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Multi-Stakeholder Design for Complex Digital Health Systems: Development of a Modular Open Research Platform (MORE)

Pavithren V S PAKIANATHAN^{a,c,1}, Daniela WURHOFER^a,

Devender KUMAR^a, Josef NIEBAUER^{a,b} and Jan SMEDDINCK^a ^a Ludwig Boltzmann Institute for Digital Health and Prevention, Salzburg, Austria ^b University Institute of Sports Medicine, Prevention and Rehabilitation and Research Institute of Molecular Sports Medicine and Rehabilitation,

Paracelsus Medical University, Salzburg, Austria ^c LMU Munich, Munich, Germany

Abstract. Background: The Modular Open Research Platform (MORE) is being developed as an open-source platform for long-term situated digital health (DH) research and observations with the potential to facilitate studies, evaluations of DH interventions, and remote telehealth monitoring. Objectives: To implement an iterative development approach that integrates multi-stakeholder perspectives to support a single platform development process. Method: Capture, fulfil and balance the requirements of a multi-disciplinary group of stakeholders interacting with the system through a Delphi-inspired, iterative and participatory design process encompassing a series of workshops and online surveys. Results: Through interaction with a multi-disciplinary group of key platform stakeholders, diverse feedback and requirements for the design and development process were elicited and integrated. Conclusion: Findings from the initial rounds of stakeholder involvement lay the stepping stone towards further iterations in the process. Experts who participated in the process.

Keywords. Design science, digital health, open innovation in science, stakeholder engagement, situated research, mHealth, in-the-wild study, user-centred design

1. Introduction

1.1. Technological developments in sensing technologies, data capture and processing capabilities have led to considerable advancements in digital health (DH). Many frameworks (such as Beiwe, AWARE, Radar-Base, CARP, and LAMP) have been developed to facilitate DH research [1], and the stakeholders who utilise them have varying motivations. Clinicians and researchers may like to evaluate their digital health interventions, regarding their capacity to improve health outcomes [2] or conduct remote telehealth monitoring of participants or patients. On the other hand, developers might be interested in robustly evaluating digital health apps, which must be assessed for

¹ Corresponding Author: Pavithren V S Pakianathan, Ludwig Boltzmann Institute for Digital Health and Prevention, Salzburg, Austria, E-Mail: pavithren.pakianathan@dhp.lbg.ac.at

compliance standards for "Digitale against regulations and such as Gesundheitsanwendungen" (DiGA) in Germany. Although current open-source frameworks provide some of these functionalities, they have generally had low uptake, especially by developers. Since 2010, 28 mobile and wearable sensing frameworks have been created, and as of January 2021, only ten are actively maintained [1]. Further, the lack of early involvement of all the stakeholders in the design process of such mHealth platforms often renders them ineffective for flexible use, e.g. in complex randomised controlled trials (RCTs).

A combination of functionalities is needed to assemble mHealth research and evaluation platforms which consist of features such as integrating sensing devices, collecting large amounts of data from various sources, such as questionnaires, managing study participants, and enabling compliance with current health data privacy and security standards. To that end, we are developing the MORE platform (**Figure 1**), which aims to allow 1) researchers to conduct scientific studies 2) developers to conduct DHI evaluations and gather evidence for regulatory clearance, and 3) healthcare professionals to conduct remote telehealth monitoring. The conceptualisation of the MORE platform follows open innovation in science (OIS) principles, building on transdisciplinary collaboration across organisational and disciplinary boundaries [3].

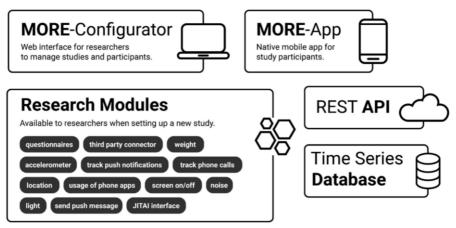


Figure 1. Schematic diagram for components of the MORE platform.

The technical design choices of the MORE platform aim to 1) allow for the integration of multiple sensor data sources with near-real-time data collection and analysis, 2) have real-time-readiness for adaptive interventions, where study data trigger actions/reactions (e.g. JITAIs [4]) build on a state-of-the-art modular technology stack consisting on proven and widely adopted components for developer friendliness, 4) have manageable deployability, 5) offer mobile applications for participants and end users, 6) offer support for designing complex RCTs and study management, and 7) be made available under a permissive open source license.

The involvement of various stakeholders, such as researchers, developers, health care and administrative support staff, brings value and diverse perspectives when developing the foundations for such a comprehensive platform. We make a decisive effort to integrate multi-stakeholder perspectives in order to position the platform for good usability, acceptance and effectiveness across the different application areas.

2. Research Questions

2.1. To better understand the viability of design and development approaches towards implementing a system which addresses the needs and interests of various stakeholders as described above, we consider the following meta-research question:

How can we develop a participatory and iterative design process that allows us to capture the voices, abilities and needs of busy professional users with a wide range of backgrounds, encompassing researchers, developers and healthcare professionals and enable them to contribute to a unified vision of a platform?

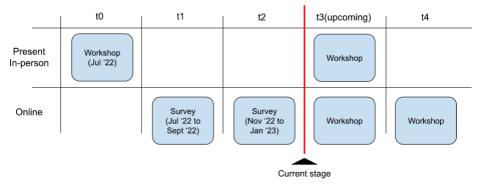


Figure 2. Milestones of the Delphi-inspired process.

3. Method

Our design process (Figure 2) involves an iterative and participatory approach inspired by the Delphi method [5], with potential stakeholders who might be interacting with the system. To kickstart the design process, a set of requirements was prepared and shared with a group of transdisciplinary stakeholders at the initial workshop (Figure 3). Subsequently, two Delphi rounds were conducted to elicit requirements, consolidating and reflecting on prior stakeholder positions in each round to achieve consensus and facilitate member checking [6] Delphi studies have been traditionally used to engage experts to design and develop tools to support clinical practice [7] and typically consist of about three rounds. They have been instrumental in seeking the opinion of experts in a particular field - in our case, digital health research - and driving them towards consensus by building on anonymous views shared by experts in the previous rounds. Our process consistently borrows the reflective element regarding outcomes of previous rounds from Delphi, but purposefully combines in-person and online/remote options to allow the stakeholders to be flexibly involved whilst also offering hands-on experience with system prototypes. In the subsequent sections, we share the reflections from previous activities: 1) initial workshop, 2) Delphi round 0 and 3) Delphi round 1.



Figure 3a. Ideas sorted using MOSCOW

Figure 3b. Idea mapping

Figure 3c. Stakeholders ideating

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3.1. Multidisciplinary Stakeholder Workshop

An initial in-person workshop was conducted at *Ludwig Boltzmann Institute for Digital Health and Prevention, Salzburg, Austria* with a multidisciplinary group of stakeholders (n=10) to identify key needs and barriers for research and evaluation support technologies. A set of design and functional requirements were formulated based on technology, healthcare, research and development experts' inputs and were used to generate first interaction concepts.

Due to the participants' diverse backgrounds, the suggested ideas varied significantly, and we analysed the inputs consolidated into a MIRO board. Next, they were grouped based on affinity diagramming and finally divided based on must-have, should have, could have and will not have (MoSCoW) prioritisation (**Figure 4**).





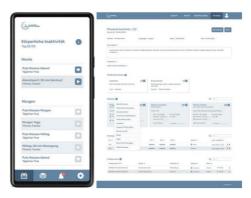


Figure 5. A selection of UI Mockups presented to experts; cf. also video walkthrough²

3.2. Delphi Round 0

Subsequently, an online survey hosted on LimeSurvey was sent to workshop participants and stakeholders working in the digital health domain. It contained mock-ups of key screens (**Figure 5**) to be found in the MORE platform, both on the web dashboard and the mobile application. Participants (n=5 full survey responses) were then asked to rate

² https://tinyurl.com/MOREDHEALTH23

the likeability ("*What did you like and/or dislike?*") and possible avenues for improvement ("*What can be improved?*"). The high-priority feedback from this round was consolidated and sent to the development partner to be integrated into the software development cycle of MORE.

3.3. Delphi Round 1

Another online survey was prepared for the second Delphi round (eliciting n=8 complete expert responses) and summarised findings from the workshop. Information on recent development and implementation steps, as well as proposed takeaway messages from the prior round were incorporated through an explainer video with supplementary materials in a PDF. This survey was divided into three sections: 1) perceptions about the developments since the initial workshop, 2) role, study lifecycle and "Create, Read, Update, and Delete" rights management functionalities of the MORE platform, and 3) personal reflection on the Delphi process. For brevity, we will omit section 2) and focus on 1) and 3) of this round.

4. Stakeholder's Reflections (from Delphi round 1)

To ensure that the Delphi process and the development works were aligned with the stakeholders' expectations, we asked two **reflection questions** (**Table 1**, questions 1 and 2).

#	Questions	Μ	SD	
	Stakeholders' reflections on takeaways			
1	Thinking back to the takeaways from the stakeholder workshop,	5.6	0.84	
	how much do you agree with them?			
2	Thinking back to the takeaways from the survey, how much do you	5.7	0.95	
	agree with them?			
	Stakeholders' engagement with the Delphi Process			
3	I feel that I could contribute my expertise.	5.5	1.27	
4	I feel that my voice is heard.	5.88	0.76	
5	I feel that the effort required to contribute to the Delphi Process	6	1.35	
	was manageable.			

Table 1. Stakeholder's responses to the questions

(scored on a 7-point Likert scale - 1 - strongly disagree to 7 strongly agree)

Participants also responded to open-ended responses, and we saw quite diverse opinions, which shows the differing priorities each stakeholder had ("Important for us is data science, how real-time prediction of future values can be realized" - P2; ("I would focus more on conducting and managing studies than on data science." - P4)

While completing the Delphi round, we asked the participants three **questions to** measure how engaged they were with the Delphi process (Table 1, questions 3 to 5).

Overall, there was keen interest in testing a prototype of the application, and one of the participants who rated a low score for **contributing their expertise** felt that their team members might be more suitable for testing the application. ("[It] *would be great if*

members of my team (name anonymised) could test/interact with a prototype. They have most of the experience with the current systems we use" - (P2)

All the participants in general felt valued in the Delphi process and that effort required for the process was acceptable. "As some of my feedback is reflected in [the] summary, I feel valued and can influence the process. I expected to put more effort into this process, but this is fine for me" - (P4)

Participants were also asked for other suggestions for improvements, and a few participants suggested reducing the time between the initial workshop and the Delphi process. Furthermore, as we were developing a digital platform, participants were eager to have a hands-on experience with a clickable prototype to "considerably improve [one's] impression and probably also feedback" - (P8).

5. Conclusion

Designing a single research platform which is intended to be utilised by multidisciplinary stakeholders (researchers, developers, HCPs) with diverse motivations, abilities, interests, and needs is a multi-faceted problem. We tackle this through an iterative and participatory, Delphi-inspired design process, capturing the essential requirements from individual stakeholders and balance them while showing them that their "voice" is heard. The development process is still ongoing; further Delphi rounds will be conducted in both in-person and online modalities, and analysis will be conducted to compare how participants' perceptions of involvement in - as well as of the adequacy of the extent of effort required, for - the design process change with modality.

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