Interreg CENTRAL EUROPE

Co-funded by the European Union

Health Labs4Value

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

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 sing 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.

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1. 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.

In addition to the standardised PREMs (Patient-Reported Experience Measures) and PROMs (Patient-Reported Outcome Measures) questionnaires, additional consent forms were required to grant access to the digital application.
These forms were prepared by the General Hospital Jesenice (SB Jesenice) and signed by all participants.

In addition to the PREMs and PROMs questionnaires, application evaluation questionnaires were developed and used in collaboration with the app developers.
These questionnaires were designed to collect information on various aspects of the application's usability, user-friendliness for both patients and healthcare professionals, and overall patient satisfaction.

2. How did you store and secure the data?
The data collected during the testing phase were stored both electronically and in paper form and were processed in accordance with applicable data protection guidelines and the internal protocols of the General Hospital Jesenice (SB Jesenice).

a) Electronic storage:
All digital data were stored on secure servers of the "Gospodar Zdravja" application provider, which comply with modern IT security standards and GDPR principles.
Access to electronic data was strictly limited to authorised personnel only.

b) Paper storage:
Written consent forms were stored in locked cabinets at the General Hospital Jesenice, accessible only to authorised staff.
The retention period was defined in accordance with internal data protection policies, and after the expiry of this period, the documents will be destroyed in compliance with data protection regulations.

c) Additional security measures:
The processing and storage of data were conducted strictly in accordance with GDPR regulations and the internal data protection guidelines and protocols of the General Hospital Jesenice.

Furthermore, no data on patients' health status were included in the forms or in the application, and therefore approval from the hospital's ethics committee was not required.

RESULTS
Present the results from pre- and post-phase test phase. Also, tables and graphs are possible to be used here.

Results from Pre- and Post-Test Phases

Pre-Test Phase

The pre-test phase was conducted with a group of 20 participants.

The main objective of the study was to explore participants' expectations and requirements regarding digital health applications, as well as to identify their needs and satisfaction with the information they receive during medical treatment.
A key point highlighted was the need for access to information beyond direct medical consultations, particularly the need for more clear and professionally verified information.

Regarding the application itself, participants emphasized that the app must be simple to use, clearly structured, and preferably based on already recognized solutions that could enable future integration with the national healthcare system, which could also lead to potential funding through the Health Insurance Institute.
Moreover, the application should offer options for evaluating its usefulness and for user feedback.

In summary, the findings from the pre-test phase indicate that verified and clear information, along with the potential for future upgrades and system integration, are highly important for users.

Post-Test Phase

The post-test phase involved 20 participants.

Participants emphasized the need for the application to be upgradeable to address more complex cases. Regarding the app's appearance and interface, it was noted that the app must remain clear, easy to use, and include options for evaluating the user experience within each individual section.

Several concrete suggestions were provided regarding the design, including:
Clearer icons, Larger text, and Reduced distractions during video playback.
All participants confirmed that the app is useful, and all agreed that it would also benefit other users. All participants highlighted that the main advantage of the app is that its content is prepared by professional medical staff.
Moste of participants indicated that adding additional content would improve the app’s usability.

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

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CONCLUSIONS:
Summarise the results with their practical application.

The results of the pre-test and post-test phases highlight both the great potential and numerous opportunities for the further development of the application in supporting patient rehabilitation. The overall positive feedback indicates that the application holds strong potential for empowering patients throughout the rehabilitation process, as patients recognize it as a high-quality and welcome service. In this way, besides empowering patients, the application also has the potential to improve the quality of healthcare delivery and contribute to faster recovery.

There is also an indication of potential use for other medical conditions and interest in integration with national digital health solutions.
Furthermore, the possibility of reimbursement through health insurance could further increase the accessibility of the application, enabling even more patients to benefit from the app as a supportive tool during recovery.

Special functionalities for evaluating user experience on multiple levels would also allow for continuous analysis, improvements, and adjustments of the application.