Table 1. Overview of challenges, consequences and strategies for mitigations

Challenge	Potential Consequence	Mitigation strategies
Create an efficient R&D process	Cumbersome coordinative work Scaling becomes unmanageable Increased overhead work	R&D tool that supports: - recruiting patients - communication with users - overview of (non-)use - easy to introduce new features to many users
Integrate all stakeholders' interests	Losing commitment from key stakeholders	Active user participation Business Model Canvas for pre-assessing the value propositions of the prototypes Adjust The Stage Gate Model using Scrum
Design within regulatory requirements	Product will not be approved	Treat regulatory issues as design parameters Integrate a regulatory process into the production process from the start

2.1. The Challenge of Establishing an Efficient R&D Process

The first challenge is to establish an efficient R&D process. In the CITH project, the R&D process progressed through three stages. As it turned out, the coordinative efforts intensified and overhead work related to preparing and setting up the experiments grew critically in the last stage where we tried out prototypes that connected people. For example, we developed and distributed information material and started to keep various spreadsheets and other documents with updated information on e.g. which version of the prototype patients were using, dates of healthcare appointments and notes on which researcher had been in contact with the patient, when and what they discussed. This was to ensure coordination among the researchers and to keep an overview of what was going on in terms of patient participation. We worked intensively to set up experiments where patients and clinicians could collaborate remotely [1].

We termed some of this work “bike-integration,” since every experiment involved personal agreement on date and time with many patients (~25), producing and mailing out information material, calling or visiting patients prior to the experiment as well as bicycling to the hospital on the day prior to the experiment to ensure the needed printouts were there for the clinicians to use during the experiment. A major reason for the overhead work in CITH was the increase in dependencies when trying out prototype features that connect different people, as well as the fact that we introduced new technology features that changed work practices and required introduction.

In the SCAUT project, we have taken measures to mitigate overhead work since we need to scale up the number of participants involved in the prototype experiments. This primarily involves designing and building a software tool - an R&D engine - to support the coordination work related to the participatory prototyping process.

Scaling up the number of participants is a means to increase the chances of delivering a product that meets users' needs and thus holds market potentials. This introduces the need for making the process more efficient than earlier. For example, we need efficient ways to communicate with individuals and groups of patients. We need to be able to keep an overview of patients' use and non-use of the different app features as well as simple ways to keep them interested and informed about progression of the project. We need to be able to communicate needs and requirements to developers so there will be a natural inflow of prototypes to be evaluated by end users. Inspired by for example customer-relation management systems, medical progress notes, and online video guides we are building a customized R&D tool that is tightly connected to the app- and web-prototypes. The purpose is to support a R&D process with fewer resources involved when experimenting with the prototypes. We will make it easy to introduce new features to many participants by providing in-app videos and by developing a message module. We aim to make use of in-app newsletters and create an idea-voting system as a way to involve many participants. We aim to make it easy to follow use and non-use by creating ‘use-scores’ and making it possible to easily keep track of individuals and groups of patients by elaborated personal profiles with information relevant to running the process. Here, we aim also to include indicators such as ‘take a look at’ or ‘contact patient’, which can be set manually or automatically.

2.2. The Challenge of Integrating All Stakeholders' Interests Up Front

The methodological approach needs to take into account that the SCAUT project will deliver a commercial product. Instead, the purpose of the CITH project was to

investigate opportunities and concepts, and progress was evaluated as the degree to which patients and clinicians found the developed concepts, features and affordances meaningful, actionable and organizationally feasible [2]. It was not part of the agenda to investigate the commercial potential in detail. However, in SCAUT the market plays a much more central role. The market interests are primarily taken care of by the software company and the device manufacturer. One of their natural concerns is the commercial potential of the prototypes. From a methodological point of view this means that we need to find ways to integrate also their interests in the transition from one prototype to the next.

We propose three mitigation strategies for this. First, we advocate involving users more than is typical in commercial settings - and in additional roles. Patients and clinicians need to be involved not only for the purpose of testing or approving assumptions, but also for the purpose of exploring, experimenting and evaluating features and affordances of the evolving prototypes [3]. Second, we pre-assess the value propositions of the prototypes by using the Business Model Canvas [14], the results of which will feed into the third mitigation strategy: The Stage Gate Model. However, the latter is inscribed in a waterfall model in order to have “well defined gates”, and prototyping is not used until requirements are fixed. Therefore, and inspired by Scrum [16], we have adjusted The Stage Gate Model to include explorative and experimental prototyping up front. This will produce more relevant materials at the gates based on real users’ real experiences with evolving prototypes.

2.3. The Challenge of Designing Within Regulatory Requirements

To be able to bring an eHealth system (all the way) to the market, means that we have to ensure the system will meet regulatory requirements. Rather than postponing this, we recommend engaging with the regulatory issues early in the process. Even though the system is solely software-based, it is considered a ‘medical device’ in regulatory terms [13] and will have to pass regulatory assessment and approval by the relevant authorities (e.g. FDA for the US market and EU MDD for the European). Many R&D endeavors postpone (or neglect to consider) the regulatory process, mostly because it is either too complicated early in the process or because the knowledge of what the product will be is too uncertain to begin structuring a regulatory process around it.

However, although it might seem wise to hold off regulatory considerations until it is clear what the eHealth system actually consists of, this will almost inevitably result in a system that is nearly impossible to get approved. This is because some of the requirements have implications that extend all the way into how the fieldwork is conducted in order to enable proper documentation of user needs, and features to support those needs, later in the process. Other requirements have implications for whether the system ‘displays’ information (lower requirements) or rather transforms information (more strict requirements). The differences in those categories are monumental [13]. Hence, we argue to engage the requirements early on and work with them as ‘just’ another actor or constraint on the project. One way we do this in SCAUT is to modularize the software (architecture) to isolate and minimize the components that ‘transform’ information. Another way is that when we sketch and mock-up features that are informed by the fieldwork, we carefully consider whether we can accomplish the same without transforming the information right away, or leave the transformation to later. In other words, we recommend that regulatory demands are treated as design parameters and seen as a resource for the project. The requirements should be dealt

with early in the process and should not be postponed to the final stages.

3. Concluding Remarks

Based on reflections on two projects, we propose mitigation strategies to be considered when engaging in R&D of marketable eHealth systems. The strategies suggest how to establish an efficient R&D process in order to scale and evaluate the system with many patients, and how to integrate stakeholders' interests early on in order to align commercial interest with those of patients and clinicians. Finally, we suggest how to consider regulatory demands and integrate them as design parameters for the project.

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