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Development of Verified Innovation Process for Healthcare Solutions (VIPHS): A Stepwise Model for Digital Health

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Abstract. Many digital health projects often stop in the pilot or test phase. Realisation of new digital health services is often challenging due to lack of guidelines for the step-by-step roll-out and implementation of the systems when changing work processes and procedures are needed. This study describes development of the Verified Innovation Process for Healthcare Solutions (VIPHS) – a stepwise model for digital health innovation and utilisation using service design principles. A multiple case study (two cases) involving participant observation, role play, and semi-structured interviews were conducted for the model development in prehospital settings. The model might be helpful to support realisation of innovative digital health projects in a holistic, disciplined, and strategic way.

Keywords. Innovation in digital health, implementation strategy, service realisation

1. Introduction

It is often difficult to go from a project phase to an operational implementation phase. Especially the failure rate of digital transformation projects is huge. The reason why 70 percent of all digital transformations fail is a lack of discipline in defining and executing proper steps for digital transformations to take off and stay ahead [1].

When it comes to innovation in digital health, making the innovation projects successful is even more challenging due to the complexity in healthcare services. Digital technologies can support and improve delivery of health services [2]. Improvements often occur by overcoming challenges in communication due to time and place and allowing people and resources to interact in easier ways [3]. This means more people and systems can be involved in digital health. Thus, various activities can be created due to the increased number of people and systems, and their relationships. Moreover, ethical issues, healthcare policies, and the ecology of health information systems adds to the complexity, and once in operation, support, service and maintenance adds to the picture.

To make innovative digital health projects successful, there is a need for guidelines and models that can support utilisation of the projects with a holistic approach. The

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existing recommendations and approaches are limited. Most of them are either focusing on interoperability issues, related to health information infrastructure, or concerning patients' accessibility to their own health data [4-7]. Two regions in Sweden reported that the most difficult thing in implementation phase of digital health projects is step-by-step roll-out of the systems [8]. There is a lack of models and guidelines that can support digital health innovation and utilisation in a holistic, disciplined, and strategic way.

Service design is a multidisciplinary, integrative, and holistic way of innovating or improving services to make them efficient for organisations and more usable, useful, and desirable for customers [9]. Service design choreographs interactions, processes, and technologies in complex systems to co-create value for relevant stakeholders [10]. The aim of this paper is to present a stepwise model for digital health innovation and utilisation following service design principles, and describe its development process.

2. Methods

A multiple case study was conducted to develop a stepwise model for digital health innovation and utilisation. Two cases were used for the development process in an iterative manner. For triangulation, participant observation, roleplay, and semi-structured interviews were used to collect data in prehospital settings in Sweden.

Two separate projects allowed to develop the VIPHS model. The development process was conducted in an iterative manner, which means that the results from the second project provided input to improve the first model from the first project. The first project, PrehospIT-Stroke, aimed to create better conditions for more efficient use of digital health within prehospital healthcare. It focused on the foundation for national harmonization of semantic and technical interoperability, with the acute stroke chain as example, aiming to improve IT support and solutions in the acute phase as well as in follow-up, business development and quality assurance at both local and national level. The second project, ViPHS (video support in the prehospital stroke chain) aimed to evaluate whether a collaborative assessment using video involving a neurologist could be effective to support the transportation decision for potential LVO (large vessel occlusion) patients, especially where there is a risk for considerable transport time to a thrombectomy facility due to geographical distance and/or first stop at local hospital.

Six principles of service design [11] were applied in the two projects. Table 1 shows the principles, their meanings, and how they were applied in our studies' contexts.

Table 1. Principles of service design and application to our studies

Principles	Meanings [11]	Application to our studies
Human-centred	Considering the experience of all the people affected by the service	Taking into account the experiences of all involved people in the care process
Collaborative	Engaging all the stakeholders in the service design process	Involving all the stakeholders in the development process
Iterative	Iterating exploratory, adaptive, and experimental approach towards implementation	Developing and improving the service through several iterations
Sequential	Visualising and orchestrating the service as a sequence of interrelated actions	Visualising the care processes
Real	Researching needs in reality; prototyping ideas in reality and evidencing intangible values as physical or digital reality	Testing the service with increasing realism of the test settings

Holistic	Sustainably addressing the needs of all stakeholders through the entire service	Conducting care process analysis and process mapping of the entire service using a holistic approach in the initial stage

The first project, PrehospIT-Stroke, carried out in the following three phases:

1. Detailed care process analysis, identification of critical decision-making points, inventory analysis, and recommendation regarding technical and semantic interoperability,
2. Tests in a lab environment of technical and semantic recommendation (Connectathon [12]),
3. Simulated full-scale operational field test in an ambulance.

The first phases included process mapping of the stroke chain, inventory of process support, standards and de-facto standards around semantics and interoperability, analysis, and preparation of a first recommendation for harmonisation. In the second phase, the system structure was tested in the PrehospIT Connectathon in a lab environment, where the project partners' proprietary solutions were tested technically together in a simulated care process utilizing the proposed interoperability standards and methods. This test showed that the different systems could communicate with each other effectively without failures. In the last phase, the system was tested in a full-scale realistic operational simulation (roleplay), where an entire ambulance mission from dispatch to handover was simulated [13]. Eleven ambulance teams (22 ambulance clinicians) were recruited to the study. The teams were instructed to either start using a computerized decision support system (CDSS), described in [13], or to work as usual. Two representative patient cases with stroke-like symptoms were created. In one case, the patient had severe stroke symptoms, and in the other case, the patient had moderate stroke symptoms. All simulations were filmed, and all participants were interviewed after the simulations. During the semi-structured interview (average 35 minutes), questions regarding the CDSS and the system were asked; how compatible the CDSS was with their current way of working, what advantages the system brought compared to their current practice, and what problems and challenges they experienced. The interviews and films were then analysed, and the management of the patients with and without CDSS were compared.

The second project, ViPHS, was conducted in the following four phases:

1. Analysis of process and inventory and recommendation regarding technical and semantic interoperability
2. Tests in a simulated prehospital environment
3. Initial field test in ambulance
4. Field tests in a larger scale

In the first phase, the market for mobile video solutions was investigated. Different solutions were tested and evaluated in terms of image quality, function, malfunctions, and so on. An ambulance was equipped with a solution that was considered as the best alternative and tests on transmission capacity were carried out by driving the ambulance around in areas with poor cellular coverage. In the second phase, a simulated test (roleplays) was performed. Four ambulance teams (eight ambulance clinicians) and four neurologists from a regional stroke centre were recruited. The simulation was set up consisting of a video-equipped ambulance standing outside in a parking lot, an office, and a bench outside. Two patient cases were constructed inspired by real patient cases. In one case, a male patient was found by a colleague in an office with severe stroke symptoms, in the other case, a female patient was found outside with moderate stroke symptoms. After the simulations, each participant was asked questions regarding the simulation design and their experience in a semi-structured interview (average 39 minutes). In phase three, the system was tested in the field in a small pilot study. Video equipment was installed in three ambulances in an ambulance organization in Region Västra Götaland in western Sweden. The staff were trained in the system and new guidelines for the care of patients with stroke symptoms were written. For each video-equipped ambulance, a person was appointed as responsible for staff training, that guidelines were updated and implemented, and managed the collection of study protocols. The pilot study lasted one year and all other ambulances in the organization served as a control group. In phase four, the study was expanded both geographically and with a number of ambulances. Twelve ambulances throughout the region were equipped with video. In this phase the technical solution was also adopted to a video-platform supported and maintained by the region. Thereby a potential expansion of the service as well as full-scale operational support and maintenance beyond the project phase should be facilitated. This study has been going on for a year and is expected to finish in year 2023.

3. Results

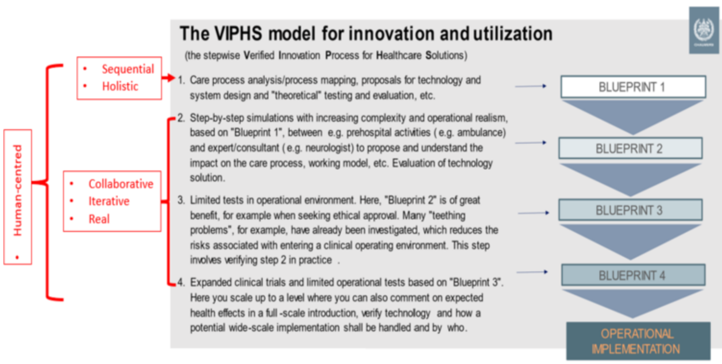

Figure 1. The VIPHS model for innovation and utilization

Figure 1 shows the stepwise model for digital health developed through the two cases. Red texts on the left side shows where the principles of service design are applied. In the VIPHS model, each step leads to a "Blueprint" which is a document with results obtained and input and recommendations to the next step. The model can also be used partially, not including all the four steps. If the project aims to define a prototype, it can stop after blueprint 2. If the project's aim is a clinical validation (e.g., operational feasibility study or clinical proof of concept), it can stop after blueprint 3. The VIPHS model provides an overall idea on what to achieve in implementation in clinical operations and allow to restart a new project from where the previous project ended.

The PrehospIT project stopped at step 3 (blueprint 3) since the goal of the project was to demonstrate the benefits for the care process deploying standards etc., enabling multi-system interoperability and improved care processes in a realistic setting. The Connectathon was the prime source for evaluating interoperability. During the user simulations the improved care process was achieved from deploying this interoperability. The ViPHS project is still running in an extended step 4 (blueprint 4) in March 2023. The clinical tests were stopped at the end of 2022. However, the tests resulted in a suggestion of modifying and updating the technical solution before going into more general deployment across the health care region. Planning is currently underway to introduce the ViPHS system in all the region's ambulances.

4. Discussion and Conclusion

In digital health, changing systems and work processes, namely digitalisation of services in healthcare, is one of the fundamental challenges. Having models that can guide and support digital health innovation and utilisations would be helpful to solve this issue. We could develop a stepwise model for digital health innovation and utilisation by applying service design principles through empirical settings. The VIPHS model with its clearly defined steps and accompanying "blueprints" could be useful to support the implementation process of digital health projects in a holistic, disciplined, and strategic way. This can contribute to increase the success rate of realizing digital health projects.

The ViPHS model's step-by-step method provides valuable data in all steps that contribute to accomplish the next step. For example, step 2 in the ViHPS project revealed that it was necessary to standardise the communication between ambulance clinicians and the neurologist. This helped to prepare step 3. In addition, the VIPHS model's stepwise approach made it easier to document and communicate our findings and recommendations to people outside the project group.

The VIPHS model was developed in a specific clinical setting, the prehospital stroke care process, which is a limitation of our study. We plan to further improve this model through more case studies in different clinical settings like trauma and fall patient care processes that use advanced technology like artificial intelligence, voice recognition, etc.

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