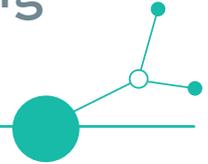


3.3.1. Reports from implementation of testing phase in territorial Health Living Labs (real-world setting)



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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.

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BACKGROUND INFORMATION

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

The Territorial Health Living Labs is planned to be established by 5 health care ecosystems with the baseline for change is 2 jointly developed solutions: Living Lab Methodology and Value-Based System upscaled by pilot experience. The adopted knowledge and practical experience will boost the mutual and beneficial cooperation of all 5 health ecosystem actors along the value chain. Therefore, the aim of the testing phase was: 1) provide the well-tested solution to the patients; 2) implement the new solution into the health-care sector according to the above described approaches; 3) obtain the necessary experience to have basis for further development of the Territorial Health Living Labs.

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

The aim of the testing phase in our case was to provide a solution to sign by the patient the electronic form of documentation which in the same time will to have legal force (biometric signature). The solution allows for the presentation of the document in a legible form with the possibility of enlarging it. It reduces the operating costs of peripheral devices and facilitates the search for patient documentation. Access to patient documentation from any place with access to the HIS system.

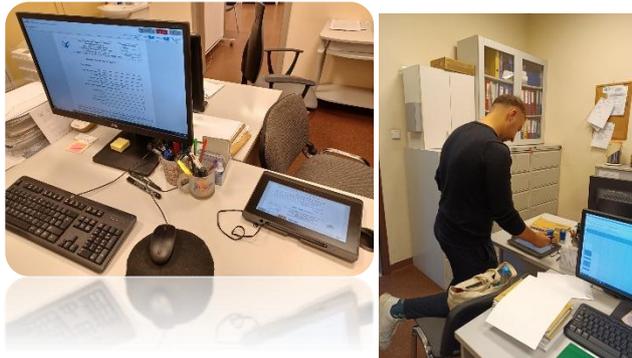
3. A brief description of the new value-based solution being tested.

The pilot involved 3 solutions. A mobile tablet used in wards, a stationary tablet used at



registration points, and a pen based on a specially printed document in a situation where the document would have to be created in physical form. The tablets allowed patients to enlarge the document when necessary. Digitization of documentation made it easier to access and increased the speed of finding specific documents.

Requirement to include some visual proofs from the testing phase (real-life photos, print-screens of patients / family members testing the prototype).



TESTING METHODOLOGY

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

Patients had to be those who belong to the Clinic in which the solution was tested. Therefore, the participants were the patients of the Clinic of Chronic Diseases of Cardiovascular and Metabolic Diseases.

2. Specify the time frame of the testing.

The solution is in on-going phase of testing. It has been installed in the Clinic and patients use it always if they are during the first visit. It is a moment when the patient needs to sign the documents. However, for the purposes of preparing the reports, partial results were collected within the planned project time frame.

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

The solution was tested in real conditions. Stationary tablets were placed at registration points: the Elective Admissions Room, the hospital emergency department and the Sports Clinic, in order to sign all consents during admission to the units.

Mobile tablets were used in the ward to sign all consents for procedures in the wards.

Pens were used as an alternative solution for older people who insisted on the possibility of signing a document using a pen on paper, and as a solution used in situations where the regulations required a document in physical form in the original.

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.

Yes, we needed to prepare a written consents, including the information about the protection of personal data if we wanted to invite the patient to participate in the OIC 2.

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



The documents were placed in the Hospital HIS system on the patient's profile in the electronic documentation tab, so that together with the medical records they were available from the level of the hospitalization they concerned. The documentation and data from the HIS system are stored on a local secured resource.

IMPLEMENTATION DETAILS

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

Medical staff registering the patients in the Clinic, patients with relatives, IT specialists and the company responsible for delivering the solution.

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

The staff was trained in the use of the devices used in the project. They were familiar with the strengths and weaknesses of the solutions, had tips on solving basic problems and actively helped patients use the tested solution. In case of problems, the staff had contact with the IT department, which solved current problems, or contacted the producer to eliminate them.

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;

The solution is intuitive in accordance with current technological standards. People familiar with touch screen technology had no problem filling out and operating the document. Of course, new technologies proved problematic for older people, but with the help of staff, older people were also able to cope with operating the devices.

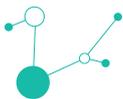
b) qualitative feedback from patients, including any challenges, concerns, or suggestions for improvement;

Patients did not report any comments. They were rather pleased with the solution, because it did not require them to look for a free seat and a table in order to fill out the documents. The only comments came from the employees serving the registration desk, where patients are admitted. They claimed that they were slower to admit a patient, because until now they could hand over the forms to fill out and admit another person, and now they have to complete the full admission of a patient and only then move on to the next one. From the patient's point of view, however, it is more beneficial and responds to the assumptions of the project, which is based, among others, on Patient-Centered Care approach.

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

Mobile devices were received positively. They allowed documents to be filled out right in front of the patient. In the case of tablets, it is mandatory to secure access to the HIS system from the document signature level, so that the patient cannot access the HIS system. In the case of pens, employees complained about the very long time it takes to generate documents. In the case of stationary tablets, employees complained about the cursor running away from the computer from which the document was generated.

d) evaluate the solution's performance based on key value-based healthcare metrics (e.g., cost-



effectiveness, improved patient care, resource allocation). Any tables and graphs are possible to be used here.

At this stage it is still difficult to assess key value-based healthcare metrics, such as cost-effectiveness, improved patient care, resource allocation. However, it is expected that the costs of patient service should decrease and the quality of services provided will improve. In the case of this solution, in order to properly assess the changes, the solution should be compared in different departments, where there is a different specificity of the patient and the required documentation to sign.

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

The comments from the patients and the medical staff was mentioned above. No additional information was obtained.

CONCLUSIONS:

Summarize the results with their practical application. Highlight key insights gained that could improve future testing phases. Discuss the following issues:

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

1. Unauthorized patient access to the HIS system on a mobile tablet after sending a document.
2. Jumping cursor from computer screen to stationary tablet.
3. Long time to generate a specially printed document for use with a pen.
4. HIS software updates caused integration failures with the document digitization system (no document sent to the system).
5. There were major doubts about the legal validity of documents created exclusively in electronic form.

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

1. Documentation on the wards is completed in the presence of staff who make the patient aware of the risk. Staff can assist the patient in completing the documentation and intervene if the patient sends the document to the HIS system, which would open the system from which it was generated. The producer is working on a solution consisting of authorization with a PIN or password after an attempt to send a document to the HIS system.
2. The producer has added an option to return the cursor to the place from which it was sent to the tablet after the patient has finished working on the tablet.
3. The producer is working on a solution to optimize the printing time. For the pilot period, the pen was limited to handling single-page documents only, because these are generated much faster (page per second) than multi-page documents. More complex documents were handled on tablets.
4. The problem was discussed with the producer of the HIS and the software digitizing the documents. Next updates took into account testing the solution and supporting the software in new versions.