

Challenges Implementing Patient and Public Involvement in a Digital Health Agile Project Which Includes Research, Business and Software Development

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Abstract. Patient and public involvement (PPI) is a practice for involving future users in the design, development, and research of health technologies. There is increasing interest and demand for PPI, but little evidence based methodological support for integrating PPI in agile development processes. Multiple sclerosis (MS) is a chronic condition that severely impacts the lives of patients and requires active patient involvement. In this paper, we present the results of a case study, examining the adoption and integration of PPI into the development of a digital therapeutics solution for MS. The results highlight five critical phases that proved to be challenging: selecting patient participants, onboarding of patient participants and employees, framing tasks for patient participants, communication between patient participants and the rest of the development team, and reimbursements. The results are useful in creating evidence-based guidelines and methods for supporting the adoption of PPI.

Keywords. Patient and public involvement, Agile development, mhealth, Digital therapeutics, Digital health, Business development

1. Introduction

Involving users early and often in the design and development process increases the chances that the result will have value and meet user's needs [1]. Patient and public involvement (PPI) is an emerging approach to increase inclusiveness, defined by the National Institute for Health Research as “research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them” [2]. PPI is one way to improve digital equity, app use rate, and user satisfaction [3]. Multiple sclerosis (MS) is a degenerative neurological condition that requires active patient involvement and would benefit from the use of digital health solutions. In this paper, we analyze barriers to putting PPI into practice in a research, business, and software development digital health project. The objectives of this paper are to increase the knowledge base of challenges in

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PPI in digital health for different contexts; responding to the research question: “What challenges can emerge when implementing PPI activity into digital health agile product development process, and what could be the reason behind them?”

2. Methods

A single case study approach using data collected from observations, experiences, archival documentation from records, development logs, media coverage, and other materials available from the design and development of a digital health solution project. The case was More Stamina project, which is an agile digital health project that includes research, business, and software development based at the University of Oulu in Finland. The present work covers the PPI implementation during the period of early 2021 until late 2023. The initial experiences of PPI implementation in this project have been reported in prior works [4].

The project designed, developed, and marketed digital health solutions for persons with MS. The team was composed of 12 individuals with multidisciplinary professional backgrounds. followed a Lean Startup approach [5], with core activities on software development. Due to the nature of software design and development, project scopes are not always known in complete detail beforehand and are highly likely to change as work progresses. It is because of this reason that the project also adopted an agile methodology approach [6] for all teams (development, business and research). Teams work following the Scrum Method [7], adapted to suit the project’s organization with 2 weeklong sprints, preceded by a Sprint Design and concluded with a Sprint Review session. Also, once a week members of all teams had a general meeting.

3. Results

A thematic analysis of the collected data provided the following five challenges that emerged from PPI process implementation:

3.1. *Selecting patient participants*

There was uncertainty of the best strategy for selecting who to involve as patient participants, and what strategy to use to find them. Existing networks for patient involvement are limited in Finland, and it was difficult to determine the profile of patients who would be participants. Further, as the project intended for patient representatives to be remunerated, that created a challenge as persons on sick leave or unemployed are not allowed to earn money according to Finnish regulations. The goal was to recruit people with real-life experience of living with the disease, but their benefits needed to be accounted for to avoid causing any problems for them. Eventually, the project contacted patients through the MS patient association, recruiting a total of 3 patient representatives.

3.2. *Onboarding of patient participants and employees*

As the project involved more aspects than simply research, its complexity made the onboarding process of new employees difficult due to the amount of new information.

This issue extended to patient representatives who were involved only a few hours per month. Patient representatives received a short onboarding session about the project and roles when they started. Soon it became apparent that it had been insufficient to clarify patient representatives' roles and expectations. Incorporating a dynamic in which patient representatives were equal design and development partners in the process was difficult. As a result, patient representatives seemed to be unable to differentiate between acting as research study participants and actual members of the team. Processes were designed to empower them and make materials as accessible as possible, to encourage active participation.

Despite the weekly meetings, there were challenges regarding software development and research miscommunications and misunderstandings. To solve this problem, the project lead successfully arranged a training session for all the employees and patient participants. This was a beneficial activity and the PPI contact person felt that understanding agile development earlier would have made it easier to guide patient participants from the beginning.

3.3. Framing tasks for patients

Framing tasks for patient participants in a versatile project was at times problematic. The intention was to include patient representatives in conversations regarding software design, research approaches, and business development. However, the range of activities was found to be too varied for non-technical individuals to follow. Input from patient representatives was kept at a very superficial level and resulted in unproductive sessions. There was much discussion from the different teams about the value that PPI was bringing. In terms of software related issues, training about the development cycle could have been beneficial, while research was more determined by the overarching goals of the project. It was not clear how much value there would be in giving patient representatives in business-related tasks, as business modelling is not something that may be intuitive to people.

3.4. Communication between patients and the rest of the team

Communication procedures were not properly defined by and for the PPI contact point. There was no structured way of presenting the information to patient representatives, and there were difficulties in finding the right communication style. Patient contact point found it hard to share enough information so patient participants could contribute, but not to share too much and cause confusion or to overburden them.. A monthly newsletter of the project was also sent to patient participants to keep them posted on what was happening in the project.

Facilitating interaction to scaffold active participation instead of informant behavior was difficult. Conversation at times felt like interviews with the patient providing answers. Creating an environment where both would equally contribute required significant work and premeditation. There were also several occasions where communication failures caused unexpected situations. For example, work time was used to post about the project on social media despite it not being a task assigned to them.

3.5. Reimbursement modelling

The project intended for patient participants to receive monetary reimbursement for their time, effort and expertise, in order for them to be equal to the rest of the team. There was uncertainty about the best way to organize reimbursement, with many models considered: a monthly lump sum, hourly reimbursement, and invoice-based reimbursement. Hourly reimbursement was chosen, because of its flexibility to adjust for involvement in different phases of the project. Coffee and snacks were provided for on-site meetings.

However, monetary reimbursement and unclear billable actions created a transactional context which led to transactional attitudes and situations of mistrust. Prioritizing PPI input, when presented with conflicts, resolution always turned in favor of patient representatives. Using hourly reimbursement sometimes led to confusion about what tasks were assigned to the patients. On the other hand, the project group appreciated and expected the patient representatives to be active and take initiative, but sometimes that led to situations in which the project received bills about tasks that were not actually assigned to the patient representatives.

3.6. Highlights

The following highlights of our learnings can help other researchers in planning PPI:

- The local context can act as a barrier to patient involvement. Consulting patient organizations for local practices is key.
- Designing an adequate onboarding process for patients and team members is vital. Onboard should include also the organization and its culture.
- Create patient profiles with defined tasks and skills. Do not expect one patient representative to master everything that happens in a complex project.
- Taking a leading role might not be easy for patients. Patients will become more active as they see that their opinions are valued.
- Reimbursement models need to be designed in a way that matches motivational goals and avoids transactional dynamics.

4. Discussion

The project adopted PPI to have direct access to valuable and actionable input to the design and development process. However, our work shows that setting up an effective PPI process is not straightforward, and there are several critical phases where more evidence-base is needed. The different challenges presented here were interconnected: Reimbursement affected the selection of patient participants, and the background of chosen patient participants affected the selection of tasks for them. Selected tasks affected the onboarding process needed. Problems in communication led to problems with reimbursement. It was considered important to have patients' point of view, but it was not easy to foresee the challenges that appeared. Diversity and existing skills that are needed are beneficial for involvement [8]. This can be difficult to implement in real-world-setting if, for example, the studied disease is not common, and the local structures and regulations don't have existing support for patient involvement. Earlier literature also highlights the importance of training [8,9] and our results support that. Not just

onboarding on tasks and roles, but also on the organization and its culture. However, there is ongoing debate about how representative a patient who has received extensive subject matter training truly is.

In the project, the PPI process was initially not efficient and created bottlenecks, relying too much on the PPI Contact Point as an interpreter of the different teams' needs and requests. A more targeted focus on software design and development would have brought adequate attention to the areas where PPI input would have been more effective, instead of diluting valuable patient representative time on areas that benefited less from their involvement. Further, structuring and better framing PPI requests could help patient participants contribute better, controlling PPI-related costs and reducing unexpected expenses.

5. Conclusions

PPI in the digital health development is increasingly important, as the digitalization of healthcare advances. However, there is still too little methodological support for integrating and adopting PPI into software development processes and practices. Our results highlight the critical phases of PPI adoption and integration, providing evidence on how effective use of PPI would benefit from methodological support and tools.

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