RecoMed

Boost medication safety in Plastic Surgery and Burns department!

Decree-Law no. 30/2011 of 2 March created, the Centro Hospitalar e Universitário de Coimbra, E.P.E., a Public Institution. The Centro Hospitalar e Universitário de Coimbra, E.P.E. (CHUC) comprises the following hospitals: Hospitais da Universidade de Coimbra (HUC), Hospital Geral (HG), Hospital Pediátrico (HP), Maternidade Bissaya Barreto (MBB), Maternidade Daniel de Matos (MDD) and Hospital Sobral Cid (HSC).

CHUC's mission is to provide high quality, differentiated healthcare in a context of training, teaching, research, scientific knowledge, and innovation, and to be a national and international benchmark in areas considered to be centres of excellence.

According to its vision, CHUC is an open organisation, made up of a network of hospital units, services and technologies structured and integrated to provide society with humanised, complete, close, reliable, and transparent care with a positive impact on the community, guaranteeing efficiency and overall sustainability in the medium and long term.

It has a workforce of more than 8,000, around 1,700 acute beds, and in the first half of 2023 there were 1,3687 emergency appointments, 2,6745 patients discharged, 2,597 patients operated on, and 62,353 Day Hospital sessions.

Plastic Surgery is an extremely wide-ranging speciality, ensuring the diagnosis and treatment of multiple pathologies such as burns and their squeal; skin and soft tissue tumours and their squeal; breast reconstruction; pharyngeal-laryngeal reconstructions; scalp reconstructions (particularly in cochlear implant exposures); oesophageal reconstructions; traumatology and its squeal (including the prevention and treatment of pressure ulcers); hand surgery; peripheral nerves and brachial plexus; congenital anomalies of the head and neck, trunk, genitals and limbs; gender reassignment surgery (including breast surgery, penis and vulvo-vaginal reconstructions); lymphatic surgery; body contouring surgery after bariatric surgery and aesthetic surgery. Plastic Surgery has an interface with all areas of surgery: from Gynaecology to Urology, including Head and Neck Surgery, Neurosurgery, Otorhinolaryngology, Thoracic Surgery, Dermatology, Orthopaedics and Paediatric Surgery.

Genetically, it is linked to the Burn Unit with which it shares clinical staff, and this is a perfect solution for the burn patient as it allows for continuity of care and the transmission of all clinical information and relevant patient characteristics.

The types of care provided by the service are the traditional ones for a surgical service, i.e.:

- Hospitalisation: 25 beds.
- Operating Theatre: access to the Peripheral Operating Theatre on a daily basis and some operating times in the Central Operating Theatre (1 operating time per week). Operating Theatre in the Paediatric Hospital (1 operating time per month).
- Ambulatory Surgery: operating times in the Ambulatory Surgery Unit (two days from 8.30am to 2pm - general anaesthesia - and one day from 2pm to 6pm - local anaesthesia).
- Outpatient Consultation: 2 offices - Consultation daily.

Challenge description

The hospital is a large and complex set of services where care is provided to promote the health of the population. An individual's visit to a health institution, either for a routine consultation, a scheduled intervention, or an acute situation, most often leads to changes in medication. It

has been described that failures in communication between transitions of care can lead to discrepancies and confusion in the usual medication.

Lack of communication during patient transition is the reason for 50% of medication-related errors and about 20% of adverse drug reactions (Institute for HealthCare Improvement, 2006).

This situation can lead to re-admissions, morbidity and mortality and increased health costs. The sustainability of resources, particularly in the health area, is a growing concern and medication reconciliation is one of the accessible and available tools to reduce the risk of these events, but also to reduce and/or minimize their consequences.

The National Plan for Patient Safety 2015-2020 (D.R. 2ª série - nº 28/2015, of February 10) and the current National Plan for Patient Safety 2021-2026 (D.R., 2ª nº 187/2021, of September 24) recognize its importance, including medication reconciliation in their objectives and setting targets for achievement.

Medication reconciliation is a formal and systematic process in which different healthcare professionals work together to obtain and evaluate the patient's medication list with the doctor's admission, transfer, or discharge prescriptions. It consists of obtaining and checking a complete and accurate list of the medicines that each patient is currently taking. This list is compared with the medicines that have been prescribed and where discrepancies are identified, these are discussed with the prescriber and the reasons for these changes are documented. When the patient is transferred, a current and accurate list of medicines is provided to the person who will be taking over the patient's care.

In CHUC's Plastic Surgery and Burns service, after the hospital implemented the electronic medical record, there is no therapeutic reconciliation process that implements the recommendations of the Directorate-General for Health (Norma 018/2016. Reconciliação da Medicação. Direção Geral de Saúde). The application for this project aims to respond with a digital solution that allows this process to be implemented.

Challenge main objectives

The main objective is to improve, with a digital solution integrated into the patient's electronic record, the accessibility and updating of the medication list of patients admitted to this clinical service, avoiding communication errors and negative consequences in terms of patient safety, with the aim, whenever possible, of active participation by the patient themselves, empowering them to better manage their medication.

The aim is to ensure accurate and complete knowledge of a patient's medication information in order to prevent medication-related incidents at all transition points in healthcare interfaces (Institute for HealthCare Improvement, 2006).

The end result will be the communication of the updated medication list to the next care provider or to the patient/caregiver.

Solution functional requirements

Compulsory functional requirements

The system to be implemented must respond to the following needs / propositions:

- Obtaining and verifying: the complete and accurate list of medicines that each patient is currently taking.
- Comparison: of the list of medicines that the patient is taking in relation to the medicines that have been prescribed.
- Documentation: where discrepancies are identified, these are discussed with the prescriber and the reasons for the changes are documented,

- Final document: when the patient is transferred, a current and accurate list of medicines (including the reasons for changes) is provided to the person who will be taking over the patient's care.

Therefore, the solution shall:

- Acquire the full list of medicines the patient is currently taking.
- Compare this list with the medicines that have been prescribed in hospital.
- Identify discrepancies.
- Emit a document with discrepancies, so that the prescriber can analyse and decide.
- To be able to export a final document, to be given to the patient, with the therapeutic list to follow, updated and exact (and with the possibility of including reasons for changes, as well as a field for free-text comments).
- Be integrated and communicate within national and hospital's medical records and hospital pharmacy systems.
- Be eased to use.

Desirable functional requirements

The solution could release alerts when occur discrepancies.

Pilot scope

The pilot will be developed in a total period of 12 months, including design, validation, testing and measuring of the impact of the co-created solution.

It will be expected to test the solution for 6 months.

The healthcare professional's teams will be composed especially with pharmacists and physicians.

End-user type	Role	Number
Pharmacists	Provide requirements, use, and validate the solution.	3
Physicians	Provide requirements, use, and validate the solution.	6
Patients	Beneficiaries (all the pilots will be developed based on different patients' medicine lists)	50

Table 1. Targeted users

Language

- The solution must be in Portuguese. There are no special language requirements for iteration with the end users in addition to those related to the description of the drugs.

Pilot set-up conditions

The pilot setup conditions correspond to the objective of capturing lists of medicines that patient is currently taken, comparing this list with what has been prescribed, identifying, and signalizing the discrepancies and creating a document to be provided to patient or caregiver. All the information must be managed around the clinical and pharmaceutical informatics system.

Ethical, legal, or regulatory

All CHUC employees, as well as the general public, including companies that collaborate with CHUC, are governed by the Privacy and Data Protection Policy (Publication of 11.08.2022, Board of Directors), which explains the terms under which CHUC processes the personal data of its users, as well as the rights they may exercise, in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council - General Data Protection Regulation (GDPR) - and other applicable national legislation on privacy and data protection.

In addition to Privacy and Data Protection, all CHUC managers and employees must take into account the Code of Ethical Conduct (Publication of 22.09.2022, Board of Directors)

Technological

The solution needs to communicate with the actual IT systems.

Data access

The tool to be developed need to extract data from the hospital existing IT system about name, dose, method of administration and schedule medicines and then bring measurements and output to the system.

Expected impact and KPIs.

With the creation and implementation of this tool, we aim to obtain benefits centred on the patient and on the efficiency of the hospital system:

- Increasing safety, reducing errors related to inappropriate medication.
- Managing the economic resources spent on medication.
- And, indirectly, increasing the satisfaction levels of healthcare professionals and patients/carers.

As a process indicator:

- 75% of admissions/discharges of patients with medication reconciliation.

Business opportunity

Market size

As mentioned earlier in this document, CHUC is a large healthcare organisation with a high volume of production. It is concerned with providing quality and patient-centred care.

CHUC has many departments and services providing care in different areas and specialities, and the problem of therapeutic reconciliation is a cross-cutting issue.

Therefore, the solution developed as part of this pilot can be replicated in all of the hospital's care centres.

Taking the first half of 2023 into account, the figures are as follows: there were 134,687 emergency attendances, 26,745 patients discharged, 25,497 patients operated on, 62,353 Day Hospital sessions.

Adoption plans

If the pilot is successful, CHUC intends to adopt the solution, by shared ownership the solution co-created and procure its maintenance.

Leading SME

GENERAL INFORMATION	
NAME OF THE SME	VirtualCare
DESCRIPTION OF THE SME	VirtualCare is an SME that excels in developing and applying IT and biomedical solutions to elevate healthcare. The company implements innovative technologies across Portuguese hospitals to streamline healthcare delivery and patient care. Adding to the previous summary, VirtualCare is currently involved in various clinical areas across 23 Portuguese hospitals, showcasing our diverse expertise in healthcare innovation: • Women and Child Health: We manage processes related to women's and children's health (gynaecology, pregnancy, childcare, breastfeeding, breast cancer), which includes interoperability with health entities' Information Systems (IS) at the time of childbirth or analysis. Our integrations extend to SClinico, medical equipment and IS related to pregnancy, the DGS to produce obstetric indicators, and EUSOMA in the context of breast cancer. We also focus on dematerialising clinical processes (emergency, hospitalization, consultation, childbirth, and surgeries). • Adverse Reaction Management: We handle adverse reactions to medications, allergies, and incidents with medical devices, including detection in clinical records using AI, integration with SClinico, INFARMED, and other IS, and follow-up in hospitals and health centres. This also includes processes to correct the mislabelling of patients mistakenly marked as allergic to beta-lactams. • Other systems include applications for Acute Pain and Difficult Airway Management, Hemodialysis, and Antipsychotic Management. This diversified portfolio demonstrates VirtualCare's commitment to enhancing healthcare quality and efficiency through innovative IT and biomedical solutions.
WEBSITE URL	www.virtualcare.pt

Table 2. Leading SME general information

Solution proposed:

MediRecon: Medication Reconciliation and Management System

MediRecon is a digital solution designed to address the challenges associated with medication management and reconciliation for patients admitted to the Plastic Surgery and Burns department at the Centro Hospitalar e Universitário de Coimbra, E.P.E. (CHUC). By seamlessly integrating with the hospital's electronic medical record system, MediRecon aims to streamline the process of obtaining and updating patients' medication lists, ultimately reducing medication-related errors and significantly improving patient safety.

Key Features:

1. **Medication List Acquisition:** MediRecon will have channels to gather a complete inventory of each patient's current medications from multiple sources, including electronic health records and pharmacy databases. This ensures accurate and up-to-date information about every patient's medication regimen.
2. **Prescription Compatibility Check:** The system will cross-reference the acquired medication list against the prescribed medications for each patient, identifying potential discrepancies or conflicts that may lead to adverse drug reactions or other issues.
3. **Discrepancy Resolution:** Upon detecting discrepancies, MediRecon will generate a report outlining the identified inconsistencies and recommended solutions. This documentation will facilitate communication between healthcare providers and enable timely interventions to rectify medication errors.
4. **Integration with Hospital Systems:** As a standalone application, MediRecon can integrate with the hospital's health records and pharmacy systems, allowing for real-time updates and synchronization of patient medication information. Create interoperability resources compatible with international standards (eg., FHIR, ATC and IDMP).
5. **Alert Notifications:** MediRecon will provide alerts to healthcare professionals when potential discrepancies are detected, enabling prompt action to protect patient safety. This solution can use the existing hospital alert system to send the alert.
6. **User-Friendly Interface:** Designed with usability in mind, MediRecon offers an intuitive platform accessible to healthcare professionals. In cases where an interface is already available, MediRecon services will be available through an API to be integrated in an existing system.
7. **Pilot Testing and Validation:** Prior to full implementation, MediRecon will undergo rigorous testing and validation during a pilot project involving a diverse team of stakeholders, including pharmacists, physicians, and nurses.
8. **Database Harmonization:** To enhance the safety and efficiency of patient care, MediRecon will include a centralized component specifically designed to collect and manage adverse drug reactions (ADRs) recorded across various systems at CHUC. This component will be able to integrate ADR data from multiple sources, including electronic medical records and pharmacy management systems. By centralizing ADR information, the system will provide healthcare professionals with a comprehensive view of each patient's reaction history, facilitating more informed decision-making and improving the response time to potential adverse events.

The system proposed has several internal components and is integrated with typical hospital information systems.

Existing Hospital Information Systems to integrate with:

- ADT (Admission-Discharge-Transfer): SONHO from SPMS

- EPR (Electronic Patient Record): SClinico from SPMS

- External Prescription: PEM from SPMS
- Internal Prescription: SGICM from Glintt
- Plastic Surgery Patient Data: B-ICU from B-Simple
- User Authentication: Active Directory from Microsoft

Internal components:

- ReconMed Smart Engine
- Interoperability engine and APIs
- Graphical User Interface for ReconMed
- Adverse Drug Reactions Component
- Drugs Knowledge Base
- Audit Trail
- Storage component

Work to be done by the leading SME

The Leading SME will execute the following activities during the 12-month project:

1. Technical Requirements of Data and Information Sources:

- Identify and consolidate various sources of drug information critical for gathering comprehensive data. This may include databases, hospital records, and other relevant digital and offline sources. We also need to define the owners of such sources of information and if they are willing to exchange information.
- Establish data quality standards to ensure that the information collected is reliable, timely, and accurate.
- Define the data elements needed from each source.

2. Interoperability development:

- Develop methods to ensure seamless interoperability among the selected data sources. This includes adopting standard data formats and protocols for data exchange and integration.
- Create a prioritized ranking system based on the importance and urgency of each data source to streamline processes and focus on critical data first.

3. Functional Requirements:

- Define the workflows intended for usage of the system in order it can obtain, verifying, and updating a complete and accurate list of medications for each patient.
- Implement a comparison feature to cross-verify the current medication list with the prescriptions issued within the hospital.
- Ensure that when a patient is transferred, the next care provider or the patient/caregiver receives a current, accurate medication list with explanations for any changes.

4. Data Aggregation and Intelligence Development:

- Integrate data from various sources to build an intelligence system that can analyse and present actionable insights.

- Develop algorithms and/or methods to detect discrepancies and potential medication errors automatically.

5. Pilot and Implementation Strategy:

- Conduct a pilot to design, validate, and test the solution, measuring its impact and effectiveness.
- Involve pharmacists, physicians, and patients in testing and refining the solution to ensure it meets the needs of all stakeholders.
- Compliance and Ethical & Legal Considerations:
- Adhere to ethical standards and data protection regulations such as GDPR, ensuring that all personal and medical data is processed with the utmost privacy and security.
- Ensure that data is only seen and analysed by authorized healthcare practitioners or patients.

6. Desired Outcomes and Impact Measurement:

- The solution should increase patient safety by reducing medication errors, manage resources efficiently, and improve satisfaction levels among healthcare professionals and patients.

Activity	Months											
	1	2	3	4	5	6	7	8	9	10	11	12
1	x	x										
2		x	x	x	x	x	x					
3	x	x	x									
4			x	x	x	x	x	x	x			
5						x	x	x	x	x	x	x
6										x	x	x

Figure 1. MediRecon Gantt Chart

Follower SME

Scope of work performed by the follower SME

The primary objective of the Follower SME is to ensure that the MediRecon system is fully prepared and compliant with regulatory requirements for certification as a medical device.

This includes achieving compliance with relevant international standards and obtaining necessary certifications that demonstrate safety and efficacy.

Scope of Work:

1. **Regulatory Strategy Development:**

Develop a comprehensive strategy for medical device certification, including identifying the specific standards and regulations applicable to the MediRecon system.

Collaborate with regulatory experts to ensure all requirements are understood and integrated into the development and testing processes.

2. **Documentation Preparation:**

Prepare all necessary documentation required for certification, such as the Device Master Record (DMR), risk management files, and clinical evaluation reports.

Ensure that all documentation is maintained up to date with the latest product specifications and test results.

3. **Quality Management System (QMS) Implementation:**

Assist in the implementation of a Quality Management System compliant with ISO 13485, focusing on the development, production, and post-market surveillance of medical devices.

Train the project team on QMS processes and requirements to ensure consistent compliance throughout the product's lifecycle.

4. **Testing and Validation:**

Oversee the execution of comprehensive testing protocols to validate the safety, functionality, and performance of the MediRecon system under various conditions.

Document all test results and ensure they meet the criteria set by regulatory bodies for medical device certification.

5. **Audit and Inspection Preparation:**

Prepare and support the MediRecon team for audits and inspections conducted by regulatory authorities or certification bodies.

Address any findings or feedback from these audits promptly to maintain the timeline for certification.

6. **Certification Submission and Liaison:**

Coordinate the submission of all necessary applications and documents to the appropriate regulatory bodies.

Act as the primary liaison between the MediRecon project team and regulatory agencies, ensuring clear communication and swift resolution of any issues that arise during the certification process.

7. **Expected Outcomes:**

Successful preparation and submission of the MediRecon system for medical device certification.

Establishment of a robust Quality Management System that supports continuous compliance and quality assurance.

Achievement of certification, facilitating the legal marketing and widespread adoption of the MediRecon system in healthcare settings.