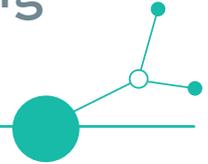


3.3.1. Reports from implementation of testing phase in territorial Health Living Labs (real-world setting)



Anna Lipert, MUL





GUIDELINE

KEY DEFINITIONS:

A **prototype** can be perceived as something being built to represent a product or experience before the actual artefact is completed.¹

Pilot test should provide insights into anything that might be missing in the innovation, so this can be adjusted before the complete roll-out to a larger group of test users.²

Real-word health care setting place/location existing or occurring in reality, e.g. hospitals, clinics and pharmacies across diverse geographies, enabling to obtain by researchers real-world evidence (RWE) based on real-world data (RWD)

Real-world evidence (RWE) is evidence about the use, safety and effectiveness of a medical product, technology or drug that is based on or derived from analysis of data generated in a real-world health care setting.³

Real-world data (RWD) includes information about the health of individuals or the delivery and/or outcomes of health care that is collected outside of traditional clinical trials and thus reflects results within the context of the particular health care system.⁴

Implementation is defined as a specified set of activities designed to put into practice an activity or program.⁵

Within innovation research and living lab projects, a crucial component is to test an innovation in a real-life context with potential end users. Such a field test can validate assumptions by combining insights on behaviour and attitudes towards the innovation. This allows for iterative tailoring of the innovation to the needs and wants of the potential end users. Moreover, relevant insights can be gathered to stop or rescope the innovation project before big investments are made. Although studies indicate that testing innovations (or prototypes) in real-life contexts improves the innovation process, there is no specific framework on how to conduct a field test for an innovation. Therefore, for the needs of the solutions proposed in the project and after reviewing the literature on the subject, the following path for implementation of testing phase in real-word setting was proposed:

1. Finish the recruitment process of 20 patients with their relatives. The recruited participants should be those who are confronted with the solution (**end of September 2024**).
2. Prepare all the necessary protocols, written consents etc. based on the national regulations or internal regulations of the institution which should be filled in and signed by the participants.

¹ Sanders, E. B.-N., & Stappers, P. J. 2012. Convivial Toolbox: Generative Research for the Front End of Design. Amsterdam: BIS.

² Coorevits, L., Georges, A., & Schuurman, D. 2018. A Framework for Field Testing in Living Lab Innovation Projects. Technology Innovation Management Review, 8(12): 40-50.

³ Chodankar D. Introduction to real-world evidence studies. Perspect Clin Res. 2021 Jul-Sep;12(3):171-174. doi: 10.4103/picr.picr_62_21. Epub 2021 Jul 7.

⁴ As above

⁵ Implementation Stages | NIRN". nirn.fpg.unc.edu. National Implementation Research Network. Archived from the original on 2022-05-23. Retrieved 2022-01-26.



3. Before the first confrontation the users with the solution, there should be a pre-test phase using PREMs and PROMs specifically adapted to the evaluated solution. Use also some other forms of evaluation if possible, e.g. measurement devices.
 4. Store all the data from pre-test phase: both forms, electronically or in paper is possible.
 5. Users react to and interact with the new solution.
 6. At the end of the testing, post-test phase using the same PREMs and PROMs should be provided to gain quantitative insights.
 7. Store all the data from post-test phase: both forms, electronically or in paper is possible.
 8. Analyse/Compare the results obtained from pre- and post-tests.
 9. Summarize the results with reporting the final feedback for the prototype improvements.
- HCOs with Teams play a key role in that phase with the support of KPs with their expertise.
 - The challenges and progress will be discussed with other piloting regions during the monthly calls facilitated by WP T3 leader on a transnational level.

Name: Helena Jurašková
Location: Czech Republic
Date: 25. 2. 2025
Institution: DEX IC, KNL

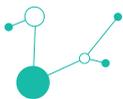
BACKGROUND INFORMATION

1. Context about the Territorial Health Living Labs and the goals of the testing phase.

In our region, the key testing environment is the Territorial Health Living Lab established at the Liberec Hospital, specifically within the spinal unit, where we focus on patients suffering from severe spinal cord injuries (SCI). SCI is a serious condition resulting from damage to the spinal cord, affecting motor, sensory, and autonomic functions. It can lead to partial or complete paralysis below the level of injury, along with secondary complications such as respiratory issues, chronic pain, increased susceptibility to infections, and pressure sores.

The objective of the Living Lab at Liberec Hospital is to create a real-life testing environment where innovative value-based solutions for post-spinal surgery care are validated and optimized. Given the complex nature of SCI, which demands a multidisciplinary approach including specialized neurological assessment, immediate rehabilitation, and comprehensive management of post-operative complications, this Living Lab aims to minimize neurological and functional deficits while enhancing patient outcomes.

This Living Lab employs a proven methodology that leverages close collaboration among the hospital, the university, SME partners, end users, caregivers, and hospital staff. By integrating co-creation, multi-method approaches, active user engagement, multi-stakeholder participation, and real-world testing, the Living Lab successfully captures real-world data (RWD) and generates real-world



evidence (RWE). These insights enable us to refine our innovative solutions to better meet the specific needs of SCI patients, ultimately improving their quality of care and quality of life.

2. Define the purpose of testing the new value-based solution with patients (e.g., improving patient outcomes, increasing efficiency).

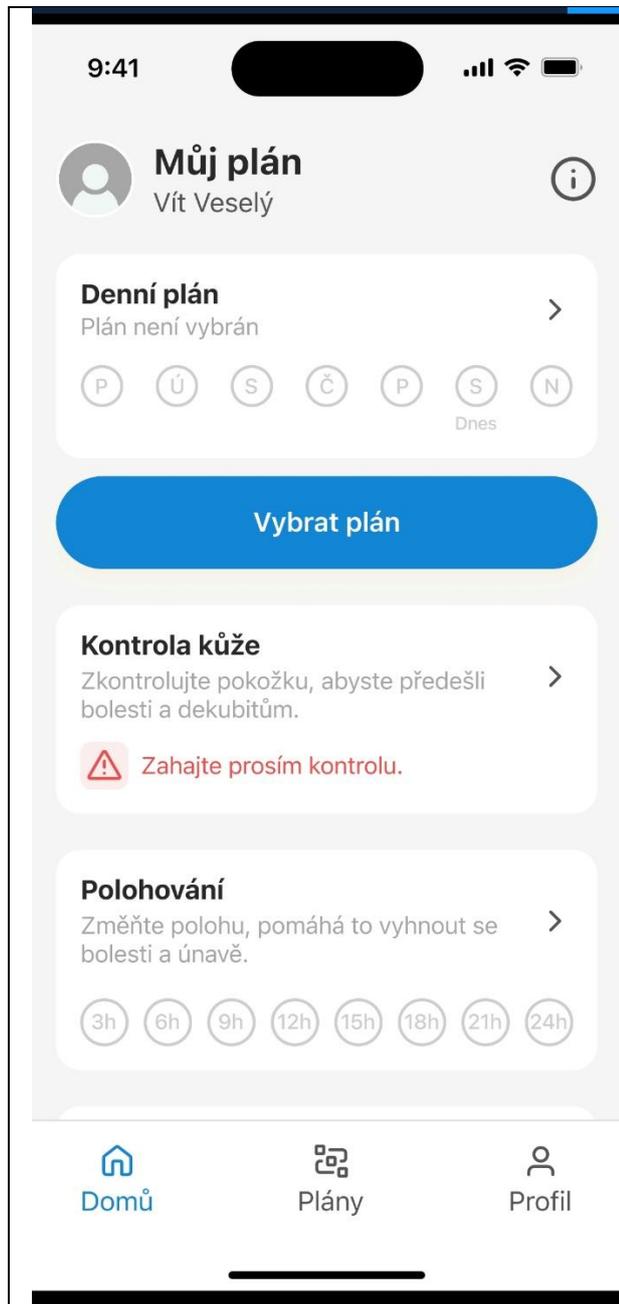
The purpose of testing the new technology is to ensure that it effectively enables systematic physiotherapy for patients after surgery, both during hospital post-operative care and in the homecare setting. The pilot is designed to evaluate how well the technology supports long-term treatment by enhancing communication, education, and monitoring for chronic patients. Specifically, it aims to:

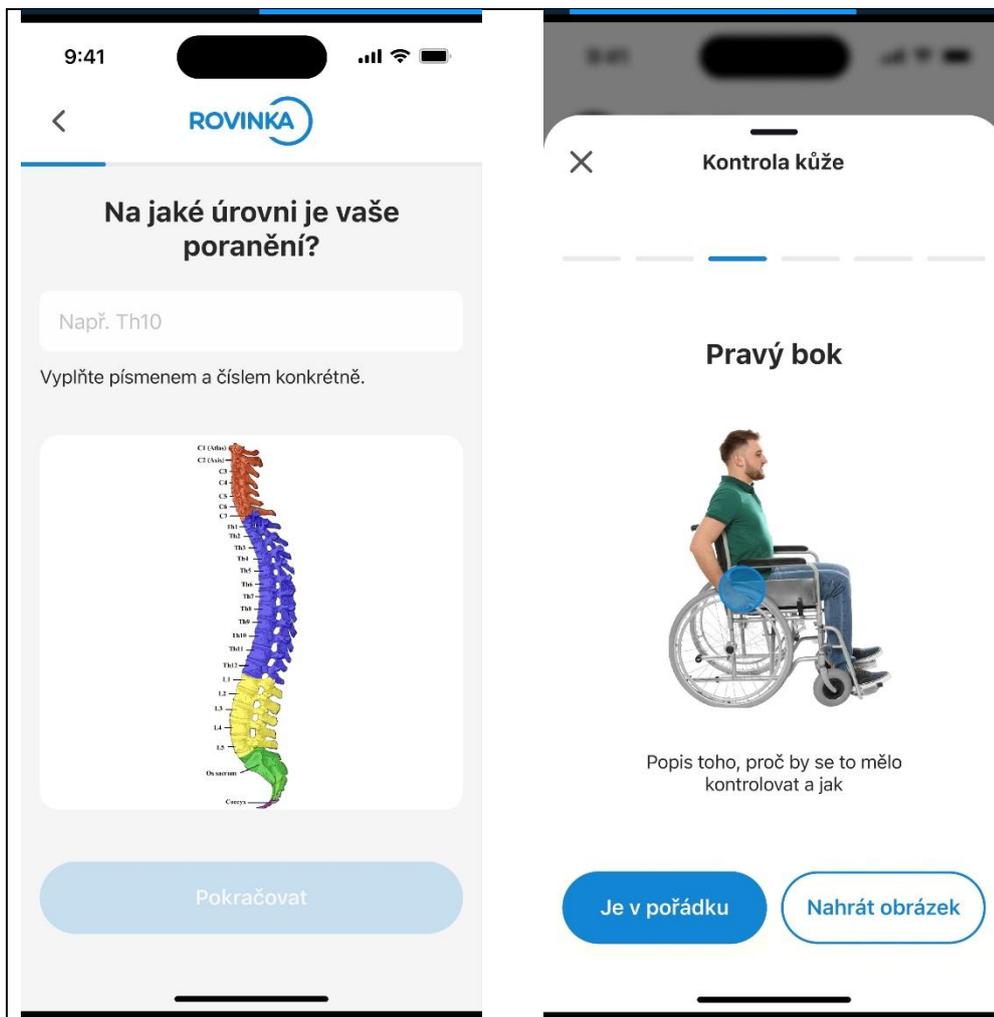
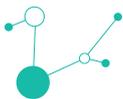
- Improve patient outcomes by ensuring that automated physiotherapy protocols are initiated immediately after surgery, thereby promoting faster and more effective rehabilitation.
- Increase the efficiency of care delivery by enabling continuous monitoring of patients' conditions at home, with direct access to healthcare professionals when needed.
- Validate the integration of the new technology into existing healthcare processes, ensuring that it meets the practical needs of patients, caregivers, and clinical staff.

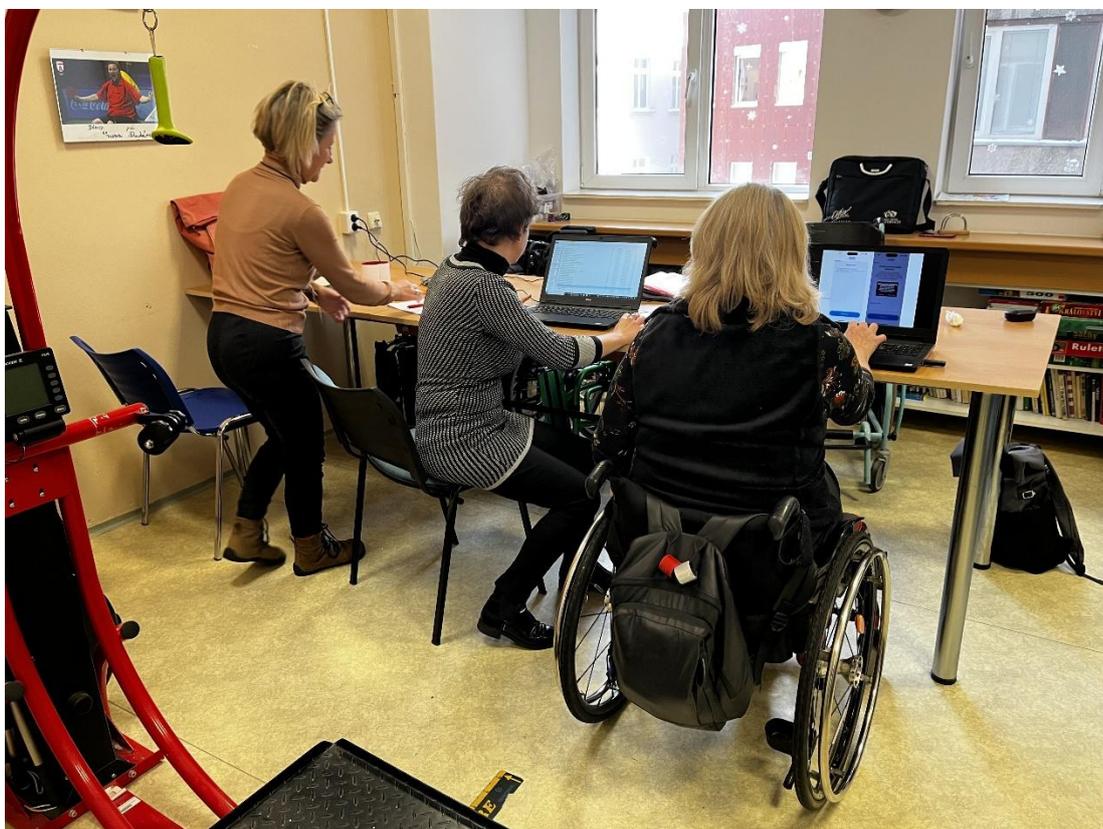
By testing this value-based solution in real-life conditions, we can gather essential data and feedback that will inform further refinements before broader implementation.

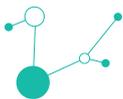
3. A brief description of the new value-based solution being tested.

Testing took place on several levels, culminating in the Open Innovation Camp II. During the reporting period, regular meetings were held between the hospital, the knowledge partner (DEX IC) and the SME partner (a start-up company developing the new solution). In addition, structured interviews were conducted directly with patients to collect data on both the solution and the application. All the data collected was continuously integrated into the development process. At the end of the period, an Open Innovation Camp II was organised to evaluate the solution and review the results from the testing phase.









TESTING METHODOLOGY

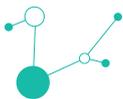
1. Describe how the 20 patients were selected (e.g., demographics, health conditions).

The target group for the Health Labs4Value project, particularly in the context of SCI, comprises a diverse demographic, including patients of varying ages, genders, and socio-economic backgrounds. Notably, men represent the majority of the SCI population, ensuring that the sample reflects real-world patient distribution. Patients were selected based on specific clinical criteria related to spinal cord injuries and post-spinal surgery recovery. The group includes individuals with varying degrees of spinal cord injury severity and different durations since the onset of SCI, capturing the broad spectrum of challenges and rehabilitation needs. This comprehensive and representative sampling enables us to identify personalized and adaptive rehabilitation strategies while providing invaluable insights into both common and unique obstacles in SCI care

2. Specify the time frame of the testing.

During our multi-month testing phase, we structured our timeline to reflect the different stages of innovation. In the early 'exploration' phase, we conducted concept and mock-up field tests to validate preliminary ideas and gather early user feedback on basic prototypes or simulated interactions.

As the innovation matured, we moved to the 'experimentation' phase, where functional prototypes were deployed in real-world environments. At this stage we focused on direct user interaction and extensive data collection. Testing was conducted both individually and in group sessions with patients through structured interviews and consultations with SCI hospital staff. Regular joint meetings between all stakeholders ensured continuous collaboration and integration of feedback



throughout the phase.

Finally, during the "evaluation" phase, we presented a refined version of the solution, incorporating the results of the previous stages. These tests, conducted under conditions that closely mirrored real-world environments, assessed the solution's readiness for wider deployment - evaluating user adoption, scalability, and the effectiveness of communication and support processes.

This sequential approach throughout the testing phase ensured that our process was thorough, adaptive and aligned with the evolving maturity of the innovative solution.

3. Outline how the solution was tested (e.g., use in real-world settings, patient interaction, clinical support).

The solution was tested in a real-world setting with spinal unit patients and hospital staff, and extended to home care, involving patients, their families and carers.

Real-world deployment: Functional prototypes were used in the hospital spinal unit immediately after surgery and in patients' homes. This ensured that the solution was evaluated in environments that closely reflect everyday care.

Patient interaction: Patients interacted with the solution both individually and in group sessions. We conducted structured interviews and consultations to gather detailed feedback on their experiences, needs and outcomes.

Clinical support: SCI hospital staff played a key role by closely monitoring patient progress and providing key clinical insights. Their support ensured that our automated physiotherapy protocols and communication processes met real-world clinical standards.

Stakeholder collaboration: Throughout the testing phase, regular meetings were held with all stakeholders - including the hospital, our knowledge partner (DEX IC), SME partners and other healthcare professionals - to continuously gather feedback and refine the solution.

This human-centred, multi-level approach allowed us to evaluate the usability, functionality and overall impact of the solution in a real-world context

4. Explain how data was collected (e.g., surveys, interviews, clinical measurements, feedback forms).

a) Did you need to prepare any additional protocols, written consents etc. except PREMs and PROMs questionnaires? If YES, describe them and explain why it was necessary.

We collected data through a qualitative approach using semi-structured interviews in facilitated focus groups. Each focus group typically included 3-4 patients from the spinal unit (and one patient from an external unit), 2-3 family members or carers, one clinical team member, one non-clinical team member and a facilitator. The interviews, conducted in two rounds of 90 minutes each, were designed to explore the challenges faced by patients and their families after discharge, during rehabilitation and when returning to everyday life. The sessions were audio-recorded, transcribed verbatim and later analysed using content analysis.



Additional protocols and written consent:

Yes. In addition to our standard evaluation tools, we developed additional protocols and obtained written consent from all participants. These documents ensured that participants were fully informed about the study procedures, the purpose of the interviews, and how their data would be used and protected. This step was essential to comply with ethical guidelines and maintain transparency throughout the data collection process.

b) How did you store the data and how did you secure them?

All data is kept in full compliance with the regulations and policies of the Regional Hospital Liberec.

IMPLEMENTATION DETAILS

1. Identify the key stakeholders involved in the testing, including healthcare professionals, patients, and technical support teams.

The testing phase brought together a diverse group of stakeholders, including

Healthcare professionals: Staff from the Spinal Unit at Liberec Hospital, including both clinical and non-clinical team members, who provided essential support, monitored patient progress and ensured that the solution met clinical standards.

Patients and their families: SCI patients representing different ages, genders and degrees of spinal cord injury, together with their family members and carers. Their participation in individual and group sessions provided critical insight into the practical challenges and needs of real-life situations.

Technical support teams: Teams from the knowledge partner (DEX IC) and SME partners who provided technical expertise and helped refine the digital application based on user feedback.

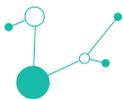
Academic partners: The Technical University of Liberec actively participated by involving its students in activities such as Open Innovation Camp I and II. This involvement provided students whose studies are related to the project with hands-on experience working with real patients, fostering a deeper understanding of the challenges in healthcare innovation and inspiring their future work.

Additional stakeholders: Other stakeholders, including facilitators and representatives from multi-stakeholder groups, ensured ongoing communication and collaboration throughout the testing phase.

This multi-stakeholder approach ensured that all perspectives were integrated, leading to a comprehensive evaluation of the usability, functionality and overall impact of the solution in a real-world context.

2. Describe how patients were supported during the testing phase (e.g., onboarding, training, technical assistance).

Thanks to the proactive approach of all stakeholders, we were able to provide comprehensive



support to patients throughout the testing phase. Patients were continuously updated on the progress of the tests, and during both individual and group sessions - such as those held during Open Innovation Camp II - fully informed facilitators guided them through the application walkthroughs and testing procedures.

Patients and their relatives had the opportunity to explore the application with the help of dedicated facilitators or during interviews conducted by our team. Any uncertainties were promptly addressed through direct consultation with the application developers, ensuring clarity and contributing to the creation of a user-friendly solution for future use.

RESULTS

Present the results from pre- and post- test phase (PREMs and PROMs results) and additional issues related to:

a) patients' overall satisfaction with the solution, ease of use, and experience;

Overall, patients expressed high levels of satisfaction with the solution. In particular, participants suggested adding a 'self-care' or 'independence' indicator to track personal progress - a feature that could, for example, allow patients to record their initial condition in a 'spinal diary' and monitor improvements over time. Ongoing support was provided through individual sessions and group meetings, with facilitators ensuring that any questions were addressed promptly. More detailed data will be available later, based on the results of the detailed surveys carried out during the activity before the end of the reporting period, and data collection is still ongoing.

b) qualitative feedback from patients, including any challenges, concerns, or suggestions for improvement;

Qualitative feedback was gathered through structured interviews and focus groups, providing valuable insights into patients' experiences of the solution. Patients reported that the app was generally easy to use and appreciated the ongoing support provided by facilitators during both individual sessions and group activities. However, several challenges and suggestions for improvement emerged:

Usability issues: Some patients experienced difficulties with certain interface elements, such as navigating the posture adjustment settings.

These issues will be addressed based on the results collected.

Visual aids and guidance: Participants expressed an interest in more visual aids, such as video tutorials, to help them understand how to use the application and perform the exercises correctly. They also suggested increasing the size of some text and icons to improve readability. Importantly, as the application develops, an increasing number of video tutorials are being produced by spinal unit staff in collaboration with the company co-developing the application. These videos are



designed to be clear and patient-friendly, enhancing the content of the app, making it easier to use and supporting preventive care.

These insights are being carefully considered for the next iteration of the solution to ensure it better meets the real needs of patients.

c) how the solution affected healthcare professionals and workflows in the Territorial Health Living Labs (e.g., time efficiency, collaboration, workload);

Healthcare professionals in the spinal unit and associated staff view the new technology as a valuable preventative tool. It is expected to help mitigate issues such as inappropriate dietary habits, insufficient rehabilitation, and inadequate physiotherapy. Notably, the solution will enable systematic physiotherapy for patients after surgery, both in hospital settings and at home, ensuring that patients receive continuous, structured care. Additionally, the application serves as an effective information carrier for patients upon discharge from the spinal unit and rehabilitation facilities, supporting their long-term treatment adherence.

d) evaluate the solution's performance based on key value-based healthcare metrics (e.g., cost-effectiveness, improved patient care, resource allocation).

Although traditional economic metrics such as detailed resource allocation were not directly measured, the solution's preventive approach - enabling systematic physiotherapy in both hospital and home care settings - is expected to result in significant cost savings by reducing complications, hospital reductions and associated costs.

Overall, these key value-based healthcare metrics demonstrate that the solution is improving patient care while offering the potential for long-term economic benefits through improved preventive practices.

If you were able to notice any additional opinions/comments about the solution except the results from PREMs and PROMs, describe them here.

CONCLUSIONS:

Summarize the results with their practical application. Discuss also the following issues:

The testing phase has provided valuable insights and practical results that underline the potential of the new value-based solution to improve patient care. Overall, the application demonstrated high usability and strong patient engagement, with positive feedback on its ability to support systematic physiotherapy in both hospital and home care settings. In practical terms, the solution is positioned to improve patient self-monitoring, facilitate better communication between patients and healthcare professionals, and provide a framework for continuing care after discharge.

a) any obstacles encountered during the testing phase, such as technical issues, patient adherence, or logistical challenges;

Technical issues: Some users had difficulty navigating certain interface elements.

Patient adherence: Patients' varying levels of digital literacy sometimes affected their ability to fully interact with the solution.

b) how these challenges were addressed or mitigated during the phase.



Highlight key insights gained that could improve future testing phases.

Technical issues: Technical issues were mitigated through continuous monitoring and rapid response by the development team. User feedback has been incorporated promptly to refine the interface and improve usability.

Improved support and communication: With valuable input from users, the solution was continually refined to remain accessible to people with varying levels of digital literacy and device capabilities. Facilitators played a key role in providing tailored guidance to ensure that all patients could effectively engage with the app, while regular collaborative meetings helped to incorporate feedback and keep the solution user-friendly and adaptable.

Key insights and best practices for future testing phases

Thorough training: Future testing efforts should include comprehensive training for interviewers, facilitators, and all personnel involved in the process to ensure they are well prepared to conduct effective interviews and guide participants through the testing procedures.

Inclusive communication: It is important to communicate not only with primary users, but also with secondary stakeholders such as carers and spinal unit staff. This broader engagement helps to gain a more holistic view of the user experience and identify additional areas for improvement.

Direct user-developer interaction: Establishing direct channels between end users and solution developers proved to be extremely beneficial. This interaction facilitates immediate feedback, accelerates the resolution of technical issues, and fosters a collaborative environment that improves the overall quality and usability of the solution.

These process recommendations will help ensure that all future testing phases are efficient, inclusive and responsive to the real-world needs of all stakeholders.