HIPRO - hip surgery patient reported outcome.

Improving patients' safety and empowerment after fast-tracking hip surgery.

Surgical Hospital Rožna dolina, Ljubljana, Slovenija is a small surgical hospital, privately own but public financed, with approximately 7000 surgical procedures performed per year. Surgery is mainly oriented to orthopaedic and general surgery. About 700 hip procedures are performed per year.

Challenge description

Hip preservation surgery is rapidly advancing. Patients are after hip surgery in some institutions discharged from hospital as soon as two days. After discharge may acute problems patient may present (hip dislocation, fracture, infection). After discharge, their first visit to surgeon is usually scheduled fourteen days after surgery. Between discharge and first post-surgery visit to doctor they are in the hands of their family. In early postoperative period they are without proper medical follow-up. self- assessment and communication with the surgeon would be beneficial for patients' follow-up. In the context of healthcare and surgical outcomes, PRO stands for "Patient Reported Outcomes." PROs are assessments or measures that capture information directly from patients about their health and well-being. They provide valuable insights into how patients perceive the impact of surgical procedures or medical treatments on their quality of life, symptoms, and overall satisfaction. Patient-reported outcome (PRO) measures are becoming an integral part of measuring treatment effectiveness. There are several Patient Reported Outcome (PRO) measures that are commonly used to assess outcomes after hip surgery (see resources. These PRO instruments are designed to capture the patient's perspective on their hip function, pain, and overall well-being following hip surgery. Yet they are in paper form and for elderly usually difficult to fill out. The current way of monitoring patients after fast-tracking hip surgery does not meet the expectations of patient and physicians.

The targeted group of patients for this challenge are elderly patients undergoing fast track hip surgery who are discharged from hospital after one or two days, though similar problems can be seen in other medical conditions, requiring surgical treatment. The telephone consultation service is insufficient to cover the demand and care of this patients after fast discharge from hospital, as it is difficult to assess full range of possible malfunctions and patient is usually invited to visit a physician.

Challenge main objectives

The main objective is to improve patient safety after fast-track surgery and discharge from hospital (and therefore improving their quality of life). As a secondary objective the Challenger also wants to learn the acceptance of tailored medical mobile solutions in elderly and to learn how to easily integrate 3rd party mobile solutions through its corporate IT (windows based) system.

Solution functional requirements

Compulsory functional requirements

- The solution shall be user friendly and adapted to digital literacy levels of the targeted patients (e.g. Elderly). The content shall be easy to digest by the patients by, for example using pictograms rather than text that captures the patient's perspective on their hip function, pain, and overall well-being following hip surgery.
- The solution shall allow information exchange between patients and their surgeon:
  - patient would choose from several templates to create the message, depending on the message type.
  - Health care professionals should be able to send the same message to patient.
- Calendar management: so, patients and physician can easily add or review patients' medical condition.
- Alert surgeon and family physician and family member that a relevant event or incidence needs their attention configurable through their channels of communication (smart phone, e-mail, etc.)
- Usable and intuitive for patients
- Tailor made mobile phone medical application for patients after fast-tracking hip surgery should be user friendly and based on pictograms rather than on classic text survey. To emphasize the basic idea an example is made from e-mojis. Here's a simplified part and creative representation:

  - Pain Assessment:
    - 😖 (Severe pain)
    - 😣 (Moderate pain)
    - 😐 (Mild pain)
    - 😊 (No pain)
  - Function Assessment:
    - 🚶 (Walking difficulty)
    - 🏃 (Able to run)
    - 🏋️ (Able to lift weights)
    - 🤸 (Able to perform sports)
  - Deformity Assessment:

  etc.

- Optimised for multi-device access.
- Including a survey to access quality of life indicator.
- When the user starts there will be available an application for local patients developed by Solver that incorporates, among others, user authentication. The new medical application must be called through authentication application, so user identification takes place under maximal safety conditions.
- The Solver application will be available for Android and iOS.

Desirable functional requirements

- Facilitate access to informative resources for self-empowerment, like documents, and videos. Including on a survey to assess quality of life indicator and to request and collect the patient outcomes over time.
- Medication management. Possibility that doctors incorporate and modify prescriptions.
- Connection with 3rd party devices like smart bands or watches to track day activity and sleep patterns.

- Information summaries and analytics on the available data to empower patients and facilitate better disease management by the patients themselves, in collaboration with their doctor.

Pilot scope

After beta version of application is prepared, 30 patients undergoing fast track hip surgery will enrol in the pilot together with two orthopaedic surgeons.

Language

- The application must be available in English and in Slovene language as the targeted population is not fluent in English.

Other aspects

- Patient must be owner of smart mobile device (smart phone).

Pilot set-up conditions

Ethical, legal, or regulatory

The approach of the pilot must be previously validated by an Ethics Committee of Medical faculty or National medical ethical board. The Committee will pay special attention to the collection of informed consents of patients by solver and the protection of personal data, observing the requirements established by the European data protection Regulation and Slovenian law.

If considered necessary, the Solver will be asked to anonymise the data according to mechanism established by the Challenger. At any case, the Solver cannot exploit or make the data for different purposes than the ones agreed with the Challenger and after pilot end, all copies of the data must be transferred back to the Challenger or deleted.

Technological

The systems and servers needed for running the piloted application will be hosted by the Solver. For safety reasons and data protection the Solver should have back up servers. Technological requirements will be established in a technical session at the beginning of the project.

Data access

No initial data will be provided for pre-load. All participants will have to register for free and fill their own data.

Expected impact and KPIs.

- Reduction in the number of physical visits of patients: a) to the doctor office at least 10% and b) to emergency room at least 20%.
- Quality of life indicator VR-12 (*see resources*). Increase of an average one point per month of usage, with a maximum 10 points during the total survey period.

Business opportunity

Market size

At the level of hospital organisation this project will be available in two hospitals with more than 20 orthopaedic surgeons. At the national level there are more than 20 hospitals with the orthopaedic units.

Presented application can be extended in a standard way with the same technology to many other pathologies, inside and outside starting hospital, with great possibility of growth.

Adoption plans

We plan to procure and scale up the solution in our organisation if the pilot is successful.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	ZenLab d.o.o.
DESCRIPTION OF THE SME	ZenLab is a software development company specialized in Enterprise System Integration, Business Process Management, Service Oriented Architecture, E-Commerce, Custom Software Development supporting digital transformation within any kind of industry or business. Within the health sector ZenLab is concentrated in finding ways to save time for clinicians and administration, so they can devote more time to real needs of the patient, starting with patient admission, treatment time, patient discharge and post treatment period.
WEBSITE URL	https://www.zenlab.eu/

Table 1. Leading SME general information

Solution proposed:

MobileCare+: Enhancing Post-Op Resilience in Fast-Track Hip Surgery

MobileCare+ is designed to revolutionize post-operative care for elderly patients following fast-track hip surgery (FTHS). This solution demonstrates significant potential in enhancing the integration of new knowledge by leveraging advanced technologies and methodologies. The main characteristics and components of MobileCare+ include a patient-centric mobile app, an HL7 FHIR big data infrastructure, a user interface for clinicians, a robust privacy and security pillar, and an advanced Language Model (LLM) pipeline for the collection of Patient-Reported Outcomes (PROs). Languages supported: English and Slovenian.

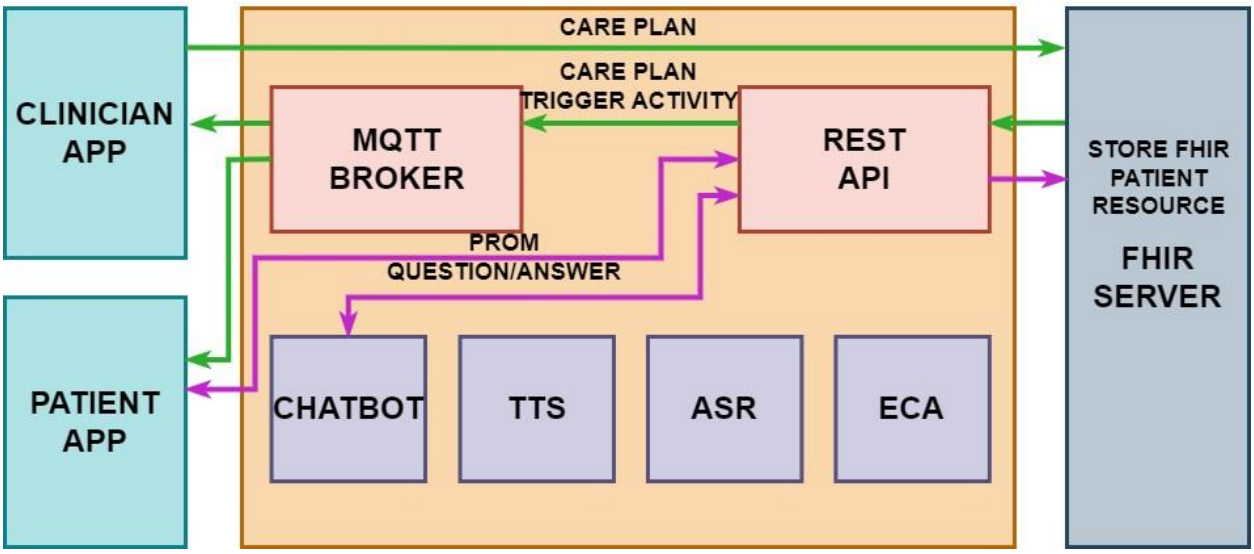

Figure 1. MobileCare+ architecture diagram

Components of the MobileCare+:

- **Mobile App for Patients (MobileCare+):** The mobile app serves as a patient-centred platform, featuring a chatbot companion that guides users through their post-operative journey. It facilitates automated follow-ups and collects valuable patient-reported data through conversational surveys. The app prioritizes user-friendliness, with pictograms for simplified information, multi-device access, and customizable communication templates. Graphical mock-ups will illustrate the user interface and will help us design the seamless navigation experience during co-creation.
- **HL7 FHIR Big Data Infrastructure:** The HL7 FHIR infrastructure ensures seamless data flow between the mobile app and hospital systems. It enables real-time interoperability with Electronic Health Records (EHR) and facilitates the aggregation of patient data for insightful analytics. Concepts such as CDS Hooks Enable Personalization and Automation of Care Plans.
- **User Interface for Clinicians:** A dedicated user interface empowers clinicians by providing real-time access to patient data and analytics. This component will be brought to TRL6 through mock-ups depicting the interface design and functionalities during co-creation.
- **Privacy and Security Pillar:** The privacy and security pillar is a cornerstone of MobileCare+, ensuring the confidentiality and integrity of patient health data. Technologies such as KeyClocak, Solver and SAPL will be used for authentication and authorization.
- **LLM Pipeline for PRO Collection:** The Language Model (LLM) pipeline supports the collection of PROs using standardized surveys and natural language processing. Mock-ups and visual representations showcase the algorithm's capabilities in extracting symptoms through medical named-entity-recognition. The setup and validation strategy for the algorithm are outlined in response to potential challenges with analytics.

Work to be done by the leading SME

WP1 focuses on requirements and design. Task T1.1 studies healthcare routines and digital interventions, establishing initial use cases with stakeholders reported in D1: Domain

Landscape and Initial Study Protocol. T1.2 delivers the initial study initiation package, including feasibility details, data flow, security, privacy requirements, and recruitment strategy. Collaborating with T1.3 and T1.4, the final study protocol is approved by ethics committees by M7. T1.3 identifies unmet needs and engages stakeholders through participatory design, setting up a co-creation methodology. T1.4 transforms outcomes into technical and functional requirements. Results are documented in D2: Platform's Requirements & Conceptual Architecture.

WP2 focuses on the development of the app for patients. Task T2.1 focuses on designing modules for patient monitoring, integrating mechanisms for collecting Patient-Reported Outcomes (PROs), chatbots, and Language Models (LLMs) for non-invasive data collection. Task T2.2 develops modules for presenting medical information, enhancing patient, caregiver, and professional empowerment. Task T2.3 concentrates on the Mobile Health Application for patients (iOS + Android), integrating smart-band functionalities. The outcomes contribute to MobileCare+'s Alpha version (i.e. D3) for co-creation refinement in collaboration with WP4, leading to the Beta Version (i.e. D4), ready for validation in the clinical feasibility study.

WP3 focuses on developing a deployable solution and back-end functionalities for seamless integration into clinical routines. T3.1 defines a common, semantically interoperable data model based on HL7 FHIR standards. T3.2 deploys advanced security and privacy mechanisms, including cryptographic tools and access controls. T3.3 delivers a backend for physicians' data access, personalization and automation (using CDS hooks) of care workflow (messages, alerts, activities. medication), and communication. T3.4 sets up the decentralized ecosystem, integrating outcomes into MobileCare+'s Alpha and Beta versions (D3, D4).

WP4 focuses on co-creation and real-world evaluation of MobileCare+. T4.1 manages study recruitment, executes a Living Lab co-creation until M12 (D5 report), and T4.2 assesses feasibility (D6 report). T4.2 analyses results through mixed methods, evaluating technical suitability, user experience, and acceptability. Gender and sex-related differences in toolkit usage will be assessed, providing insights for refinement.

WP5 aims to ensure timely and high-quality project results through technical and administrative coordination, along with ethical monitoring. It implements an effective dissemination and communication strategy aligned with the HealthChain Consortium. At M4, a project handbook, encompassing management and communication strategies, will be delivered. The final report at M18 will assess MobileCare+ against non-technical and non-clinical Key Performance Indicators (KPIs), summarizing all activities.

Follower SME

Scope of work performed by the follower SME

The follower SME contributions are divided into Work Packages:

WP1: Focus on requirements and design, participatory design, jointly setting up a co-creation methodology, technical and functional requirements and conceptual architecture.

WP2: Focus on development of the app for patients in corelation with the functionalities supported by the system developed by ZenLab, Developing the modules for presenting medical information, enhancing patient, caregiver, and professional empowerment.

Mobile Health Application for patients (iOS + Android), integrating smart-band functionalities.

WP3: Focus on developing a backend for physicians' data access, personalization and automation (using CDS hooks) of care workflow (messages, alerts, activities. medication), and communication., advanced security and privacy mechanisms, including cryptographic tools and access controls, on top of the ZenLab architecture.

WP4: Focus on co-creation and real-world evaluation of MobileCare+. T4.1 manages study recruitment, executes a Living Lab co-creation until M12 (D5 report), and T4.2 assesses feasibility (D6 report). T4.2 analyses results through mixed methods, evaluating technical suitability, user experience, and acceptability. Gender and sex-related differences in toolkit usage will be assessed, providing insights for refinement.

WP5: Focus on Quality assurance, administrative coordination and ethical monitoring. Implementation of the dissemination and communication strategy aligned with the HealthChain Consortium.