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Conceptual Design of a Patient-Centric Clinical Record Module Integrated into an Electronic Health Record System

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Abstract

The digital transformation of healthcare has increased the demand for interoperable, patient-centred information systems that are capable of supporting continuity of care across different institutions. Despite the widespread adoption of Electronic Health Records (EHRs), significant challenges remain, including information fragmentation and duplicated documentation. These limitations compromise clinical decision-making, efficiency and patient safety.

This dissertation proposes a conceptual design for a module integrated into an EHR, designed to enable the registration and visualisation of patient information independently of healthcare encounters and the institution/software where the information was recorded initially. The module aims to provide healthcare professionals with a longitudinal and holistic view of patient health while supporting the generation of an International Patient Summary (IPS) aligned with both national and international interoperability standards.

A mixed-method approach was employed, combining semi-structured interviews with healthcare and Information Technology (IT) professionals, a survey of 108 healthcare professionals, benchmarking of existing systems, and user-centred design methodologies. Functional and non-functional requirements were derived from this research, guiding the development of mockups and a prototype. Usability testing, performed through Cognitive Walkthrough and Heuristic Evaluation, validated the feasibility of the design and highlighted areas for refinement.

The results demonstrate that the proposed module addresses key user needs by consolidating patient information, enhancing interoperability, and incorporating critical features such as timelines, structured summaries and audit logs. Furthermore, mechanisms such as “Break the Glass” ensure patient safety in emergency contexts while maintaining compliance with the General Data Protection Regulation (GDPR).

This research contributes a conceptual foundation for the evolution of EHR systems towards a unified, interoperable, and patient-centred software. Future work should focus on technical validation, broader user testing and longitudinal studies to assess the impact on clinical workflows, patient safety, and healthcare costs. By aligning with European and international standards, the proposed model supports the long-term vision of an integrated health information system.

Resumo

A transformação digital dos cuidados de saúde aumentou a necessidade de sistemas de informação interoperáveis e centrados no doente, capazes de suportar a continuidade de cuidados entre diferentes instituições. Apesar da ampla adoção dos *Electronic Health Records* (EHRs), persistem desafios significativos, incluindo a fragmentação da informação e a duplicação da documentação. Estas limitações comprometem a tomada de decisão clínica, a eficiência e a segurança do doente.

Esta dissertação propõe um desenho conceptual para um módulo integrado num EHR, concebido para permitir o registo e a visualização da informação do doente, independentemente dos episódios de cuidados e da instituição/software onde a informação foi inicialmente registada. O módulo visa fornecer aos profissionais de saúde uma visão longitudinal e holística do estado de saúde do doente, ao mesmo tempo que permite a criação de um *International Patient Summary* (IPS) alinhado com os *standards* de interoperabilidade nacionais e internacionais.

Foi adotada uma metodologia mista, em que foram realizadas entrevistas semiestruturadas com profissionais de saúde e da área da informática médica, um inquérito a 108 profissionais de saúde, benchmarking de sistemas existentes e pesquisa de metodologias de design centradas no utilizador. Os requisitos funcionais e não funcionais derivaram desta investigação, orientando o desenvolvimento de mockups e de um protótipo. A avaliação da usabilidade, realizada através de *Cognitive Walkthrough* e de valiação Heurística, validou a viabilidade do desenho e destacou áreas a melhorar.

Os resultados demonstram que o módulo proposto responde a necessidades-chave dos utilizadores, ao consolidar a informação do doente, reforçar a interoperabilidade e incorporar funcionalidades como linhas temporais, resumos estruturados e registos de auditoria. Além disso, mecanismos como o *Break the Glass* garantem a segurança do doente em contextos de emergência, mantendo a conformidade com o Regulamento Geral sobre a Proteção de Dados.

Esta investigação contribui com uma base conceptual para a evolução dos EHR no sentido de sistemas unificados, interoperáveis e centrados no doente. Trabalhos futuros deverão focar-se na validação técnica, em testes mais abrangentes com utilizadores e em estudos longitudinais que avaliem o impacto nos fluxos de trabalho clínicos, na segurança do doente e nos custos em saúde. Ao alinhar-se com *standards* europeus e internacionais, o modelo proposto apoia a visão de longo prazo de um sistema integrado de informação em saúde.

Table of Contents

List of figures	xii
List of tables	xv
Acronyms	xvii
1 Introduction.....	3
1.1 Context	3
1.2 Motivation	4
1.3 Objectives.....	4
1.4 Contributions.....	5
1.5 Structure of the Dissertation	5
2 Background and Literature Review.....	6
2.1 Health Information System	9
2.2 Standards, Interoperability and Terminologies.....	11
2.2.1 Health Level Seven International.....	15
2.2.1.1 Version 2.X and 3.0.....	16
2.2.1.2 CDA.....	17
2.2.1.3 FHIR	17
2.2.2 API.....	19
2.2.3 Terminologies	21
2.3 International Patient Summary	24
2.3.1 Definition and Purpose	24
2.3.2 Standards and Governance	25
2.3.3 IPS Dataset and Structure	27
2.3.4 European and National Context	29
2.3.4.1 MyHealth@EU	30
2.3.4.2 European Health Data Space (EHDS)	30
2.3.4.3 The Portuguese Case	30
2.3.5 Value, Facilitators and Barriers to the IPS Implementation.....	30
2.4 European Health Data Space (EHDS).....	32

2.5	Registo de Saúde Electrónico Único (RSEu)	33
2.6	Privacy and Security	34
2.7	Usability	36
2.8	Summary	37
3	Development of the Conceptual Design	39
3.1	Stakeholders	41
3.2	User Research	42
3.2.1	Semi-Structured Interviews	42
3.2.1.1	Semi-Structured Interviews Design and Implementation	43
3.2.1.2	Semi-Structured Interviews Results	44
3.2.2	Surveys	44
3.2.2.1	Survey Design and Implementation	45
3.2.2.2	Survey Results	45
3.3	User Personas	47
3.4	Benchmarking	48
3.4.1	Patients Lists	48
3.4.2	Summary	50
3.4.3	Patient Timeline	51
3.4.4	Patient Documents	53
3.5	Requirements	53
3.5.1	Use Cases and User Stories	53
3.5.2	Conceptual Module	54
3.5.3	Non-Functional Requirements	73
3.5.4	Functional Requirements	74
3.6	Mockups and Prototype	75
3.7	Usability Testing	87
3.7.1	Cognitive Walkthrough	87
3.7.2	Heuristic Evaluation	89
3.8	Summary	91
4	Conclusion	93
4.1	Conclusions	95
4.2	Future Work	96
5	References	97
6	Annexes	105
6.1	SOFTWARE	107
6.2	SEMI-STRUCTURE INTERVIEWS	108
6.2.1	HEALTHCARE PROFESSIONALS' INTERVIEWS	108
6.2.2	IT PROFESSIONALS' INTERVIEWS	109
6.3	SURVEY	110
6.4	USE CASES AND USER STORIES	117

6.5	USABILITY TESTING	128
6.5.1	HEURISTIC EVALUATION	128

List of Figures

Figure 2.1 Types of standards in healthcare informatics [1]	13
Figure 2.2 Semantic interoperability taxonomy of health record systems [2]	14
Figure 2.3 IPS global standards and specifications [3]	26
Figure 2.4 IPS data blocks [3]	27
Figure 2.5 Implementation guide for portuguese use cases [4]	28
Figure 2.6 IPS composition according to HL7 FHIR IPS implementation guide [5].....	28
Figure 2.7 Implementation guide for portuguese use cases – allergies and intolerances [4]	29
Figure 3.1 Patient list in Cerner	49
Figure 3.2 Customisation of the patient list in Cerner	49
Figure 3.3 Patient list in Epic.....	50
Figure 3.4 Inpatient summary in Cerner	51
Figure 3.5 Ambulatory summary in Cerner	51
Figure 3.6 Patient timeline in VCI.....	52
Figure 3.7 List of patient's encounters in Cerner	53
Figure 3.8 Use case diagram - healthcare professional	55
Figure 3.9 Use case diagram – administrator.....	56
Figure 3.10 Use case diagram – DPO	57
Figure 3.11 Activity diagram – log in	57
Figure 3.12 Activity diagram – view patient's information	58
Figure 3.13 Activity diagram – break the glass mode.....	59
Figure 3.14 Activity diagram – manage patient's information	59
Figure 3.15 Activity diagram – manage patient's document	60
Figure 3.16 Activity diagram – send messages to other users.....	61
Figure 3.17 Activity diagram – view audit logs	61
Figure 3.18 Activity diagram – manage access permissions	62
Figure 3.19 Activity diagram – log out	62
Figure 3.20 Sequence diagram – log in.....	63
Figure 3.21 Sequence diagram – view patient's information (healthcare professional)	64
Figure 3.22 Sequence diagram – view patient's information (administrator and DPO)	65
Figure 3.23 Sequence diagram – break the glass.....	66

Figure 3.24 Sequence diagram – manage patient information	67
Figure 3.25 Sequence diagram – manage patient's documents (create document)	68
Figure 3.26 Sequence diagram – manage patient's documents (edit document)	69
Figure 3.27 Sequence diagram – manage patient's documents (cancel document).....	70
Figure 3.28 Sequence diagram – send messages to other users	71
Figure 3.29 Sequence diagram – view audit logs	71
Figure 3.30 Sequence diagram – manage access permissions	72
Figure 3.31 Sequence diagram – log out.....	73
Figure 3.32 Mockup - Patients' Lists	76
Figure 3.33 Mockup - Patients' Lists with filter	77
Figure 3.34 Mockup - Patients' Lists with Patient's Summary	78
Figure 3.35 Mockup - Patients' Lists with Patient's Timeline	78
Figure 3.36 Mockup - Patients' Lists with break the glass mode justification (1)	79
Figure 3.37 Mockup - Patients' Lists with break the glass mode justification (2)	80
Figure 3.38 Mockup - Patient's Summary.....	81
Figure 3.39 Mockup - Patient Summary with a form allowing information to be edited	81
Figure 3.40 Mockup - Allergies menu	83
Figure 3.41 Mockup - Allergies menu with a form allowing information to be edited	83
Figure 3.42 Mockup - Evaluations menu	84
Figure 3.43 Mockup - Timeline menu.....	85
Figure 3.44 Mockup - Messages menu	86
Figure 3.45 Mockup - Search functionality	87

List of Tables

Table 2.1: FHIR cardinality	18
Table 2.2: FHIR flags	18
Table 2.3: Clinical terminology standards used by Portugal in 2021	23
Table 2.4: IPS implementation guidance	25
Table 2.5: Main terminologies used in the IPS	26
Table 3.1: User personas	47
Table 3.2: Non-functional requirements	73
Table 3.3: Functional requirements	74
Table 3.4: Cognitive walkthrough results	89
Table 3.5: Heuristic Evaluation	90

Acronyms

API Application Programming Interfaces

CDA® Clinical Document Architecture

CEN Comité Européen de Normalisation

CNPD *Comissão Nacional de Proteção de Dados*

CTC Centro de Terminologias Clínicas

DICOM Digital Imaging and Communications in Medicine

ECL Expression Constraint Language

EHDS European Health Data Space

EHR Electronic Health Records

EMR Electronic Medical Record

EU European Union

FHIR Fast Healthcare Interoperability Resources

G7 Group of Seven

G20 Group of Twenty

GDHP Global Digital Health Partnership

GDPR General Data Protection Regulation

HIMSS Healthcare Information and Management Systems Society

HL7 Health Level Seven

IHE Integrating the Healthcare Enterprise

JSON JavaScript Object Notation

IPS International Patient Summary

ISO International Organization for Standardization

IT Information Technology

LOINC® Logical Observation Identifiers Names and Codes

OCDE Organization for Economic Cooperation and Development

PCE *Processo Clínico Eletrônico*

REST Representational State Transfer

RFH Resources for Healthcare

RSE *Registo de Saúde Eletrónico*

RSEu *Registo de Saúde Eletrónico Único*

SDOs Standards Development Organizations

SNOMED-CT Systematized Nomenclature of Medicine-Clinical Terms

SOAP Simple Object Access Protocol

UML Unified Modelling Language

UX User Experience

VCI *Visão Clínica Integrada*

WHO World Health Organization

XML Extensible Markup Language



Introduction

1. Introduction

1.1 Context

The digitization of healthcare and the shift towards patient-centered care has increased the need to have information systems that prioritize access, interoperability, and data security. In this context, several projects have emerged in Portugal and across Europe.

A development in this direction is the European Health Data Space (EHDS), adopted by the European Parliament in April 2024. This initiative aims to grant control to the patients over their digital health data and enabling cross-border access to this information across the European Union (EU). With these new regulations, individuals can access and share their health data anywhere in the EU, minimizing repeated tests and supporting evidence-based decision-making [6]. The EHDS is expected to save an estimated €11 billion across the EU over a decade through enhanced data accessibility and reduced redundancy in care delivery, underscoring the economic and clinical benefits of these standards.

In Portugal, there is a clear move toward unifying health data from different sources, both public and private with the development of the *Registo de Saúde Eletrónico Único* (RSEu). This initiative aligns with broader European guidelines, which endorse Fast Healthcare Interoperability Resources (FHIR) for data sharing in health settings [7]. The growing volume of EHRs brings challenges in achieving semantic interoperability, essential for ensuring that healthcare providers can interpret data shared from different sources, providing healthcare professionals vital information to deliver care in unplanned or emergency situations [8]. These integration efforts not only address immediate healthcare needs but also support secondary uses, such as research and policy-making, as recommended in the Regional Digital Health Action Plan for the World Health Organization (WHO) European Region [9].

To enhance the continuity and quality of care, the IPS document has been implemented as a digital record summarising essential clinical data. The IPS is intended to improve care coordination by offering clinicians quick access to critical patient information, both for planned and emergency care situations [4]. However, to access data independently of clinical encounters remains limited in many current EHRs [10]. Developing a module that enables data viewing without an encounter and that is able to integrate information from various systems could foster a more holistic approach to patient care and allow for dynamic updates to patient health data, better aligning with person-centric models of healthcare.

1.2 Motivation

The digitization of healthcare has driven a profound shift toward patient-centered information systems that emphasize accessibility, interoperability and security.

Integrating a module within an EHR that consolidates information from different healthcare encounters, provides an IPS, and features a well-designed user experience (UX) has several benefits. Access to information would be simpler and more efficient, reducing the cognitive load on healthcare professionals, allowing them to access relevant patient information, follow trends, and avoid errors – which is vital in an environment where time is limited.

Additionally, this module would strengthen continuity of care by providing a unified view of a patient's health history across various settings. This continuity is essential for managing chronic conditions and coordinating specialist care. Furthermore, these functionalities would help providers to make informed decisions based on a patient's full clinical background and current needs.

The benefits of this module could be extended to research and public health initiatives. The existence of a repository of data that could be used securely and anonymously would be highly valuable for generating insights on a larger scale. Such a repository would support health research and contribute to the development of public health strategies.

In summary, a fully integrated, UX-driven EHR module that retains all the patient's information contributes to patient safety, care continuity, and system efficiency, while supporting wider healthcare goals and public health benefits.

1.3 Objectives

As healthcare becomes increasingly data-driven, there is a pressing need for EHR systems to support comprehensive data-sharing frameworks that can adapt to each patient's unique journey.

Also, a module that supports interoperability would improve clinical decision-making, since healthcare professionals would have a full view of the patient's health data. By having immediate access to a patient's health history, medications, allergies, and responses to treatments, professionals are more prepared to make decisions that enhance patient outcomes.

Therefore, the main objective of this dissertation is to develop a conceptual design of a module integrated into an EHR that supports the visualization and recording of patient information independently of healthcare encounters and the institution in which the data were originally registered. This model should facilitate continuous data updates and provide a holistic view of the patient's health status.

Also, this module is intended to have the capacity to generate an IPS that aligns with the requirements of the RSEu and other interoperability standards such as FHIR, and it can exchange data bidirectional with the RSEu, enhancing communication between healthcare providers in public and private sectors.

This dissertation ultimately aims to provide a conceptual foundation for EHR enhancements that facilitate a truly integrated, patient-centered healthcare ecosystem, aligning with national and international standards in health data interoperability and supporting the long-term vision of a unified health information system.

1.4 Contributions

This dissertation makes the following key contributions:

- Development of a conceptual design for an EHR module that enables the registration and visualisation of patient information independently of healthcare encounters and the institution in which the data were originally registered.
- Provision of a longitudinal and holistic view of patient health information, enhancing continuity of care and supporting evidence-based clinical decision-making.
- Integration of mechanisms for generating an IPS in compliance with the RSEu and international interoperability standards such as HL7 FHIR.
- Application of a mixed-method user research, including semi-structured interviews, surveys with healthcare professionals, and benchmarking, to elicit requirements and inform the design process.
- Development of mockups and a prototype, validated through Cognitive Walkthrough and Heuristic Evaluation.

1.5 Structure of the Dissertation

This dissertation is divided into four chapters and five appendices which are organized as follows:

- Chapter 1 introduces the topic and presents the main objectives this work aims to achieve, as well as the motivation of this thesis.
- Chapter 2 provides the theoretical foundation of the study, covering key aspects such as terminologies, the use of application programming interfaces (APIs), privacy, security and usability. Particular attention is given to the IPS, including its dataset and structure as defined by different organizations, its implementation in the EU and Portugal, as well as the values, barriers, and facilitators associated with its adoption.
- Chapter 3 presents the process of developing the conceptual design. It begins with the identification of stakeholders, followed by the results of the user research conducted through a mixed-method approach. Subsequently, user personas, Unified Modelling Language diagrams, and both functional and non-functional requirements are described. Finally, mockups are introduced and the results of usability testing, carried out using Cognitive Walkthrough and Heuristic Evaluation, are discussed.
- Chapter 4 highlights the main contributions of this work, followed by overall conclusions and suggestions for future work.

The appendices provide supporting materials:

- Appendix 6.1 lists the software mentioned by the participants during the semi-structured interviews and survey.
- Appendix 6.2 contains the interview guides used with healthcare professionals and IT professionals working in the field of health informatics.

- Appendix 6.3 presents the questionnaire administered in the survey of healthcare professionals.
- Appendix 6.4 includes the user stories developed for the proposed application, together with the associated use cases.
- Appendix 6.5 provides the form filled by participants in the Heuristic Evaluation.



Background and Literature Review

2. Background and Literature Review

The digital transformation in healthcare and the concomitant demand for useful and accurate information have elevated the importance of a robust Health Information System (HIS) in the collection, management, exchange and use of healthcare data. The aforementioned HIS comprised a diverse array of interconnected components, including but not limited to EHR, laboratory systems and billing systems.

The present chapter investigates the significance of EHRs in contemporary healthcare delivery, and the infrastructures, standards and frameworks that are necessary for facilitating semantic interoperability across healthcare institutions. The importance of interoperability, the Health Level 7 (HL7) standard and the use of Application Programming Interface (API) is mentioned. Furthermore, the importance of the use of terminologies such as Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) and Logical Observation Identifiers Names and Codes (LOINC®) in supporting semantic coherence across disparate systems is mentioned.

In addition, the specification regarding the IPS is mentioned, as are some initiatives such as the EHDS and the RSEu.

Moreover, this chapter elucidates the ethical and legal concerns affecting healthcare interoperability, including privacy and security issues. Moreover, the significance of user-friendliness in the design of applications utilised by healthcare professionals is emphasised.

2.1 Health Information System

HIS play a pivotal role in contemporary healthcare delivery by facilitating the aggregation, examination, storage, distribution, and utilisation of health-related data. According to the WHO, HIS are infrastructures that extend beyond data collection, encompassing the monitoring of health activities, population health outcomes, and policies with a substantial impact on health. This facilitates the interpretation and dissemination of information by healthcare professionals and other users [11].

A HIS is not a single system but rather a network of various systems, including EHR, laboratory systems, scheduling tools, billing software, and public health databases, being responsible for the generation of information that underpins evidence-informed decision-making processes at all levels of a health system. The HIS fulfils four primary functions: data generation, compilation, analysis and synthesis, and communication and utilisation [11].

The EHR is defined as a repository of comprehensive patient medical information in machine-readable formats, that is maintained and shared by healthcare providers and stored securely in an electronic system. The patient record has traditionally been used to document care provided to patients during periods of illness. However, in contemporary practice, it plays a pivotal role in facilitating continuity of care [12], [13].

Furthermore, an EHR contains information recorded from multiple Electronic Medical Records (EMRs), which can then be shared and re-used across healthcare settings. The aim is to contain a record of contact with the healthcare system for individual patients from multiple organisations that deliver care. An EHR comprises data pertaining to the provision and outcomes of therapeutic and diagnostic interventions, encompassing the domains of pathology and radiology [14].

With regard to EMRs, they are defined as a computerised medical record created in a healthcare organisation for the benefit of its patients. An EMR system is organisation-centric in nature and enables the storage, retrieval and modification of patient record [14].

A survey conducted in 2021 in Organisation for Economic Co-operation and Development (OECD) countries revealed the widespread utilisation of EMRs. Specifically, 21 countries reported that EMRs are employed in at least 90% of hospital inpatient care settings, while 20 reported the use of EMRs in 90% of emergency rooms. Furthermore, 18 of the 27 countries reported that electronic records are used in at least 90% of primary care physician offices, and 17 report that this is the case for medical specialists. Japan and Korea reported the lowest EMR coverage across healthcare settings, with approximately 45% and 85% of settings, respectively, covered on average [14].

It is also pertinent to mention two additional categories of information systems employed in healthcare. One such system is the Personal Health Record (PHR), which is defined as a collection of information about a person's health that allows the person to manage and track their own health information. As so, the management of an PHR system is the responsibility of the data proprietor, enabling patients to access their personal health data [12].

The other concept is that of Population Health Record (PopHR), which was firstly defined by Friedman and Parrish as a repository of statistics, measures, and indicators regarding the state of and influences on the health of a defined population, in computer processable form. Accordingly, the core function of PopHR is to concentrate on the overall health of a given population, whilst eschewing the storage of identifiable information pertaining to individual members of said population [12].

At present, the *Serviços Partilhados do Ministério da Saúde* (SPMS) in Portugal provide several platforms that are designed to contain aggregated user information:

- *Processo Clínico Eletrónico*
- *Visão Clínica Integrada*
 - A project that allows clinical information recorded in the Hospital Clinical Record to be consulted chronologically or in a list of episodes. It also makes it possible to consult a clinical summary of

the patient [15].

- *Registo de Saúde Eletrónico*, which contains SNS24
 - This portal makes it possible to integrate the user with the system, but the possibilities for interaction and the availability of services that are actually offered are still limited [16].
- *Registo Nacional de Utentes* (RNU)
 - This contains the user's personal identification data, contact details, health subsystems and more. This data is used in intercommunication with all the platforms of the National Health Service (SNS) as well as other organisations in the social and private sectors that work in complementarity with the SNS [16].
- RSE SIGA
 - This is a clinical referral system that replaces referral letters and aims to facilitate the integration of care between different healthcare institutions [16].
- *Prescrição Externa Medicamentosa* (PEM)
 - PEM is an electronic medical prescription application that is available both in the public sector and in the social and private sectors, and which allows the prescription of medicines, home respiratory care and medical devices [17].

Thus, there are numerous platforms where you can consult information about users, but the basic issue remains: the information is fragmented, difficult to find and difficult to interpret in order to make clinical decisions.

2.2 Standards, Interoperability and Terminologies

Healthcare organizations are increasingly adopting diverse digital healthcare applications to address specific workflows and needs associated with different healthcare professionals' roles and clinical pathways. While these systems offer benefits, they are often proprietary, locally designed, and vary across institutions, resulting in fragmented ecosystems, leading to patient information being scattered across multiple facilities, making it inaccessible to healthcare professionals when needed. Without comprehensive data, providers cannot make fully informed decisions, especially if patients are unable to communicate their medical history [1].

To address this issue, integration mechanisms between health information systems are imperative to ensure seamless access to patient information across institutions [1]. As clinical data continue to grow in both volume and complexity, achieving EHR interoperability will be essential for establishing a more efficient and sustainable workflow for healthcare professionals [8]. Furthermore, the functionality of the same EHR platform can vary when implemented in different healthcare facilities. The rationale behind this phenomenon

is that clinical processes are tailored and usage patterns vary among healthcare professionals, thus rendering customisation essential to adapt the EHR to the specific needs of each institution [18].

Interoperability is defined as the capability of diverse information systems, devices, and applications to access, exchange, integrate, and utilize data in a coordinated way. This coordination occurs within and across organizational, regional, and national boundaries, ensuring timely and seamless information portability [19].

According to the Healthcare Information and Management Systems Society (HIMSS), there are four levels of interoperability [19]:

- Level 1 – Foundational: defines the interconnectivity requirements necessary for one system or application to securely communicate and receive data from another.
- Level 2 – Structural: specifies the format, syntax, and organization of data exchange.
- Level 3 – Semantic: establishes common underlying models and data codification, utilizing data elements with standardized definitions from publicly available value sets and coding vocabularies, to ensure a shared understanding and consistent meaning for users.
- Level 4 – Organizational: includes governance, policy, social, legal, and organizational aspects to enable secure, seamless, and timely data communication and usage within and across organizations, entities, and individuals. These elements foster shared consent, trust, and the integration of end-user processes and workflows.

To achieve interoperability the use of standards is essential. Standards are defined as technical norms or specifications that establish rules and guidelines to guarantee that a product, process or service is fit for purpose. In the context of health informatics, the use of standards ensures consistency and supports interoperability of clinical information across different organizations [20].

Standardization not only addresses technical integration but also supports organisational and regulatory alignment. By establishing common frameworks and governance structures, standards promote collaboration among stakeholders and help overcome challenges such as different organisational cultures and regulatory environments [21].

The adoption of international standards, supported by organizations such as International Organization for Standardization (ISO) and WHO, is essential for enabling cross-border health data exchange and improving global health equity [21]. Standards also benefit both healthcare providers and IT vendors by facilitating the exchange, integration, and retrieval of clinical data from diverse systems, ultimately contributing to more efficient and patient-centred care delivery [18].

According to the HIMSS and regarding the available standards, they can be categorized into different

types, such as the following [19]:

- **Vocabulary/Terminology Standards:** intend to represent concepts in an unambiguous manner between systems, for instance SNOMED-CT and LOINC®.
- **Content Standards:** define the structure and organization of the electronic message or document's content as well as the definition of common sets of data for specific message types. For example, HL7 Version 3 Clinical Document Architecture (CDA®).
- **Transport Standards:** address the format of messages exchanged between systems, namely FHIR and Digital Imaging and Communications in Medicine (DICOM).
- **Privacy and Security Standards:** define a set of administrative, physical and technical actions to protect the confidentiality and integrity of health information. One example is the GDPR.
- **Identifier Standards:** used to identify patients or providers.

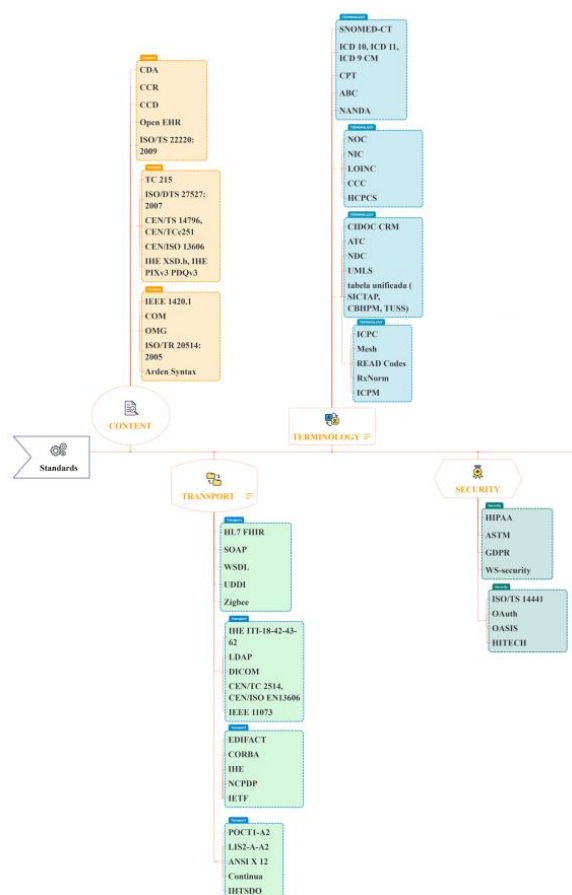


Figure 2.1: Types of standards in healthcare informatics [1]

Other authors, while analysing studies included in a systematic review, identified five main categories of taxonomy: 1) Health Standards, 2) Classification and Terminologies, 3) Semantic Web, 4) Data Storage, and 5) Evaluation. It is also noted that, despite this organization, articles often combine multiple themes to achieve semantic interoperability, meaning that these categories are not mutually exclusive [2].

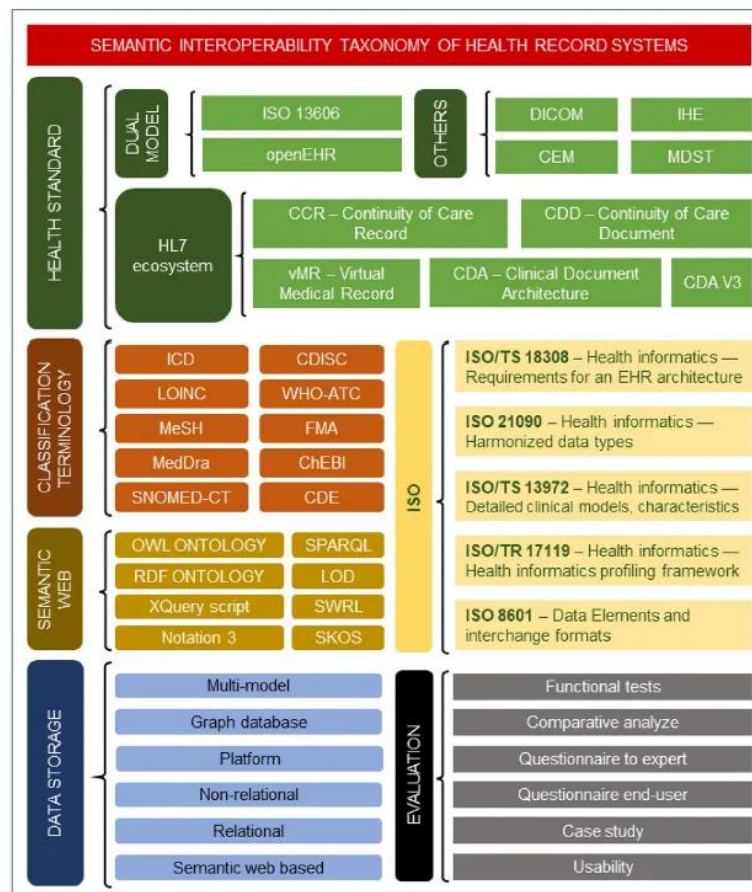


Figure 2.2: Semantic interoperability taxonomy of health record systems [2]

Achieving seamless and effective interoperability offers multiple benefits, such as:

- Improving care coordination: providing care often involves multiple stakeholders, requiring data to move across platforms and among service providers in real time [19].
- Enhancing patient safety and satisfaction: having a complete view of a patient's health journey helps avoid duplicate testing, reduces adverse events, and ensures appropriate follow-up procedures. Implementing interoperable EHRs is also associated with reduced data entry errors and improved data quality however, the impact on timeliness and clinical workflow improvements remains inconclusive [8].
- Optimizing time management: interoperability can eliminate time-consuming tasks within

healthcare systems. For instance, if a patient cannot effectively communicate, providers can access essential information without contacting general practitioner offices or other agencies. Also, by integrating data into existing systems, healthcare providers can spend more time on patient care [1].

- Promoting value-based care: population-level data analysis is essential for managing high-risk populations and supporting public health systems. By enabling stakeholders to collaborate and address community care needs, interoperability contributes to more cost-effective and efficient care delivery [19].

Semantic Interoperability aims to enable data sharing between organizations and ensure accurate understanding and interpretation, regardless of the parties involved. This type of interoperability is not only important in the context of patient's care but also plays an important role in the use of secondary data, since the improvement of data quality is one of the consequences of semantic interoperability [2].

Achieving semantic interoperability relies on the use of terminologies, ontologies and global classifications. However, the absence of worldwide consensus on health standards means that selecting which standards to adopt remains a technical challenge when it should be an organizational decision. Additionally, the existence of legacy data, semi-structured data, non-structured textual data and complex systems that are sometimes incompatible with effective information exchange presents further challenges to achieving semantic interoperability [1]. As a result, succeeding in semantic interoperability remains one of the main challenges for the healthcare system [2].

Interoperability is a topic that is highly relevant to the objectives of this dissertation, which aims to develop a conceptual design for an application functioning as a unified repository of health information. This repository intends to centralize clinical data and allow for continuous updates, regardless of the institution where the data is recorded. Thereby, achieving interoperability is crucial for this model to function effectively, ensuring seamless data exchange between various health information systems and enhancing the accessibility and comprehensiveness of patient information.

2.2.1 Health Level Seven International

The HL7 is a non-profit organisation that was established in 1987 as a group of companies that came together in Palo Alto to collaborate on standardising healthcare data exchange, especially between applications within a hospital [22].

Shortly after the establishment of the HL7 organization, the initial version of the HL7 standard (HL7 1.0) was developed. Following HL7's accreditation by the American National Standards Institute (ANSI), the subsequent publications (HL7 2.x versions) became widely adopted [22].

HL7 was originally designed to communicate patient-related administrative data. Since that time, this standard has been expanded to include the exchange of medical data that encompasses the whole spectrum

of healthcare and social services [22]. Its present mission is to provide a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems [23].

The HL7 comprises the following primary standards (most popular standards) [23]:

- C-CDA (HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes, Edition 4 - US Realm)
- CDA® Release 2
- FHIR
- HL7 Context Management Specification (CCOW), Version 1.6
- HL7 Version 2 Product Suite
- HL7 Version 2.9.1 Messaging Standard - An Application Protocol for Electronic Data Exchange in Healthcare Environments
- HL7 Version 3 Product Suite

2.2.1.1 Version 2.x and 3.0

The second version of the standard was developed in 1990 and served as the foundation for the widely adopted HL7 Version 2.x standards, which have been released in the form of successive iterations, each identified by specific version number (e.g., v2.1, v2.2, etc) [22].

HL7 version 2.x is a message-oriented data exchange standard that is designed to support the exchange of patient-related administrative and clinical data in the form of messages. These messages are event-driven (e.g. triggered by a patient admission) and the content of the exchanged information varies according to the specific use case [22].

HL7 v2.x defines messages using an abstract framework. The HL7 specifies hierarchical rules for constructing messages using building blocks referred to as elements. These elements include segment groups, segments, fields, components, and sub-components. Each element is characterized by attributes that include optionality, cardinality, table, length, and data type. HL7 v2.x does not impose strict constraints on how messages, segments, or fields are defined; instead, elements are created on demand to address specific requirements [22].

Version 3.0 was initiated in 1995 with the expectation, from the standpoint of the standards organization, that it would supplant v2. However, in practice, the extensive installed base of v2, combined with the

technical complexity of v3, impeded this from occurring. Unlike its predecessor, v3 introduced a model-driven approach to data exchange, built upon the Reference Information Model (RIM), which provides a formal representation of healthcare concepts and their relationships [22].

2.2.1.2 CDA

The CDA is a specification that defines the structure of clinical documents, with the objective of creating a framework for the medical context in which a clinical document of any type (doctor's letter, notes, discharge letters, etc.) can be implemented. The objective is to format any document in such a manner that it is both readable by humans and by the computer. Hence, structuring and encoding of the text is contingent upon the utilization of a markup language. This encoding is achieved using the eXtensible Markup Language (XML) which can contain any text, including known markups for semantic information [22].

The CDA document is divided into two sections: the header and the body. The patient's details and the author's information are placed in the header as meta-data, and the body contains the text and additional clinical data [22].

CDA has become a prevalent standard due to being an XML based standard for clinical document content. This standard is distinguished by its flexibility, which enables it to be both machine-readable and human readable. Consequently, CDA facilitates the consolidation of a patient's comprehensive medical history into a single document, thereby enhancing its reusability across a range of applications [8].

2.2.1.3 FHIR

In 2011, Grahame Grieve proposed a new interoperability standard called Resources for Healthcare (RFH) to improve interoperability in digital health. This standard was later renamed as FHIR [24].

Designed for web technology, FHIR was conceived to provide a set of resources and to enable HTTP-based REST APIs for accessing and utilizing these resources. The standard uses JavaScript Object Notation (JSON) and XML format. Furthermore, FHIR not only supports resource exchange through RESTful, but also manages and documents an interoperability paradigm [24].

The basic building blocks of FHIR are referred to as Resources. These are defined as the smallest discrete concept that can be managed independently, representing the smallest unit of a transaction. Also, resources are generic definitions in healthcare, such as "patient" or "observation" [24]. All resources share the following characteristics [25]:

- A common way to define and represent them, building them from datatypes that define common reusable patterns of elements;
- A common set of metadata;
- A human readable part.

In the current version of FHIR (R5) there are 157 resources, which are divided into 5 main categories: Foundation (bundle, CodeSystem), Base (Patient, Practitioner), Clinical (Observation, AllergyIntolerance), Financial (Covorage, ChargeItem) and Specialized (ResearchStudyConditionDefinition) [24], [26].

Each resource has several elements, each with defined cardinality (defining whether an element is mandatory and how many repetitions are allowed) and flags (specifying their behaviour), as mentioned in the following table [22], [27].

Table 2.1: FHIR cardinality

Cardinality	Description
0..1	This element may optionally occur only once.
0..*	This element may optionally occur.
1..1	This element must occur exactly once.
1..*	This element must occur but may repeat.

Table 2.2: FHIR flags

Flags	Description
?!	This element is a modifying element, so it cannot be ignored since it changes the meaning of the element.
C	This element defines or is affected by constraints.
S	This element is an element that must be supported.
Σ	This element is an element that is part of the summary set.
NE	This element cannot have extensions (some infrastructural elements only).
TU	This element has a standards status of Trial Use.
N	This element has a standards status of Normative.
D	This element has a standards status of Draft.

Usually, conveying a single resource alone is not sufficient in simple contexts. In most cases, multiple resources need to be grouped together to establish a specific context or to aggregate specific data. In FHIR, such a collection of resources is encapsulated within a resource called Bundle, which serve as a container for grouping resources in a structured manner [22].

Furthermore, resources are accessed and manipulated via RESTful operations defined by FHIR, including GET (to retrieve resources) and POST (to perform queries) [22].

Despite the number of resources, a key principle of FHIR is to only specify data elements that are applicable in at least 80% of the use cases, thereby simplifying implementation. To cover information not included in the standard resources, FHIR provides a built-in extension mechanism, allowing adaptation to specific use cases while ensuring interoperability. Additional rules and constraints within resources can be defined in Profiles. Consequently, FHIR covers a wide range domains of health care with its resources and can be used for different purposes and in various contexts and workflows [22], [28].

Since its beginning, FHIR gained significant popularity and has been increasingly adopted by the healthcare industry. In 2018, six large technology companies, including Microsoft, IBM, Amazon, and Google, pledged to remove barriers to healthcare interoperability and signed a letter that explicitly identifying FHIR as an emerging standard for the exchange of health data [24].

The main objective of FHIR is to reduce implementation complexity while preserving information integrity, allowing the developers to create standardized web-based applications that enable users to access clinical data from any healthcare system, regardless of the operating systems and devices in use [24].

Despite its strengths and growing popularity, FHIR has faced technical criticism, particularly regarding the development of API-based interoperability applications, where implementation can become complex [29].

2.2.2 API

API-led integration refers to an architectural approach that uses Application Programming Interfaces (APIs) to enable data exchange between different systems and applications. In this model, APIs act as intermediaries that allow different software components to communicate, enabling the integration of systems without the need for extensive modifications to existing infrastructures [14], [21].

API-led integration architecture represents a systematic approach that organizes the integration of systems and applications around APIs as the primary medium for data exchange. This architecture is characterized by a layered model comprising three distinct layers [21]:

- Experience APIs are designed to provide tailored data access to specific user interfaces or applications, supporting user-centric interactions.
- Process APIs act as intermediaries that encapsulate business logic, enabling systems to communicate effectively.
- System APIs provide direct access to underlying data sources and applications by abstracting the complexities of interacting with different systems, allowing other APIs and applications to retrieve or manipulate data seamlessly.

In addition, there are different types of APIs, with the Representational State Transfer (REST) and Simple Object Access Protocol (SOAP) being the most relevant in healthcare. REST APIs are characterized by their stateless communication and reliance on standard HTTP protocols for data exchange, where each resource is identified by a unique URL. REST APIs are particularly popular in modern healthcare applications due to their simplicity, ease of use and flexibility. On the contrary, SOAP APIs operate on a more rigid and complex framework [21].

As mentioned previously, APIs can support standardized data formats such as FHIR, which facilitate the structured exchange of health information across various platforms. This capability is particularly relevant in today's healthcare landscape, characterized by rapid technological advancements and an increasing reliance on data-driven decision-making [21].

There are several differences between the use of APIs and the traditional integration methods. Traditional approaches rely on point-to-point interfaces that become increasingly complex as new systems are introduced, making them difficult to scale and maintain. This leads to higher costs and a significant maintenance burden compared to API-based architectures. Additionally, as healthcare continues to evolve towards a more patient-centered model and with the rise of mobile health applications, it is essential to enable access to real-time data from various sources, empowering healthcare professionals to make informed decisions and leading to better patient outcomes. While the traditional methods often fail to support this dynamic and collaborative environment, the use of APIs promotes the sharing in real time of patient data [21], [30].

Furthermore, APIs play a critical role in enhancing administrative workflows and processes, such as scheduling, billing, and patient registration. By facilitating communication between different systems, APIs help reduce the manual workload and improve operational efficiency [21], [30].

Additionally, the adoption of API-led integration enhances the ability of healthcare organizations to support a diverse range of applications and services, creating a flexible infrastructure that can accommodate future growth [21], [30].

Despite these benefits, the use of APIs also presents several challenges. The financial implications associated with implementing an API-led infrastructure represent a significant barrier to its adoption. Moreover, integrating such solutions with legacy systems can be highly complex due to differences in architecture and data formats. Another challenge is ensuring compliance with the regulations such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States and the GDPR in the EU. Achieving regulatory compliance requires comprehensive planning and implementation of robust security measures, which can add complexity and time to the integration process [21], [30].

In addition, the integration of APIs into healthcare systems presents a multitude of security challenges that necessitate comprehensive examination and strategic mitigation. APIs are exposed to various attack vectors, such as unauthorized access, data breaches and injection attacks [21], [30].

The use of APIs in healthcare is expanding. For example, in the United States, the 21st Century Cures Act (Section 4002), establishes a condition of certification that requires health IT developers to publish APIs, allowing information to be accessed, exchanged and used without special effort. Also, in Sweden, a new linked database on prescription data, enabled via the National Medicines List Act and implemented by the Swedish eHealth Agency, is creating a standardised registry accessible to healthcare providers, pharmacies

and patients [14].

2.2.3 Terminologies

Given that healthcare institutions share sensitive information, it is imperative that the various systems in place are able to preserve the meaning of the information exchanged. One possible approach to this issue would be to establish a local repository and maintain an environment based on proprietary concepts. However, the adoption of international terminologies ensures semantic consistency, allowing global terms and classifications to retain their intended meaning across different systems and recipients [2].

Terminologies can be defined as collections of terms within a knowledge domain, with the objective of standardising language and promoting a shared understanding. The utilisation of formal classifications is essential to prevent the use of local expressions, neologisms and free text in an EHR [2].

Following, there is an overview of the most used terminologies [14], [31], [32].

Systematized Nomenclature of Medicine-Clinical Terms (SNOMED)

SNOMED CT is regarded as the most comprehensive multilingual clinical terminology globally, including over 366,000 concepts with multiple descriptions and logical definitions organised hierarchically. It encompasses a broad spectrum of clinical concepts, including diseases, procedures, medications, and outcomes, for documentation in EHR. The core components of the SNOMED are concepts, descriptions and relationships [32]:

- **Concept:** defined as a unique clinical entity, organised hierarchically to reflect varying levels of granularity.
- **Description:** fully specified names that capture the meaning of a concept and synonyms that are employed as alternative expressions of that concept.
- **Relationship:** represents an association between concepts, facilitating the logical definition of a concept.

SNOMED CT encompasses a broad range of healthcare concepts. However, the scope of the terminology is often too extensive for implementation in specific domains. To address this, reference sets (refsets)—curated subsets of SNOMED CT—are used to focus on the most relevant concepts for particular use cases [31].

For instance, in the context of the IPS, a specific subset was developed with the objective of optimising the use of SNOMED CT, while focusing on the intended use case. It has been demonstrated that all concepts in the IPS freeset have equivalent definitions to those in the SNOMED CT terminology, with no loss in relevant semantics. The only difference is that the number of concepts is restricted to the scope of the IPS terminology. For instance,

the Expression Constraint Language (ECL) query `<< 105590001 |Substance (substance)` can be specified for the causative agents of allergies in FHIR, returning just over 500 relevant substances in the IPS terminology, whereas there are over 27,000 substances in the full SNOMED CT [31].

International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10)

The ICD is a global statistical classification for coding the causes and consequences of diseases and deaths. Primarily designed by WHO for statistical purposes, the ICD was developed to enhance the comparability of morbidity and mortality data internationally.

This nomenclature employs alphanumeric codes ranging from three to seven characters. The initial three characters designate the disease category, the subsequent three characters indicate the related etiology, anatomical site, severity or other clinical details. The seventh character is used to document care episodes for injuries and other conditions with external causes. ICD-10 employs a monohierarchical structure, incorporating residual categories for diseases that do not fall into other categories [32].

Anatomical Therapeutic Chemical Classification System (ATC)

Another significant domain in clinical terminology is medication, for which a variety of coding standards are employed across different countries. One of the most widely adopted is the ATC, which is used for coding for patient medication [14]. The ATC only expresses active substances, without referring to commercial drug products, which may limit its applicability in certain clinical contexts [33].

Logical Observation Identifiers Names and Codes (LOINC)

LOINC is a standardised terminology that is employed for the description of laboratory and clinical observations. Laboratory LOINC encompasses a range of tests, measurements and observations about a specimen, covering domains such as chemistry, haematology, cell counts and antibiotic susceptibilities [32].

At present, there are over 100,000 LOINC codes, each comprising six parts: component, property measured, timing, specimen type, scale type, and method. It is standard practice to assign each LOINC concept is assigned three names: the six-part fully specified name, the clinician-friendly long common name, and a short name suitable for column headers in reports [32].

In recent years, there has been an increasing emphasis on collaboration among terminology developers with a view to improving semantic interoperability. In 2022, a significant agreement between the Regenstrief Institute and SNOMED International led to the development of a LOINC extension in SNOMED CT format, in which each LOINC concept is mapped to an equivalent, fully defined SNOMED CT concept. This alignment enables each component of a LOINC code to correspond to a formal SNOMED CT concept, thereby providing a richer and computable semantic layer for laboratory data [32].

For instance, SNOMED CT is being mapped to classification systems such as ICD-10, through a joint initiative between WHO and SNOMED International, with the mappings available via the SNOMED CT browser. Further mapping endeavours encompass the establishment of links between SNOMED CT and CPT (in the United States), as well as between SNOMED CT and OPCS-4 and ICD-10 in the United Kingdom [32].

The OECD has published a report in which 27 countries were surveyed. It was established that a plurality of terminology standards are employed for a given data category across diverse countries, and within a single country as well. For instance, ICD is utilised for recording of diagnoses in 21 countries, while Australia and Switzerland employ SNOMED CT and Greece, Hungary, and the United States utilize both terminologies for this purpose. With regard to medication, the ATC classification is used in 16 countries. However, Australia and Switzerland utilise SNOMED CT, while other countries employ locally developed terminology standards, including Costa Rica (Lista Oficial de Medicamentos – LOM), Korea (Korea Drug – KD) and the United States (RxNorm and National Drug Code – NDC). With regard to surgical procedures, 8 of the 27 countries utilize ICD, such as ICD-9-CM and ICD-10-PCS; 5 employ SNOMED CT; and the remainder utilise national codes. Laboratory tests are captured using LOINC in 16 countries, whereas SNOMED CT is used in Iceland, Slovenia, and Sweden [14].

A further analysis was conducted of the Portuguese case, based on a survey completed by SPMS [14]:

Table 2.3: Clinical terminology standards used by Portugal in 2021 [14]

Terminology	Data Elements
HL7 Profiles	Patient socioeconomic data
ATC/EDQM and National Coding System (CNPEM)	Patient medications
ICD-10-CM & ICPC-2	Patient diagnosis
LOINC	Patient laboratory test results
DICOM	Patient medical imaging results
ICD-10-CMPCS	Patient surgical procedures
SNOMED	Patient vital signs
ICPC-2	Patient clinically relevant behaviours
ICPC-2	Patient clinically relevant psychosocial or cultural issues

Whilst terminology standards are imperative for achieving semantic interoperability in healthcare, their adoption poses several challenges. A significant challenge pertains to the coexistence of multiple standards for domains such as laboratory medicine, which hinders efforts to achieve consensus on a unified terminology. This challenge may be mitigated by recognising the complementary nature of existing standards and accepting their inherent differences. For instance, LOINC is particularly effective for the coding of laboratory tests, whereas SNOMED CT is more appropriate for the representation of non-numerical results and broader clinical concepts. The enhancement of interoperability can be achieved through cross-mapping between these standards or by adopting SNOMED CT as a reference terminology to mediate between diverse coding systems [32].

In summary, the generation of high-quality, semantically interoperable data is contingent upon the accurate and unambiguous collection and dissemination of information, guided by robust terminology standards. In order to enhance the practical usability of these terminologies, a multi-faceted strategy is required, encompassing the adoption of complementary terminologies and active contribution to the evolution of standards [32].

2.3 International Patient Summary

The IPS has emerged as a key initiative to enhance the accessibility and interoperability of essential health information across borders. This section outlines the principles, structure, and role of the IPS, highlighting its relevance to the development of interoperable and patient-centred digital health solutions. Furthermore, it references projects in which the IPS plays a substantial role.

2.3.1 Definition and Purpose

The IPS is a minimal and non-exhaustive set of clinical data regarding a patient, designed to be specialty-agnostic and condition-independent, while still being readable and usable by healthcare professionals involved in patient care [3]. Being minimal and non-exhaustive does not imply that the data are unimportant or irrelevant, rather that the IPS represents a snapshot extracted from the digital health record. It should not be equated to an EHR, since it has a different purpose: to condense and present the most relevant clinical information in a format that is quickly accessible [34].

The development of the IPS has been prompted by the acknowledgement that, in certain cases, a patient may require emergency care outside of their home health system (e.g., when a patient is travelling abroad) and, in such a case, the healthcare professionals may have little or no access to the patient's previous health information [35]. Therefore, this summarized version of the patient's clinical data gives healthcare professionals the essential information required to provide care in unplanned or emergency situations such as allergies, current medication, previous illnesses and surgeries. These types of information are necessary for the proper treatment and care of a patient, especially when there is a language barrier between the health professional and the patient [36].

While the IPS primarily supports unplanned care, it can also be used in the context of planned medical care. It has been demonstrated that the IPS can be equally useful in facilitating care across organizational boundaries, for example within the Portuguese healthcare system when both public and private healthcare facilities are involved in treating the same patient [35].

2.3.2 Standards and Governance

Standards are defined as technical norms or specifications that establish rules and guidelines to guarantee that a product, process or service is fit for purpose. In the context of health informatics, the use of standards ensures consistency and supports interoperability of clinical information across different organizations [20]. Furthermore, the use of code systems allows the unambiguous exchange of clinical information in the context of IPS [36].

Accordingly, the IPS has been collaboratively developed across multiple standards development organizations (SDOs) such as CEN, HL7, IHE, ISO, and SNOMED and is also actively supported by international initiatives such as the Global Digital Health Partnership (GDHP), the G7, the G20 and WHO [3].

Regarding the implementation guidance, there are several documents and technical specifications available. Below is a table summarising the main implementation guides followed by a diagram that illustrates how these guidelines are interconnected (the diagram also refers to a code system – SNOMED – that will be discussed in greater detail later in this section).

Table 2.4: IPS implementation guidance

Implementation Guidance	Objective	SDO	Latest Version
ISO 27269	Based on the initial EN 17269 (withdrawn after the publication of the ISO 27269), is a data model standard that defines the meaning of each of the sections of the IPS [3]. Additionally, it formalises the dataset of the eHealth Network guidelines and has the goal to delivering a single, common IPS core content [36].	ISO	2021
CEN TS 17288	Provides guidance on the implementation of the specific European requirements which may not be applicable throughout the world. It is tightly connected with EN 17269 and when the European Norm is superseded by the ISO standard, TS 17288 will undergo revision. [3].	CEN	2020
eHN EU PS Guideline	Provides guiding principles for the development and implementation of national Patient Summary data set initiatives across the EU [36].	eHealth Network	2024
HL7 CDA IPS Implementation Guide	Provides the specification on how to implement the IPS in the HL7 CDA [3]. This implementation guide is a practical example of derived implementations conformant with the standards ISO 27269 and eHN EU PS Guideline [36].	HL7	2024
HL7 FHIR IPS Implementation Guide	Provides the specification on how to implement the IPS in the HL7 FHIR [3]. This implementation guide is a practical example of derived implementations conformant with the standards ISO 27269 and eHN EU PS Guideline [36].	HL7	2025
IHE IPS Profile	Refers to both HL7 Implementation Guides and provides the basis for actual testing of an IPS interface to be provided by clinical information systems [3].	IHE	2023
IHE Document Sharing	Method of publication, discovery, and retrieval of the IPS [3].	IHE	2023

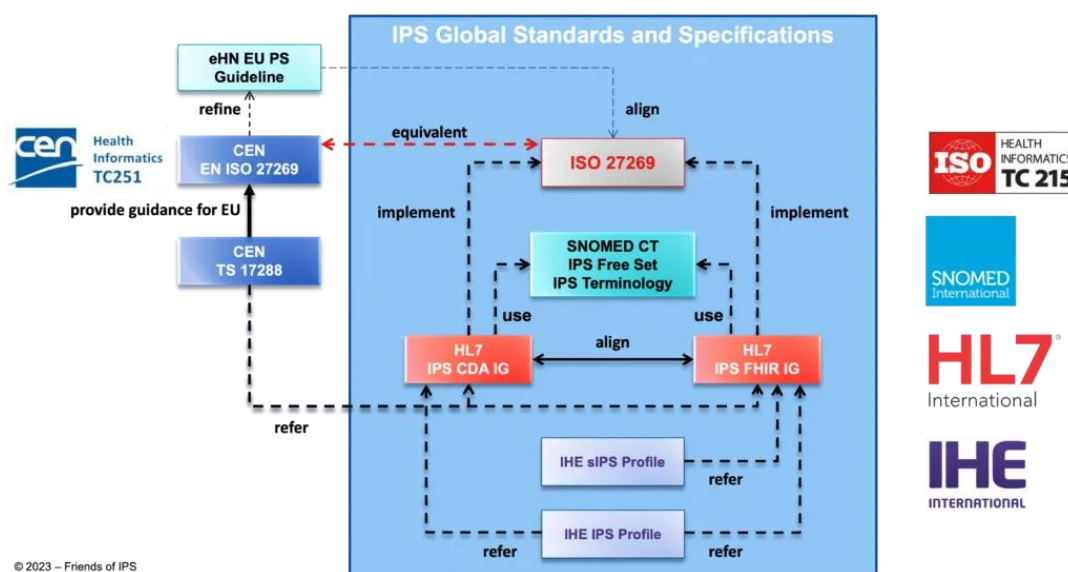


Figure 2.3 IPS global standards and specifications [3]

The EU Member States are free to choose the technical implementation of their Patient Summary although it is mandatory that the format of the document for exchange shall be based on standards and profiles as agreed by the eHealth Network [36].

Additionally, several code systems should be used in the IPS. At present, different code systems are employed by the EU countries, but the long-term goal is to gradually converge towards the use of international code systems across Europe [36].

The following table summarises the main code systems that should be used in the IPS. Further details on each coding system will be explored in a different section.

Table 2.5: Main terminologies used in the IPS

Terminologies	Objective
SNOMED	Comprehensive medical ontology used in health care sectors across the world covering a wide range of concepts that support diversity at the point of healthcare [31].
LOINC	Diagnostic tests (laboratory medicine) and clinical observables [36].
ICD-10	Diseases and medical conditions [37].
ATC	Active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties [38].
IDMP	Specify the use of standardised definitions for the identification and description of medicinal products for human use [39].
UCUM	Include all units of measures being contemporarily used in international science, engineering and business [40].
EDQM	Classifies chemical substances and attributes related to active ingredients and medicinal products [41].
NPU	Identification and communication of examination results from clinical laboratories [42].
ICF	Classification of health and health-related domains that is used for measuring health and disability at both individual and population levels [43].

Finally, Member States must comply with the GDPR, which serves as the legal basis for data processing and

data protection. Besides the conditions outlined in the GDPR, the EU countries may introduce further limitations concerning the processing of the Patient Summary documents [36].

2.3.3 IPS Dataset and Structure

The IPS document is composed of a set of robust, well-defined and potentially reusable sets of core data items [5], referred to as IPS Data Blocks in ISO 27269:2021(E).

In accordance with the ISO 27269:2021(E), a Patient Summary must include six mandatory IPS Data Blocks (one of which is conditional upon the need for any cross-border application of the IPS). Additionally, there are six further IPS Data Blocks that are required when known. The document may also contain seven optional Data Blocks, as defined in ISO 27269:2021(E) and may include non-IPS data components, if necessary. These non-IPS data components fall outside the scope of the ISO 27269:2021(E) [44] but can be used in non-IPS patient summaries although this only provides a limited conformance to the IPS Data Set [44].

The following image illustrates which IPS Data Blocks are mandatory, required when known and optional [3].

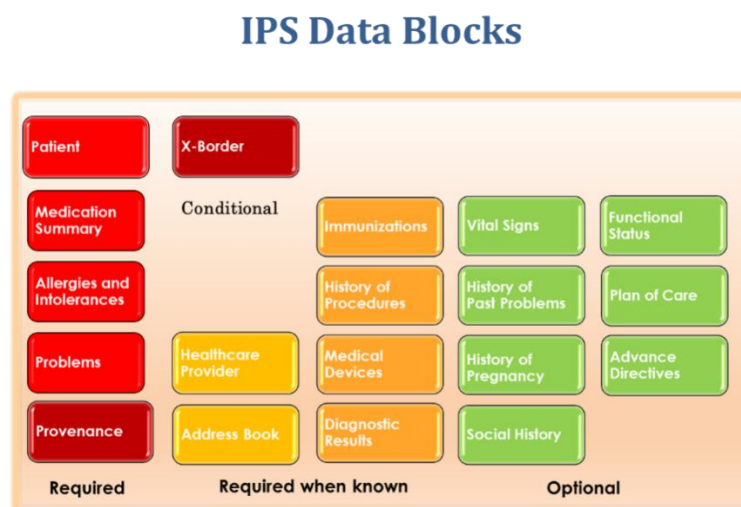


Figure 2.4 IPS data blocks [3]

As previously mentioned, the IPS Data Set can be extended with non-IPS components. However, the derived model, including implementable specifications, must remain compliant with the IPS standards. To ensure this, the extensions must follow the principle that the recipient of the Patient Summary must be able to provide care even if they are not able to process the semantics of the extensions. Therefore, the extensions must not alter the meaning of any IPS elements [34].

The IPS Data Blocks and their structure are very similar to those described in the Implementation Guide for Portuguese Use Cases. The differences lie in the Provenance, Cross-Border, Patient, Healthcare Provider, Address Book and Vital Signs sections, which are not included in the Portuguese Implementation Guide, as illustrated in the following image [4].

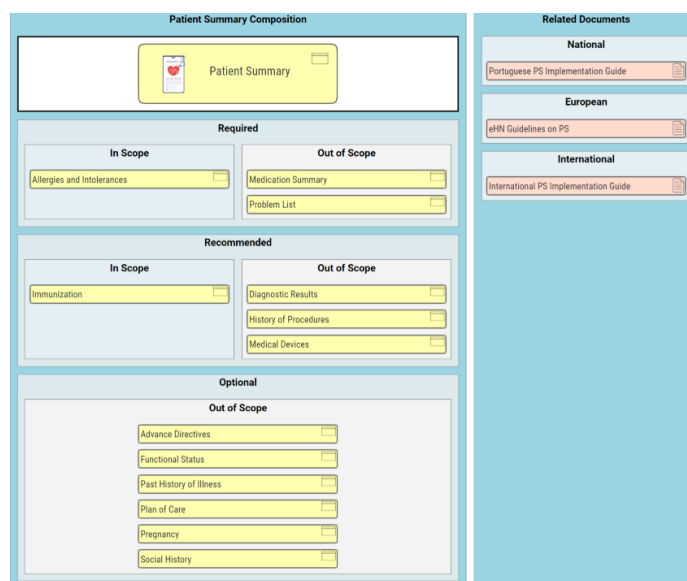


Figure 2.5 Implementation guide for portuguese use cases [4]

The Portuguese Implementation Guide has certain limitations, as it currently provides guidance only for the “Allergies and Intolerances” and “Immunisations” sections. Nevertheless, it outlines the overall composition of an IPS and shares strong similarities with the HL7 FHIR IPS Implementation Guide, as it is based on this international specification, as illustrated in the following image [5].

The IPS Composition

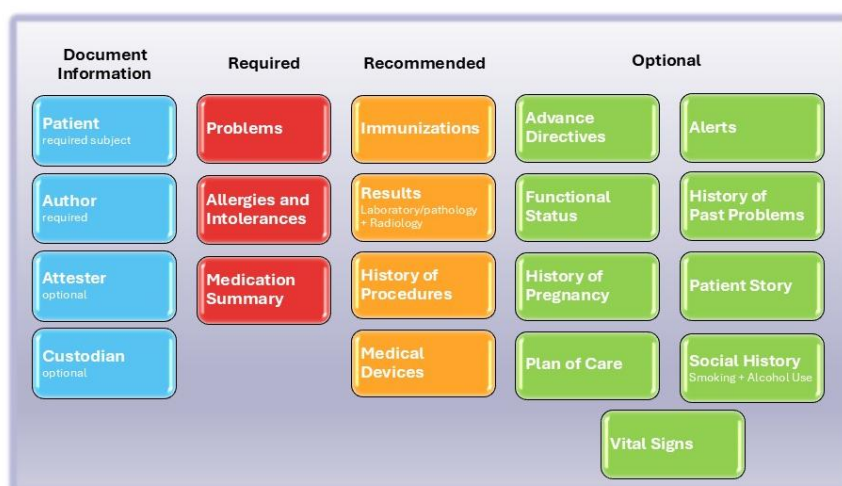


Figure 2.6 IPS composition according to HL7 FHIR IPS implementation guide [5]

Regarding the specific information contained in each IPS section, the HL7 IPS Implementation Guide provides FHIR profiles that define data constraints, value sets, cardinality, terminology bindings, and metadata. Additionally, the Portuguese Implementation Guide – limited to the two sections previously mentioned – also offers guidance on the value sets applicable within the Portuguese context. In the following image, the value sets shown in dark yellow are those represented in the *Centro de Terminologias Clínicas* (CTC), where catalogues

include value sets with Portuguese translations of items originally available in SNOMED and LOINC [45].

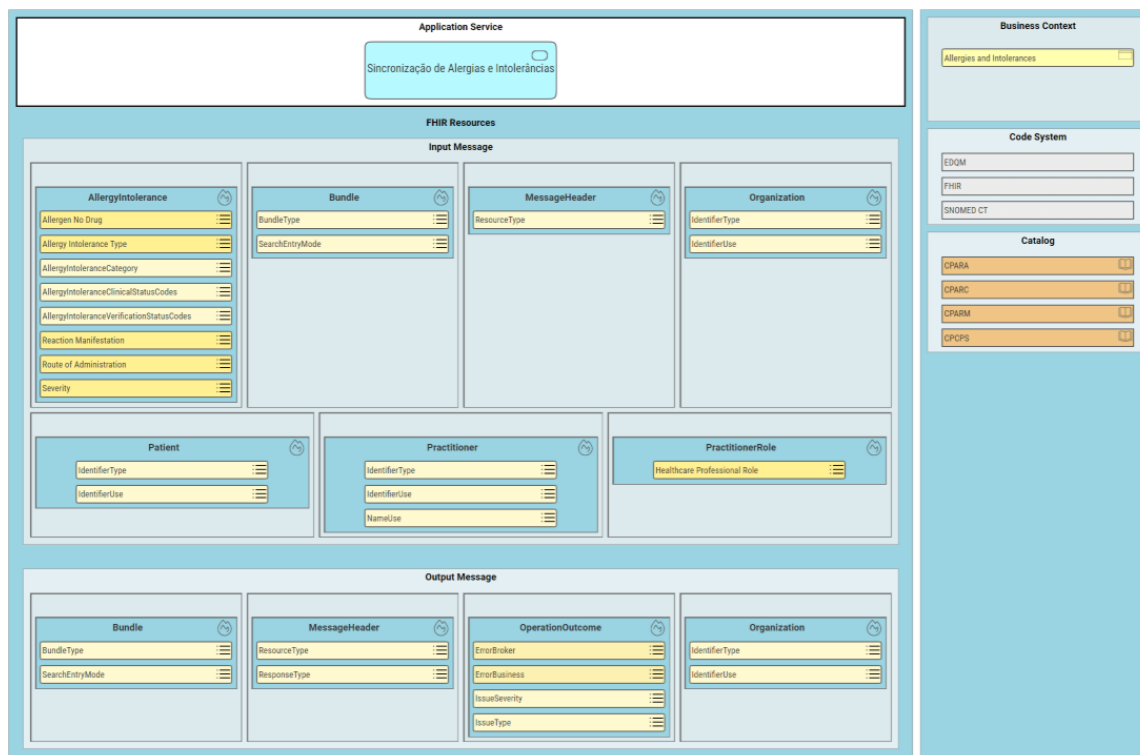


Figure 2.7 Implementation guide for portuguese use cases – allergies and intolerances [4]

Furthermore, the eHN EU Patient Summary Guideline provides recommendations on the type of information that each IPS section should contain, as well as the terminologies to be used in each case. However, this document does not provide guidance on the cardinality of the elements. Another important aspect highlighted in the guideline is the language of the IPS. It specifies that the structured and coded content of the IPS should be made available to healthcare professionals in two languages: the language of Country A (the patient's country of origin) and a translation into the language of Country B (where the IPS is being accessed). If Country B's language is not available, the dataset may be provided in English [36].

2.3.4 European and National Context

The successful adoption and implementation of the IPS depends not only on technical standards but also on the broader policy and organizational context. Accordingly, several initiatives and projects in both EU and Portugal aim to promote the implementation of the IPS, ultimately contributing to its adoption on a European scale.

The IPS originated from initiatives led by the EU such as epSOS. This project, which lasted from 2008 to 2014, tested the cross-border sharing of essential clinical data for unplanned care and electronic prescriptions. These efforts were expanded towards global interoperability and led to projects such as Trillium Bridge (2013–2015) and Trillium II (2017–2019). Additionally, since 2015 the IPS has been recognised by the JIC and promoted by major standards development organisations such as HL7, CEN, IHE, ISO, and SNOMED International [20].

2.3.4.1 MyHealth@EU

Currently, in the EU, there is the MyHealth@EU, also known as eHealth Digital Service Infrastructure – eHDSI, an infrastructure that aims to ensure the continuity of care for European citizens when travelling in the EU. Launched in 2014, it aims to enable Member States to exchange health information in a secure, efficient and interoperable way [46].

Since 2020, Portugal has participated in the initiative, sharing information on the Patient Summary (as discussed in the next chapter) and ePrescription. The SPMS has been the national representative [47].

2.3.4.2 European Health Data Space (EHDS)

The EHDS Regulation aims to establish a framework for the use and exchange of health data across the EU. It enhances individuals' access to and control over their personal electronic health data, while also enabling certain data to be reused for public interest, policy support, and scientific research purposes [48].

In March 2025, the EHDS was officially published, making the beginning of the transition phase towards its application. The IPS forms part of this regulation and is scheduled to become applicable in all EU Member States from March 2029 [48].

2.3.4.3 The Portuguese Case

In Portugal, it is already possible for both citizens and healthcare professionals to access the IPS. However, the available information currently only reflects data recorded within the public health sector [24].

Currently, the Portuguese IPS can be shared with the following countries: Croatia, Luxembourg, Malta, France, Czech Republic, Spain, the Netherlands, Estonia, Latvia, and Ireland [24]. Additionally, Portugal can receive and use IPS documents produced in Malta, Croatia, the Czech Republic, Spain, Estonia, Luxembourg, and Latvia [24].

Furthermore, SPMS is developing the RSEu, which will serve as a digital platform for sharing Portuguese citizens' health information (currently dispersed across various public, private, and social healthcare providers) thus initiating alignment with the EHDS Regulation [2].

To support this objective, SPMS has published an Implementation Guide for the Portuguese IPS use case. At present, guidance is available only for the “Immunisations” and “Allergies and Intolerances” sections [5].

2.3.5 Value, Facilitators and Barriers to the IPS Implementation

There are several advantages and value in implementing the IPS, including:

- **Improved quality of care:** findings indicate that the use of the IPS contributes to improved quality of care and a reduction in healthcare disparities. Notable improvements were observed in medication reconciliation and immunization, along with a decrease in care variance. Further findings highlight

various aspects of quality improvement, such as the avoidance of repeated imaging, a reduction in unnecessary laboratory tests, diminished time required to deliver care and a decrease in medication errors [49].

- **Reduced healthcare costs:** this reduction is attributed to a decrease in unnecessary imaging and other medical procedures. Also, the reduction in length of stay has indirectly contributed to lowering the overall healthcare cost incurred during hospitalization [49].
- **Hospital readmission rate:** the reduction in hospital readmissions is attributed to the availability of comprehensive health information and improved access to patient information. Although variations in readmission rates were reported in different studies, the overall findings suggest a clear correlation between the utilization of information exchange and a reduction in hospital readmission rates [49].
- **Health record completeness:** the adoption of the IPS contributed to the seamless exchange of patient data between different healthcare settings, ensuring that health records were comprehensive and consistent across care providers. This contributed to a more comprehensive health record, facilitating better communication among healthcare providers, and reducing the chances of critical information being overlooked or misinterpreted [49].
- **Improved patient safety:** the use of the IPS and interoperable EHR-to-EHR data sharing has been shown to be safer compared to other methods of information exchange, such as email. Although some studies suggest a likely positive impact on patient safety, the evidence remains inconclusive [49].
- **Improved communication among healthcare providers:** improved communication among healthcare providers is a direct and valuable outcome resulting from the successful implementation and adoption of patient information exchange systems. Additionally, the exchange of information contributed to better care coordination [49].

Despite the proven advantages and value of implementing the IPS, significant barriers to its adoption remain. This is partly due to the fact that, although the IPS is a simple technology when considered in isolation, its complexity arises from the need to approach it holistically [25]. A few of the challenges faced when implementing the IPS include the harmonisation of international standards, the safeguarding of patient data privacy and security and the level of interoperability between heterogeneous systems [49].

The main challenges identified can be divided into technical, organisational and regulatory. Looking at the technical challenges, semantic and technical interoperability are complex due to the diversity and complexity of existing standards, as well as difficulties in data transformation and conversion. Regarding the organisational perspective, they include stakeholders' resistance to change and the absence of coordinated governance or clear implementation guidelines. Finally, in the regulatory domain, the major difficulties are related with privacy, data security and compliance with GDPR regulations in cross-border contexts [20].

To address the challenges mentioned above, there are several strategies that can be adopted. For example, the use of open-source technologies and modular infrastructure based on microservices and RESTful APIs facilitate system integration and technical interoperability [20].

Regarding the semantic domain, although different parts of the world will encode health data differently, the IPS establishes guidelines for which terminologies should be used [3]. These terminologies include SNOMED-CT, and LOINC, along with the use of automated terminology mapping services, have been widely recommended [20].

At the organizational level, strategies such as coordinated and participatory governance aligned with strong stakeholder engagement can improve the implementation of IPS [20]. Additionally, funding was identified as a critical facilitator for the IPS adoption, ensuring an effective implementation process. The expectation of reduced costs over time positions IPS as a financially viable option for healthcare organizations [49].

Regarding the regulatory domain, the application of concepts such as Privacy and Security by Design, along with the compliance with GDPR can diminish the concerns regarding this topic [20].

Finally, it is important to mention that the successful adoption of the IPS depends not only on technology but also on integrated governance and collaboration among diverse stakeholders. Governmental institutions, universities, hospitals, and private sector organisations must be coordinated to overcome technical, regulatory and cultural barriers, leading the effective implementation of the IPS [20].

2.4 European Health Data Space (EHDS)

The EHDS, established by Regulation (EU) 2025/327, aims to ensure that natural persons have immediate, free-of-charge, and secure access to their personal electronic health data, thereby enabling them to exercise enhanced rights of access, rectification, portability, and selective sharing. In addition, its applications encompass the utilisation of electronic health data in research, innovation, policymaking, health threats preparedness and response, including the prevention and management of future pandemics, patient safety, personalised medicine, official statistics and regulatory activities [50].

The EHDS focuses on the primary and secondary use of healthcare data. However, it also ensures rigorous safeguards to uphold data protection, security, and ethical use, in line with the General Data Protection Regulation (GDPR). The regulation enables natural persons to opt out of the secondary use of their data, while allowing Member States, under strict conditions, to override such opt-outs for pressing public interest purposes, such as epidemic response or rare disease research [50], [51].

In order to operationalise the EHDS, Member States are mandated to establish national digital health authorities and health data access bodies. These entities are responsible for the enforcement of the Regulation, the facilitation of interoperability, and the enablement of the secure and lawful exchange of health data through dedicated infrastructures, such as MyHealth@EU for primary use and HealthData@EU for

secondary use. It is evident that both infrastructures have been meticulously designed to facilitate cross-border healthcare services [50].

At present, the number of Member States supporting the sharing of patient summaries and ePrescriptions via MyHealth@EU stands at eleven (data from 2024). However, there are plans for almost all Member States to join MyHealth@EU in 2025. The commencement of exchanges under the EHDS is scheduled for all Member States in 2028, with the addition of further data categories planned for 2030 [51].

In order to transform the EHDS into a tangible entity, it is imperative that further digitalisation is initiated at the national level. Accordingly, the European Commission will allocate a budget of over €810 million to support the EHDS. A budget of €280 million has been allocated for the EU4Health Programme, with the remaining financial requirements to be covered by the Digital Europe Programme, the Connecting Europe Facility and Horizon Europe [51].

Moreover, the Regulation establishes mandatory self-certification schemes for EHR systems, with the objective of ensuring conformity with interoperability, security, and logging requirements. The mandatory conformity self-assessment, which would be in the form of an EU declaration of conformity by the manufacturer, should ensure that those requirements are fulfilled in a proportionate way, while avoiding an undue burden on Member States and manufacturers [50].

The EHDS is indicative of the EU's broader vision for a resilient and patient-centred digital health ecosystem. The EHDS has been developed to harmonise standards and governance structures, and to embed ethical and security considerations into every stage of data handling. The implementation of these measures is intended to position the Union at the forefront of global digital health governance.

2.5 *Registo de Saúde Electrónico Único (RSEu)*

The SPMS is currently leading the development of a unified Electronic Health Record (*Registo de Saúde Electrónico Único* – RSEu) in Portugal, as part of the national digital health transformation agenda. This initiative, integrated into the Health Digital Transition Programme of the Recovery and Resilience Plan, allocates €300 million to the advancement of digital health infrastructures, with SPMS responsible for its definition and implementation [52].

The RSEu aims to aggregate and share information regarding the health of Portuguese citizens. One of the objectives of the initiative is to consolidate and index fragmented health data. Currently, these data are dispersed across a variety of institutions in the public, private and social sectors, and consolidation facilitates a comprehensive and patient-centred view of individual health records. Moreover, the objective of this project is to enable citizens to access their health information, manage permissions regarding who can access their data and under what circumstances, and to add information directly to their health records through self-reporting functionalities. These objectives are in alignment with the principles of the European Health Data

Space (EHDS), approved in April 2024 by the European Parliament [7].

The realisation of this vision is contingent upon the establishment of interoperability. Consequently, SPMS has initiated a public consultation on a set of Interoperability Technical Specifications with the objective of harmonising and standardising data exchange processes. This step signifies a fundamental endeavour to consolidate heterogeneous information systems, thereby ensuring seamless communication irrespective of the delivery setting [52].

The establishment of national interoperability mechanisms by the RSEu is in alignment with broader European strategies to enhance digital health services, supporting both primary and secondary uses of health information.

2.6 Privacy and Security

In the context of contemporary, integrated personalised healthcare systems, the quality of information is of critical importance. Furthermore, patients have been found to place a significant degree of trust in healthcare providers with regard to the security and confidentiality of their clinical data. It is imperative that the stipulated requirements for safeguarding patient privacy are adhered to with rigour [1].

A number of regulatory acts have been created with the objective of ensuring the privacy and security of individuals' data. In the United States, the Health Insurance Portability and Accountability Act (HIPAA) exists with the purpose of ensuring the rights of individuals, including the right to access their health records and request a copy of their data. The General Data Protection Regulation (GDPR) was implemented in the European Union in May 2018. This legal framework governs the processing of personal data and the protection of privacy in the digital age [2].

In accordance with the provisions stipulated within the GDPR, healthcare-related information is classified as a special category of personal data, necessitating heightened protection. Processing of such information is permitted exclusively for health-related purposes, and only when it is deemed necessary to achieve the intended objectives, benefiting both individual persons and society as a whole [53].

In order to be compliant with the GDPR, it is incumbent upon institutions to implement privacy by design and privacy by default. Privacy by design is the concept that concerns regarding privacy should be considered throughout the entire process of creating or contracting a product, service or project. Privacy by default is defined as the mechanism of ensuring that only the necessary amount of personal data is collected, used and stored for each task, both in terms of the amount of data collected and the time for which it is kept (minimisation, pseudonymisation and transparency) [54].

The advent of the GDPR has resulted in the establishment of novel legal entitlements for individuals, including the right to [54]:

- Strengthening data subjects' right to information and access: the data subject is entitled to be informed of

the parties who will process their data and/or to whom it will be transmitted.

- Right to be forgotten: implies that, when confronted with a request to erase data, organisations employ mechanisms to guarantee that the data in question has been fully deleted, including any copies or reproductions.
- The right to restriction of treatment: the data subject can oppose the erasure of their personal data and request, in return, that the processing of their data be restricted.
- The right to data portability: the data subject has the right to receive personal data concerning themselves in a structured, commonly used and machine-readable format.
- Pseudonymisation and encryption of personal data.

Furthermore, the GDPR stipulates that institutions are obligated to ensure the continuous confidentiality, integrity, availability and resilience of their processing systems and services. In the event of a physical or technical incident, they are required to restore availability and access to personal data in a timely manner. Moreover, institutions are expected to implement a process for the regular testing, assessment and evaluation of the effectiveness of technical and organisational measures, with the aim of guaranteeing the security of data. In the event of a data breach, institutions are required to notify the *Comissão Nacional de Proteção de Dados* (CNPD) in Portugal [54].

Additionally, the GDPR stipulates the appointment of a Data Protection Officer (DPO) within institutions. The responsibilities of a DPO include monitoring compliance with personal data protection rules, managing and recording all relevant documentation, and regularly monitoring projects that have an impact on privacy [54].

A survey conducted among OECD countries has revealed that a variety of approaches have been adopted by these nations to ensure security. The most prevalent method employed is data encryption, a technique utilised in 14 out of 27 countries (namely, Australia, Canada, the Czech Republic, Hungary, Iceland, Israel, Italy, Japan, Korea, Luxembourg, Portugal, Slovenia, Switzerland and the United States). Conversely, Denmark employs a digital signature to facilitate access and utilizes a secure network for data exchange. In Lithuania, eHRs are signed by public key infrastructure (PKI) certificates. In the Netherlands, access to the network of the National Exchange Point is subject to stringent restrictions. For instance, providers are required to utilise a designated ID-card and password for authentication [14].

In the context of a healthcare system that is becoming increasingly digital and data-driven, it is imperative that the effective implementation of health information systems and electronic health records is accompanied by robust mechanisms that ensure data security, interoperability, and user trust. As healthcare systems evolve towards more integrated and personalised models of care, the alignment of technological, regulatory, and ethical dimensions will be fundamental to realising the full potential of health information systems in supporting safe, effective, and person-centred healthcare.

2.7 Usability

ISO defines usability as the extent to which a system, product or service can be used by specified users to achieve specific goals with effectiveness, efficiency and satisfaction in a specified context of use [55].

According to Nielsen, usability can be measured by five criteria [56]:

- **Learnability:** the ease with which simple tasks can be performed when encountering a design for the first time. For an interface to be considered as having learnability, the design must be easy to understand, easy to find specific information in and easy to identify the navigational mechanisms.
- **Efficiency:** measures the speed with which a task is completed after studying the design. This factor has indicators that can demonstrate that an application has met the efficiency criteria, such as providing quick access to information and easy navigation.
- **Memorability:** measures how quickly the user regains proficiency when returning to the design after some time.
- **Few error detections:** measure how many mistakes the user made, how severe the errors were and how easy they were to resolve.
- **User satisfaction:** measures the level of satisfaction experienced when using the design. This factor has indicators that the system is pleasant to use and does not burden the user.

Currently, doctors spend almost half of their working day using EHRs, which includes over one-third of their time in the examination room while delivering care. It is imperative that healthcare professionals adapt to using systems with complex interfaces, which have the potential to increase the number of tasks and decrease the efficiency of accomplishing these tasks. This ultimately leaves healthcare professionals at the mercy of EHR design flaws. Moreover, the pervasiveness of the EHR in mediating clinical tasks signifies that even minor inefficiencies or design flaws in EHRs can exert a substantial influence on clinical workload [57].

As is evident in research, issues concerning the usability of health information systems are well documented. While electronic health systems represent an improvement on paper-based systems, healthcare professionals have expressed frustration with the level of usability of these systems [55]. It has been suggested that these usability issues have a harmful effect on healthcare professionals and may be a contributing factor to clinician burnout [58].

In addition to the impact on healthcare professionals, usability problems may negatively affect patients. There is evidence that suggests that the poor design of health IT is linked to patient safety consequences. For instance, a study [58] reported that 36% of medication safety events in paediatric hospitals were associated with EHR usability issues, such as inadequate system feedback and poor visual information display.

Alarming, 19% of these events had the potential to result in patient harm. A similar set of findings from intensive care units has revealed several preventable adverse drug events related to EHR technology. These events include incomplete orders and duplicate medication entries. These examples emphasise the critical need for user-centred design approaches that prioritise both clinical workflows and patient safety [58].

The development of systems with high usability is of critical importance. This approach ensures that such systems are not only functionally robust but also effectively support clinicians in delivering safe, efficient, and patient-centred care.

2.8 Summary

This chapter has examined the critical role of HIS in the actual healthcare landscape, also focusing on the interoperability of EHR as a foundation for integrated, efficient, and patient-centred care. The importance of the utilisation of international standards and terminologies, including but not limited to HL7, FHIR, SNOMED CT, and LOINC, to ensure semantic consistency and system interoperability was outlined.

The IPS has been identified as a facilitator for cross-border health data exchange, with a positive impact on quality of care, cost reduction and patient safety. The chapter proceeded to contextualise these findings with two initiatives, one in the European landscape (EHDS) and the other at the national level (RSEu).

Finally, the significance of privacy and security mechanisms under the GDPR was highlighted, with emphasis placed on the necessity of user-friendly systems to alleviate clinician burden and facilitate safe healthcare delivery.



Development of the Conceptual Design

3. Development of the Conceptual Design

This chapter delineates the methodology employed and the outcomes of the development of the conceptual design for a module intended to enhance the registration and visualisation of patient information. The objective of this module is to facilitate the creation and maintenance of a comprehensive, longitudinal health record that enables the continuous updating of patient data and the generation of an IPS.

In order to ensure that the conceptual design is grounded in real-world practice and responds to the needs of its users, this chapter commences by identifying the key stakeholders involved in the health information ecosystem. The following section discusses the user research that was conducted. This research was employed a mixed-method approach, incorporating semi-structured interviews and a survey. The objective of this approach was to ascertain the needs and perspectives of stakeholders with regard to the current limitations and future improvements of EHR systems.

Subsequent sections of this chapter describe the development of user personas based on research findings. These are followed by a benchmarking analysis of existing EHR solutions. The aim of this analysis is to identify patterns and design strategies that could be used in the conceptual design.

Following there is presented a comprehensive specification of functional and non-functional requirements, accompanied by the construction of use cases, user stories, and UML diagrams. In conclusion, a concise explanation is provided concerning the mockups and prototyping process, in addition to an exposition of the evaluation conducted on the non-functional prototype.

The integration of stakeholder perspectives, benchmarking insights, and formal modelling techniques is a key aspect of the chapter's approach. This integrated approach provides a foundation for designing a module that is informed by user needs, promoting continuity of care, enhance clinical decision-making, and support semantic and structural interoperability within a unified health information framework.

3.1 Stakeholders

When designing an application with the aim of serving as a repository of patient information and providing an IPS, there are a number of stakeholders that should be taken into consideration.

The primary use stakeholders are the individuals who are directly involved in the origination, exchange and

use of the application for the purpose of healthcare delivery. These include[16], [35]:

- Healthcare professionals: they fulfil two distinct roles in the context of patient summaries and repositories of patient information. Firstly, they are users of these summaries and repositories, and secondly, they add information. It is expected that the application facilitates the addition and editing of information, as well as the consultation of information previously entered into other applications. It is anticipated that interfaces will be straightforward to utilise.
- Healthcare provider organisation: where the responsibility for the procurement, implementation, and maintenance of EHR lies, as well as the determination of the data to be captured and the modalities of its dissemination. It is expected that data security will be guaranteed and that different systems can communicate and exchange information.

There are other stakeholders that enable, support or regulate the direct use of patient summary, such as:

- Vendors of EHR: are incumbent to provide functionalities necessary to capture, generate, share, request, validate, and incorporate patient summary data across the various workflows within their systems.
- Government organisations: have the capacity to adopt the use of patient summary data within the framework of their policies. They can also guide and finance the implementation of patient summary data by healthcare provider organisations. Furthermore, government organisations are able to regulate the market for EHR systems in such a manner as to include the ability to share and use patient information.

To summarise, there are a number of stakeholders involved in the ecosystem. This ecosystem is inherently multi-layered, and consequently requires continuous dialogue and collaboration among technical, clinical, regulatory, and civil society actors.

3.2 User Research

This section presents the mixed-method approach that was used to conduct user research. Semi-structured interviews and a user survey were carried out to explore the practical needs of healthcare professionals and IT stakeholders regarding the registration and visualization of patients' health data.

3.2.1 Semi-Structured Interviews

Semi-structured interviews are a data collection method in which an interviewer asks the participants questions, guided by an interview script mainly composed of open-ended questions, aligned with the research objectives [59].

The interview script is designed to provide structure to the natural flow of conversation, allowing the discussion to remain focused but still give the researcher the flexibility to explore relevant ideas that may arise during the interview. This level of depth and adaptability is not achievable through quantitative methods alone, however, in

a mixed-method approach, semi-structured interviews can enhance the understanding of quantitative data [59].

Additionally, semi-structured interviews are suitable for exploring complex social and behavioural research questions. These may include assessing whether a proposed service is needed, how it should be implemented in practice, and how different stakeholders—such as healthcare professionals or IT professionals—perceive and interact with that service [59]. Given their potential to generate in-depth insights and complement quantitative findings, semi-structured interviews were chosen as a method to collect qualitative data.

3.2.1.1 Semi-Structured Interviews Design and Implementation

Two types of semi-structured interviews (script available in annex 6.2) were conducted, one focused on healthcare professionals and the other on IT professionals with experience in the field of health informatics. The semi-structured interviews aimed to gather qualitative information and had three main objectives:

- Identify the needs, challenges, and preferences of healthcare professionals and health IT professionals regarding access/management of a patient's medical records.
- Determine the essential features and functionalities needed to support continuous data updates and provide a holistic view of patient data.
- Validate the concept of an EHR module that facilitates the visualization and registration of patient information, enables continuous data updates, provides a holistic view of the patient's health status, and supports interoperability.

When defining the study sample, there should be a balance between representing individuals with the most knowledge of the subject matter and those who can provide different perspectives, within the limits of available resources [59].

Regarding the sampling approach, non-probability sampling was used, more precisely purposive sampling. This decision was because non-probability sampling is the approach most frequently used in qualitative data since generalizability is not the purpose; and purposive sampling allows the selection of participants based on meeting certain criteria of interest [59]. Accordingly, the participants' selection aimed to ensure a multidisciplinary perspective on health data access and clinical workflow needs.

Eight semi-structured interviews were carried out between the 21st of December of 2024 and the 18th of January of 2025. The participant group included three nurses, two physicians, one pharmacist, and two IT professionals working in the informatics department of two Portuguese hospitals.

The semi-structured interviews were conducted via remote video conferencing, with each session lasting approximately 30 minutes. The interviews were guided by a pre-defined set of open-ended questions and were recorded, with the participants' consent, for subsequent transcription and analysis. Any identifying information was removed from the transcript to ensure confidentiality [59].

3.2.1.2 Semi-Structured Interviews Results

Interviews with healthcare professionals revealed several challenges and requirements relating to the current EHR landscape. One of the concerns reported was the amount of time spent documenting patient information. Also, participants reported that there were cases where the same data had to be entered into multiple systems. For example, professionals working in community care (Equipa de Cuidados Continuados Integrados) described having to register information in both SClínico and JustCare (list of applications mentioned during the semi-structured interviews available in the annex 6.1). It was noted that this redundancy consumes valuable time and increases the administrative burden on clinicians.

The fragmentation of patient's information across various applications was another issue raised by the participants. It was mentioned that healthcare professionals often need to access multiple systems to have a comprehensive understanding of a patient's health status. Frequently, due to time constraints during consultations and high workloads, professionals are unable to retrieve all the necessary information, leading to, for example, duplicate diagnostic test requests. While participants acknowledged that electronic records offer greater accessibility than paper-based systems, they also emphasised that the current EHR landscape needs to be improved in terms of interoperability and user-friendly interfaces.

Access to information from the private sector was identified as a particular challenge for professionals working in the public sector. Participants also reported difficulties in contacting other healthcare professionals involved in the care of the same patient who are based in different institutions. For example, it was mentioned that there is often no direct way to contact the physician responsible for a patient in another hospital or unit, which can delay coordinated care efforts.

Healthcare professionals widely recognised the potential benefit of a unified application that consolidates all relevant patient information in a single interface, however, they also expressed concerns about data privacy and security.

Regarding the two health IT professionals interviewed, the participants revealed divergent opinions. One participant emphasised the need for a single application through which healthcare professionals could access all the patient information they need. It was mentioned that several applications had been developed to address this issue but none had fully resolved the problem with fragmented information sharing. In contrast, another IT professional argued that many of these problems are already mitigated by existing solutions, such as the PCE.

Collectively, these interviews underscore the need for an integrated, interoperable EHR module that centralises patient information, supports seamless collaboration among professionals and institutions, and upholds the highest standards of data protection and privacy.

3.2.2 Surveys

Survey research is a type of research that uses statistical data to study a group of people and how they feel, think and/or act, based on the idea that the characteristics of the sample (participants) can be generalized

to the whole population [60].

The use of questionnaires has several advantages, some of these are the ability to collect data from many people, lower cost and faster implementation when compared to other methods. Also, it allows the researchers to collect information about people's feelings and pain points using numerical data [60].

Despite the advantages of this method, there are some disadvantages such as the need for a large sample of participants to guarantee the proper representation of the population. Additionally, there is a risk of lacking depth and failing to capture participants' nuanced interpretations. However, this risk was mitigated using a mixed-method approach and the conduct of semi-structured interviews prior to the survey [61].

3.2.2.1 Survey Design and Implementation

To identify the functionalities healthcare professionals consider crucial in an app designed to consult and add information regarding patients' medical history, a survey was conducted.

The survey was conducted following a series of semi-structured interviews. The insights collected from the interviews were employed in the questionnaire, to ensure that the questions covered the most relevant topics identified by the participants. Using a survey after semi-structured interviews allowed the validation of the initial insights gathered from them and to ensure that the visions of the participants were generalizable and applicable to a wider audience.

The survey (available in annex 6.3) aimed to gather quantitative data and had 2 main objectives:

- Identify the needs, challenges and preferences of healthcare professionals regarding patient information access and management (questions 7 to 12 of the questionnaire).
- Determine the features that healthcare professionals consider relevant for the app (questions 13 to 15 of the questionnaire).

The survey was directed at healthcare professionals and also collected information regarding the participants' professional backgrounds to contextualize the responses according to their roles and fields of work (questions 1 to 6 of the questionnaire).

The survey was conducted using Google Forms and distributed electronically to healthcare professionals who work in diverse roles, specialties and contexts, including hospitals, primary care and private sector. Participation was voluntary and all responses remain anonymous.

3.2.2.2 Survey Results

A total of 115 participants answered the survey. There were 108 valid responses considered based on the inclusion criterion that only healthcare professionals should complete the questionnaire. The sample included 80 nurses, 18 doctors, 2 physiotherapists, 3 psychologists, 3 pharmacists, 1 cardiopneumologist and 1 radiology

technician. The participants came from a variety of fields and specialities. Within the doctor group, specialities varied from anaesthesiology, endocrinology, general practice, oncology, paediatrics, and psychiatry. In the nursing group, 31% of respondents reported not holding a speciality, while 12.5% held a specialisation in medical-surgical nursing. Regarding the pharmacists, 1 participant was specialised in hospital pharmacy and the other 2 were from the community pharmacy sector.

Most of the participants worked in a hospital, and 43% had 10 or more years of experience.

Additionally, most of the participants used several softwares for registration and/or consulting patients' information, with 4% using more than 5 applications, 14% used 4 to 5, 51% used 2 to 3, 28% used only 1 application and with 3% using none.

Part of the survey used a Likert scale with five levels, where participants could report on the availability of patients' information. When asked whether healthcare professionals could find all the information they needed about a patient, 47% responded that they disagreed or strongly disagreed, while 21% agreed or totally agreed. Furthermore, 64% of professionals reported that they agreed/totally agreed with the statement "I have difficulty accessing patient information registers in other healthcare facilities within the same organisation", indicating that this problem occurs not only in the exchange of information between public and private sectors. Also, 94% of professionals reported that they agree or strongly agree with the statement "I would like to be able to consult the entire clinical trajectory of a patient more efficiently", with no one responding that they disagree or totally disagree.

A multiple-choice question was presented in relation to the types of information and functionalities that healthcare professionals would like to have. Respondents were able to select predefined options and suggest additional functionalities. The insights gathered during the interview phase were displayed as options.

The most common answers regarding the information that healthcare professionals consult the most during their workday were active problems (80%), medical history (75%), nursing records (65%) and clinical notes (65%).

When asked what information they would like to see summarised in a patient's notes, 93% of healthcare professionals said active problems, 88% said medical history, 85% said medication summary and 83% said allergies and intolerances.

In terms of functionalities, 68% said they wanted to be able to access information independently, regardless of whether it was registered in the public or private sector. Meanwhile, 66% said they wanted to be able to filter information by specialty, and 63% said they wanted to be able to access a patient timeline containing active problems and medical history.

These results are consistent with the information collected during the interview process, thereby confirming the need to improve information exchange and ensure comprehensive patient summaries are available. The opinions regarding functionalities were also considered when designing the application.

3.3 User personas

For user-centred design and design thinking processes to be effective, it is essential to transform the abstract concept of “user” into a person with thoughts and emotions. User personas are essential for achieving this goal [62].

A user persona represents the user and their goals, needs and pain points and defines the target users who will use the system. Designing a product based on user personas helps to meet the requirements of a wider range of users with similar goals [63].

For this reason, a set of user personas was designed. Due to time constraints and the multiple user personas that could be implemented, the ones with profiles similar to those of the participants interviewed and with more participants in the survey were chosen: doctors, nurses, pharmacists and psychologists. In addition to the information collected through interviews and surveys, literature was also used to construct these user personas [16], [64], [65].

Table 3.1: User personas

User Persona	Requirements
Doctor	Profile - Dr Ana Silva is a Pneumologist working in an inpatient respiratory unit and in outpatient consultation. Goals - Diagnose, monitor and manage patients with chronic respiratory conditions. Pain Points - Fragmented access to clinical information, leading to time-consuming searches. - Limited visibility of patient history. Needs - A holistic overview of the patient’s respiratory history, including tests, medications, and relevant lifestyle factors. - Access to structured data relevant to chronic disease management.
Nurse	Profile - Nurse Maria Rocha specialises in rehabilitation and works in a community team. Goals - Monitor and document the health status and evaluation of a patient. - Contribute to multidisciplinary care plans, providing information to other specialties about patient evolution and needs. Pain Points - Duplicated records. - Difficulty contacting other specialists who are treating the patient. Needs - Access to a shared and updated care plan, including interventions from other professionals. - Access to information about a patient's social context and medical history.
Pharmacist	Profile Pharmacist José Silva, who specialises in hospital pharmacy, works in a hospital.

	Goals • Ensure patient safety by reviewing and validating prescriptions. Pain Points • Incomplete access to information about a patient's medical summary. Needs • Real-time access to an up-to-date and comprehensive medication profile. • Traceability of therapeutic adjustments made in other care settings.
Psychologist	Profile • Psychologist Cláudia Sousa is a psychologist who works in private practice. Goals • Deliver individualised care to patients based on their clinical history. Pain Points • Limited access to patients' clinical records from other practices or institutions. Needs • Secure access to patient information. • Ability to contribute to the patient's health record.

3.4 Benchmarking

The benchmarking process was conducted through an analysis of EHR systems, with the objective of identifying practices and design strategies applicable to the development of the proposed application. The data collection process combined the review of official technical documentation, observation of system demonstrations and direct exploration of system functionalities (the figures presented in this section that contain names are derived test cenarios, most of which are available in videos or official documentation released by the provider).

The applications analysed included Cerner, EPIC, *Processo Clínico Eletrónico* (PCE), *Visão Clínica Integrada* (VCI), *Registo de Saúde Eletrónico* (RSE) and *Portal SNS24*. The latter mentioned, although it is intended for patient use, was also analysed since it enables the access to the IPS and includes examples of patient timelines – features that are reflected in the modules designed for the proposed system.

3.4.1 Patients Lists

The analysis explored whether any of these systems had the functionality of a patient list that would allow healthcare professionals to see information regarding multiple patients. Based on the available information, Cerner and Epic provide this functionality, and, in addition, they allow healthcare professionals to create customised patient lists. For example, it was possible to choose which columns were displayed, their order and apply filters to different types of patient information.

Location	Name	Length of Stay	MRN	FIB	Age	DOB	Admitted	Admitting Physician	Visit Reason	Primary Care Physician
2C CVH 2304 0	TEST, NEWMERGE ONE JANE	109.7 Days	64002090	1200289389	56 years	01/01/61	05/23/17 20:00	CDT Sanders MD, Michael Lawrence	TESTING MERGE ACCOUNTS	Sanders MD, Michael Lawrence
2C CVH 2311 0	TEST, NOT IN DIRECTORY	48.0 Days	64002920	1200290626	47 years	05/19/70	07/20/17 12:43	CDT Sanders MD, Michael Lawrence	testing directory	Sanders MD, Michael Lawrence
2E Card Intern 2416 0	MERGE, TWO TEST	36.9 Days	64003273	1200291099	96 years	09/02/23	07/31/17 16:04	CDT Sanders MD, Michael Lawrence	HEAT STROKES	Sanders MD, Michael Lawrence
2E Card Intern 2420 0	UCTEST, CPABLINGCOMB	183.9 Days	64003205	1200289116	8 years	10/24/90	03/06/17 15:00	CST Sanders MD, Michael Lawrence	headache	Sanders MD, Michael Lawrence
2E Card Intern 2422 0	PHARMDC, EIGHTYEAR	186.8 Days	64003243	1200289311	8 years	05/22/09	05/22/17 12:12	CDT Sanders MD, Michael Lawrence	pain	Sanders MD, Michael Lawrence
2E Card Intern 2425 0	TESTISOLATION, TELTRACING	23.0 Days	64003267	1200291091	87 years	01/01/50	08/24/17 12:02	CDT Sanders MD, Michael Lawrence	text	Sanders MD, Michael Lawrence
2E Card Intern 2431 0	ZZZTEST, TERRELLPORTER	146.5 Days	64003660	1200288736	68 years	01/01/49	04/12/17 15:11	CDT Sanders MD, Michael Lawrence	chest pain	Moulder MD, Rebekah Wilbourn
2N Cardiology 2212 0	MEDTEST, JR	79.2 Days	64002556	1200290166	41 years	09/24/75	06/18/17 09:15	CDT Sanders MD, Michael Lawrence	headache	Sanders MD, Michael Lawrence
2N Cardiology 2220 0	UCTEST, CPADFFECTTWO	100.9 Days	64003227	1200288188	25 years	10/14/91	03/09/17 13:10	CST Sanders MD, Michael Lawrence	CHF	Hays Jr, MD, James Clay
25 Telemetry 2502 0	DYNDCTESTING, DYNERORR	0.0 Days	64003569	1200291500	45 years	09/06/52	09/06/17 12:10	CDT Sanders MD, Michael Lawrence	test bedmaster	Sanders MD, Michael Lawrence
25 Telemetry 2503 0	BEDMASTERFOUR, EXCEL	14.0 Days	64003377	1200291262	47 years	05/19/70	08/23/17 13:25	CDT Sanders MD, Michael Lawrence	HIGH BP	Torrey MD, Brian Scott
25 Telemetry 2505 0	MEDSTAFF, PATIENTFOUR	13.9 Days	64003384	1200291268	52 years	08/23/65	08/23/17 15:06	CDT GuymerTEST, MD, Richard Dennis	chest pain	LayneTEST MD, Scott Christopher
25 Telemetry 2507 0	TESTJACKSON, HEART TRAINING	0.1 Days	64003108	1200291389	54 years	12/29/62	06/29/17 11:08	CDT GuymerTEST, MD, Richard Dennis	Donavon Testing	Sanders MD, Michael Lawrence
25 Telemetry 2509 0	BEDMASTER ONE, EXCEL	21.0 Days	64003314	1200291153	115 years	06/14/02	08/26/17 12:22	CDT Sanders MD, Michael Lawrence	chest pain	Sanders MD, Michael Lawrence
25 Telemetry 2514 0	AWESOMEDEUDONE, MEME	105.9 Days	64002066	1200289374	54 years	12/29/62	05/23/17 16:20	CDT Sanders MD, Michael Lawrence	abnormal lab	Sanders MD, Michael Lawrence
25 Telemetry 2515 0	POWERPLAN, TESTING	44.2 Days	64002951	1200290663	61 years	07/08/56	07/24/17 08:27	CDT Sanders MD, Michael Lawrence	nausea/vomiting	Sanders MD, Michael Lawrence
25 Telemetry 2516 0	BEDMASTER TWO, EXCEL	21.0 Days	64003316	1200291155	92 years	08/23/25	08/16/17 12:26	CDT Sanders MD, Michael Lawrence	renal failure	Sanders MD, Michael Lawrence
3E Renal/Urol 3403 0	QUALITYCONNECT, AMY	268.8 Days	64000472	1200287658	29 years	02/10/88	11/22/16 18:54	CST Sanders MD, Michael Lawrence	surgery	LayneTEST MD, Scott Christopher
3E Renal/Urol 3406 0	NURSING, RENAL	123.0 Days	64003354	1200289375	65 years	02/02/52	05/26/17 14:04	CDT Sanders MD, Michael Lawrence	back pain	Sanders MD, Michael Lawrence
3E Renal/Urol 3416 0	PHARMDC, THIRTEEN	106.9 Days	64002628	1200289277	53 years	05/23/04	05/22/17 14:53	CDT Sanders MD, Michael Lawrence	chest pain	LayneTEST MD, Scott Christopher
3E Renal/Urol 3427 0	TEST, DIANNA	30.2 Days	64003160	1200290920	61 years	06/15/56	08/07/17 07:41	CDT Sanders MD, Michael Lawrence	HIGH FEVER	Sanders MD, Michael Lawrence
35 PostOp Surg 3502 0	QUALITYCONNECT, OMNICELL ONE	200.9 Days	64000575	1200287187	43 years	06/10/74	11/28/16 13:33	CST Sanders MD, Michael Lawrence	pain	Sanders MD, Michael Lawrence
35 PostOp Surg 3503 0	QUALITYCONNECT, SENTRI SEVEN	200.9 Days	64000576	1200287188	71 years	05/10/46	11/28/16 13:46	CST Sanders MD, Michael Lawrence	testing	Sanders MD, Michael Lawrence
35 PostOp Surg 3505 0	QUALITYCONNECT, ORDERS	28.0 Days	64003210	1200291003	41 years	08/15/76	08/09/17 14:01	CDT Sanders MD, Michael Lawrence	HEAT STROKE	Sanders MD, Michael Lawrence
35 PostOp Surg 3512 0	PHARMDC, ONEMONTH	106.9 Days	64002036	1200289284	4 months	04/22/17	05/22/17 15:35	CDT Sanders MD, Michael Lawrence	pace maker checkup	Sanders MD, Michael Lawrence
3W-WICU 3616 0	NURSING, NEUROEAST	112.8 Days	64002973	1200289136	49 years	05/07/68	05/26/17 18:45	CDT Sanders MD, Michael Lawrence		
4E Med Surg 4402 0	TESTANGY, DONOTDISCHARGE	245.0 Days	64000761	1200287454	25 years	01/04/92	01/04/17 11:23	CST Sanders MD, Michael Lawrence		
4E Med Surg 4403 0	TEST, ALLERGY	111.0 Days	64002995	1200289229	22 years	05/02/95	05/28/17 13:47	CDT Sanders MD, Michael Lawrence		
4E Med Surg 4404 0	TESTMERGE, ONE	64.9 Days	64003272	1200291096	94 years	09/02/23	07/03/17 15:47	CDT Sanders MD, Michael Lawrence		
4E Med Surg 4407 0	WBTPATIENT, TESTFIVE	96.0 Days	64002316	1200289843	27 years	05/27/90	06/02/17 13:42	CDT Sanders MD, Michael Lawrence		

Figure 3.1 Patient list in Cerner



Figure 3.2 Customisation of the patient list in Cerner

Hyperspace - EMH MED SURG - TWSOURCEQA - SIDNEY A.

Epic Patient Lookup ED Track Board OR/Procedural Areas Clinical Calculator My Reports On-Call Finder

Patient Lists

Edit List Sign In Sign In Others Sign Out Pre-assign Pt Location Event Management Work List Flowcharts MAR Data Validate Bedside Tablet Status Patient Transport Assignment Wizard More

My Lists

- My Patients
- My Unit
- Shared Patient Lists

Available Lists

- Recent Searches
- Epic Hospital
- Preadmitted Patients
- Recently Discharged

My Patients 4 Patients Refreshed just now Search Current Locat.

Bed/Location	Patient	Problem	RN	Orders	Primary Contacts	Code	Infection/Isolation	Precaution	Unvali Pt-Rptd	Shift Doc	Discharge Med Rec Complete?	MEV
207-02	Olson, Ellie 11 y.o. / F	Appendicitis, acute (Principal Hospital Problem)			Martin Stich, MD - Attending (Tel. 555-555-5555)	F...						2
Med/Surg (131-02)	Warchol, Edward 60 y.o. / M	Renal insufficiency (Principal Hospital Problem)			Walt Whitecoat, MD - Attending (Tel. 555-555-5555)	F...						2
MS 150-1	Farzon, Ellen 18 y.o. / F	Asthma			Sam Stethoscope, MD - Attending (Tel. 555-555-5555)	Not on file						1
MS 150-1 (130-01)	Moran, Dennis 17 y.o. / M	Diabetes mellitus type 2, controlled (CMS-HCC)			Sam Stethoscope, MD - Attending (Tel. 555-555-5555)	Not on file						5

Select a patient to get started

Figure 3.3 Patient list in Epic

3.4.2 Summary

Regarding the Summary feature, it was observed that Cerner, VCI, and the SNS24 Portal support this functionality.

The SNS24 Portal was designed for patients' use but allows individuals to view their own Patient Summary, providing access to information such as medications, allergies, diagnoses, immunizations, surgeries and, medical devices.

In VCI, there are different types of clinical information available, such as alerts, allergies, prescribed laboratory tests and data from previous healthcare encounters. The sections are presented in a scrollable format, and the user has the possibility to access more detailed information from each section. Although some filters are available, customization options are limited (for example, in the diagnosis section, it is possible to filter diagnoses by the setting where they were registered – such as ambulatory care).

In Cerner, there are two types of patient summaries available: the “Ambulatory Summary” and the “Inpatient Summary.” The Ambulatory Summary is designed to provide an overview for professionals working in ambulatory settings, such as general practitioners, whereas the Inpatient Summary is tailored to meet the needs of professionals working in hospitalisation contexts. Each summary may contain distinct sections, and the user has the possibility to expand or collapse content, add new information and select which visit's information to view. Also, the user can access the menu related to the section by clicking on the section's title. Finally, there is limited scrolling in the patient summaries since the sections are displayed across three columns, allowing more information to be shown to the user without requiring scrolling.

Regarding the customization features in Cerner, users are able to choose the order of the sections, whether they appear collapsed or expanded by default and to adjust the colour scheme. In some cases, users may specify whether they wish to view data from a specific visit, all visits, or other defined time frames, although this level of customization is not available for all sections.

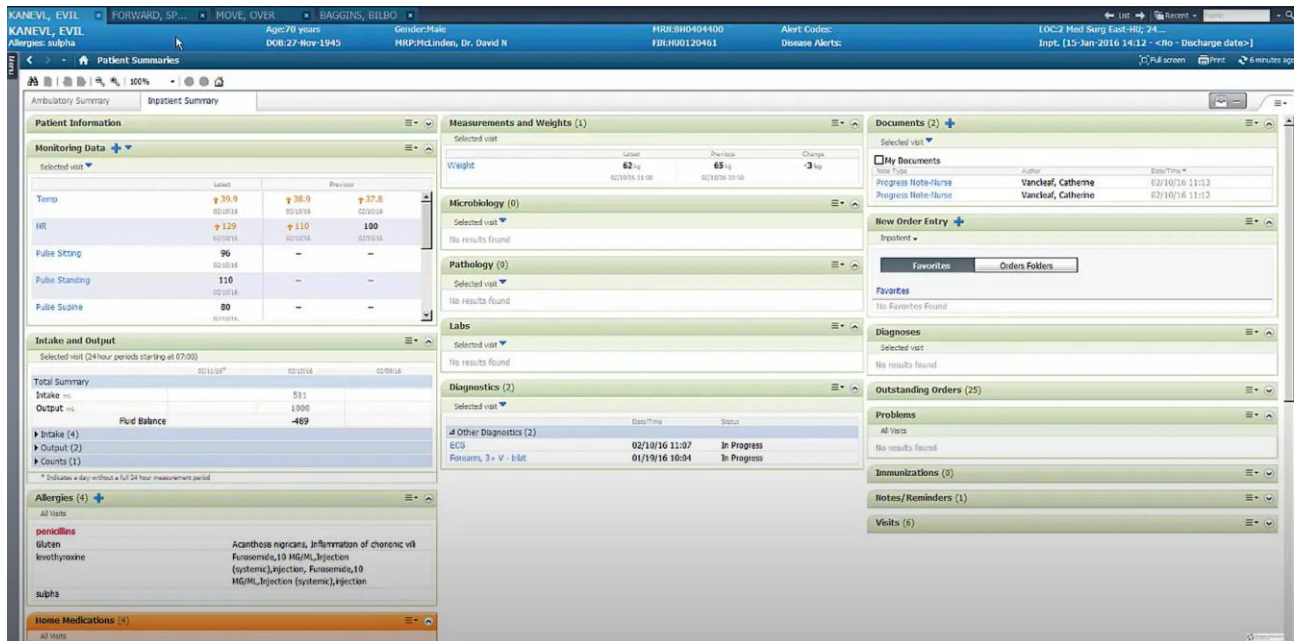


Figure 3.4 Inpatient summary in Cerner

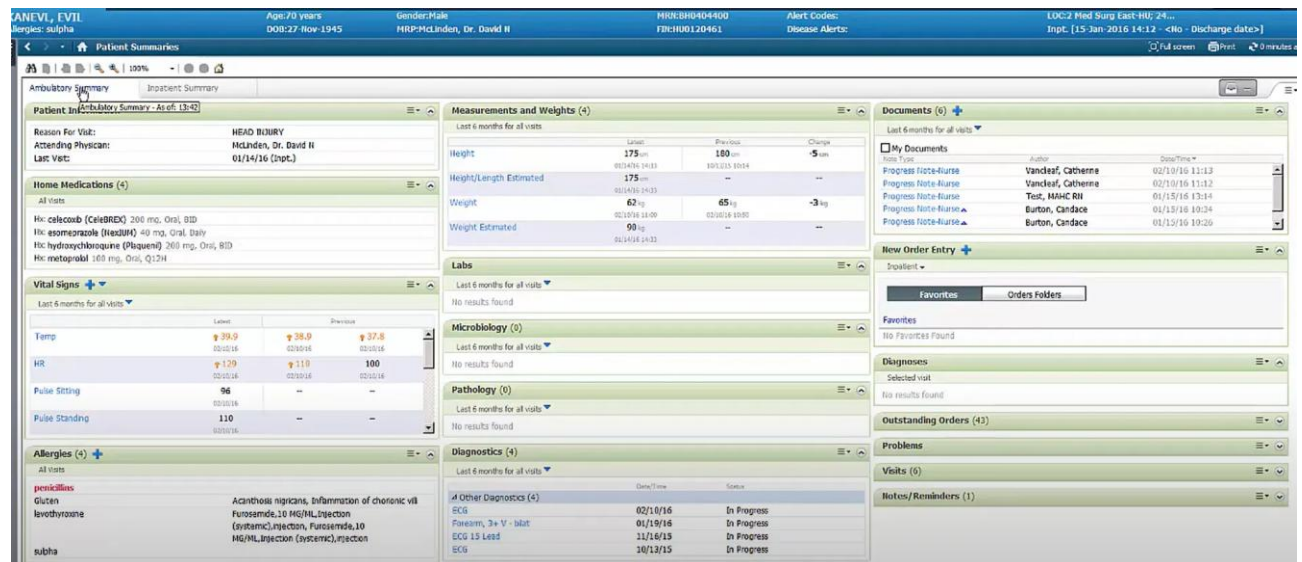


Figure 3.5 Ambulatory summary in Cerner

3.4.3 Patient Timeline

Regarding the patient timelines, it was observed that Portal SNS24, VCI, RSE, and Cerner all incorporate this functionality.

In Portal SNS24, patients can consult past and upcoming appointments in various formats, including a calendar, a list and a horizontal timeline. Furthermore, it is possible to view records of specific episodes, such as visits to the A&E department.

In VCI, there are two types of timelines available: the “Timeline” and the “Timeline Clínica”. The standard Timeline displays information such as the type of episode, the start date of the episode, the speciality, and the episode number. Also, healthcare professionals can filter the information by type of episode, by date and by episode number. To access more detailed information regarding an episode, the user can click on the episode and will be redirected to a dashboard with further details. The structure of “Timeline Clínica” is similar but it focuses on clinical information, such as pressure ulcers, falls and infection. Additionally, in VCI, it is possible to view episodes in a list format; the context is the same as shown in the “Timeline”, but it has a different presentation, and the encounters are pre-filtered according to their type.

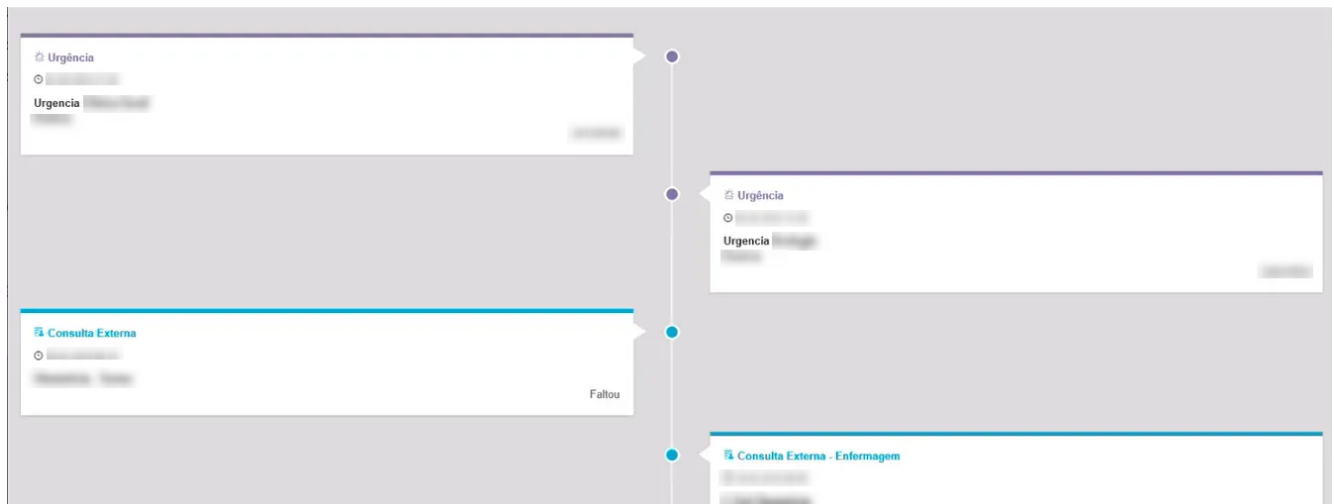


Figure 3.1 Patient timeline in VCI

In the RSE, users can consult a timeline of patient episodes. For each episode, the type of episode is displayed, the healthcare facility and the date. It is also possible to open the corresponding clinical file and view detailed information regarding the episode.

In Cerner, based on the analysis conducted, encounters are shown in a list format, where it is possible to consult the admission date, the discharge date, reason for visit, healthcare facility, service and visit type. If the healthcare professional wishes to view more information regarding the episode, the user can click on the row to access additional data, including the admission source and the length of stay.

Selected	FBI	Admit Date	Discharge Date	Visit Reason	Facility	Location	Service	Visit Type
X	HU0120461	13-Jan-2016 14:12:00	15-Jan-2016 13:00:00	ROAD INJURY	MAHC-HU	2 Med Surg East-HU 240 1-OF	Medicine	Inpt.Ac.
	HU0120443	14-Jan-2016 14:32:00	15-Jan-2016 13:00:00	COUGH	MAHC-HU	2 Med Surg East-HU 230 2	Medicine	Inpt.Ac.
	BR0117542	21-Dec-2015 12:03:27		FOLLOW UP	MAHC-BR	Surgical Clinic-6R	Medicine	Outpt.
	HU0120324	13-Nov-2015 08:46:00	25-Nov-2015 10:15:00	FRACTURED CLAVICLE	MAHC-HU	2 Med Surg East-HU 232 2	Medicine	Inpt.Ac.
	HU0120258	13-Oct-2015 10:11:00	14-Oct-2015 13:51:00	COUGH	MAHC-HU	2 Med Surg East-HU 230 1-OF	Medicine	Inpt.Ac.
	HU0120495	10-Oct-2015 12:57:08		CLINIC	MAHC-HU	Emergency-HU	Medicine	Outpt.

Patient Identifiers		Health Plans	
Type	ALIAS	Type	PLAN NAME
FOUNDER	HU0120461	Prev. Health Card	MOH Ontario Health...
MRN	94649400		MOH Ontario

Relationships					
Type	NAME	RELATION	HOME PHONE	BUS PHONE	HOME ADDR
Insured	KANEVIL, EVLI	SELF	(705) 555-5588		100 LAKE RD
Default Guarantor	KANEVIL, EVLI	SELF	(705) 555-5588		100 LAKE RD
Next of Kin	KANEVIL, MESSIAS	Spouse	(705) 555-5588		100 lake road

Figure 3.2 List of patient's encounters in Cerner

3.4.4 Patient Documents

In VCI, patient documents can be sorted by date, description, and information type. It is possible to consult documents such as discharge summaries, as well as documents that have been digitalized and attached to the patient's clinical record. Attached files can be further sorted by document type, medical speciality, and the healthcare professional responsible for the upload.

3.5 Requirements

Software requirements can be classified as functional or non-functional. Functional requirements refer to the explicit features and functionalities of the system, whereas non-functional requirements describe quality attributes, defining how the system should perform [66].

Following the analysis of interviews, surveys and the benchmarking, it was possible to construct use cases, user stories and UML diagrams. This section presents those elements and provides an overview of the functional and non-functional requirements.

3.5.1 Use Cases and User Stories

The utilisation of user stories has been on the rise in the context of software development, particularly within the framework of agile software development methodologies. User stories represent the most widely utilised artefact in the context of agile software development, as they articulate requirements from the perspective of the user [67].

A user story is defined as a concise, semi-structured sentence that illustrates requirements from the perspective of the user. This concept comprises of three distinct aspects, namely the who, the what, and the why. The term "who" refers to the system user or actor, "what" refers to the actor's desire, and "why" refers to the reason. These aspects are then arranged into one sentence, which is characterised by a specific structure. A variety of formats

and templates are typically employed, including [67]:

As a <aspect of who>, I want <aspect of what>, so that <aspect of why>

As a <aspect of who>, I need <aspect of what>, so that <aspect of why>

As a <aspect of who>, I can <aspect of what>, so that <aspect of why>

In order to <aspect of who> as a <aspect of what>, I can <aspect of why>

Given the importance of user stories in software development, a set of user stories was designed, which are available in annex 6.4.

3.5.2 Conceptual Module

The Unified Modelling Language (UML) is a general-purpose graphical description language which consists of an integrated set of diagrams supporting the specification, visualisation, documentation and design of software systems. UML can be readily applied to the modelling of various technical and business [68].

Use case diagrams illustrate the relationship between the system and its use cases. They ensure that customers, end users and developers can interpret the system's functionality and requirements in the same way. Use case diagrams are necessary for illustrating the possible interactions between actors and the system, as well as the results or effects of these interactions. Three use case diagrams were created, one for each profile (healthcare professional, DPO and administrator) [68].

The following diagram is a use case diagram for healthcare professionals that illustrates the essential interactions between the user and the module. It demonstrates the ability to consult and update patient information and access the IPS and manage clinical documentation. Additionally, it highlights messaging functionalities and the use of the “break the glass”.

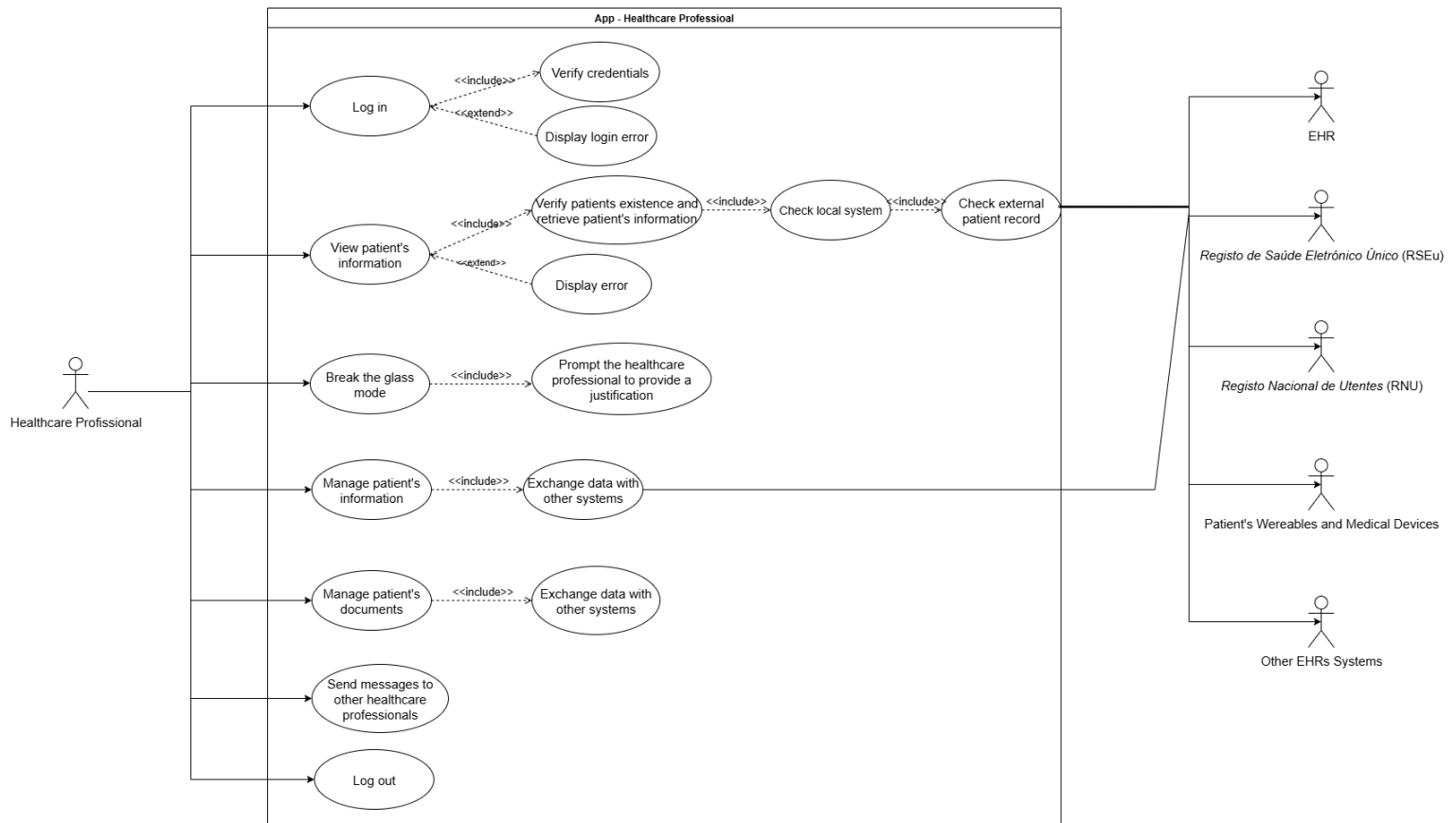


Figure 3.8 Use case diagram - healthcare professional

The administrator use case diagram outlines the responsibilities associated with the configuration, maintenance, and governance of the system. It represents activities such as managing access permissions and view audit logs, to ensure the patient confidentiality is maintain. These functions are critical to ensuring that the module operates efficiently and in compliance with institutional and legal frameworks.

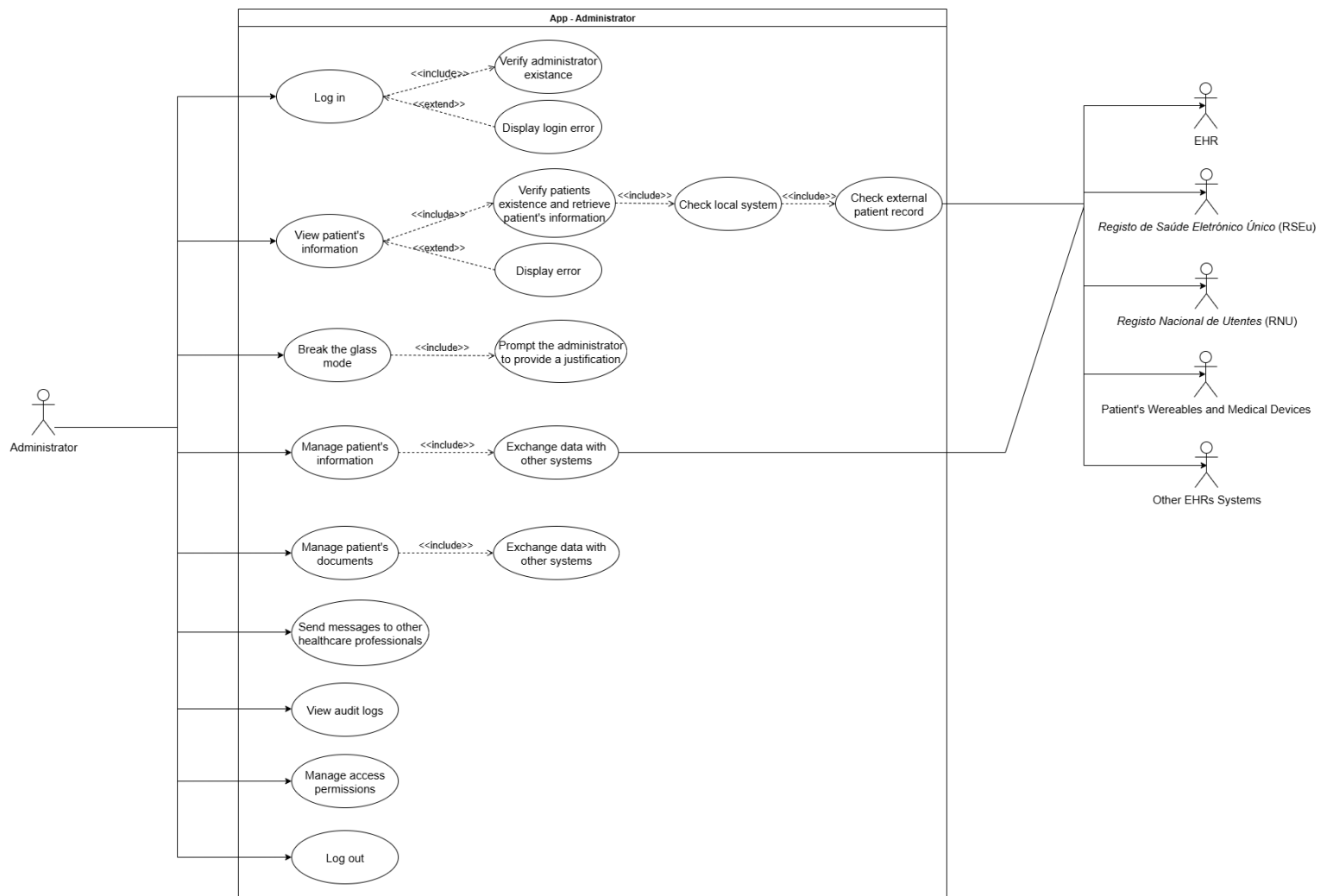


Figure 3.9 Use case diagram – administrator

The DPO use case diagram reflects the oversight role associated with data security and compliance. It highlights functions such as reviewing access logs, auditing data use, and investigating breaches or complaints.

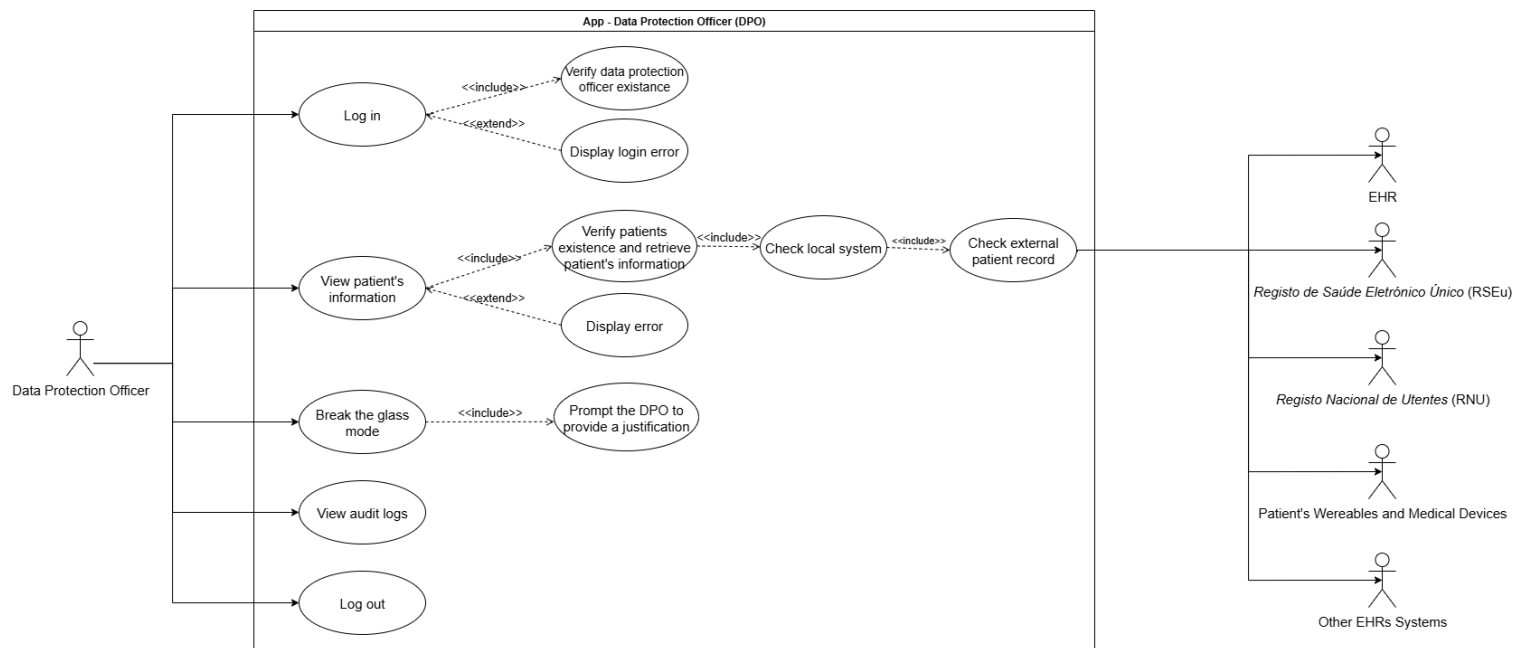


Figure 3.10 Use case diagram – DPO

An activity diagram describes a set of activities and how they are sequenced or branched, as well as the values they generate or use. Activity diagrams illustrate the dynamic view of a system and they are particularly useful for modelling the functionalities of a system. Activity diagrams were created for all the use cases mentioned in the previous sub-chapter [68].

The following activity diagram portrays the authentication process for different types of users, including healthcare professionals, administrators, and the DPO. It highlights the steps involved in validating user credentials and granting appropriate access rights.

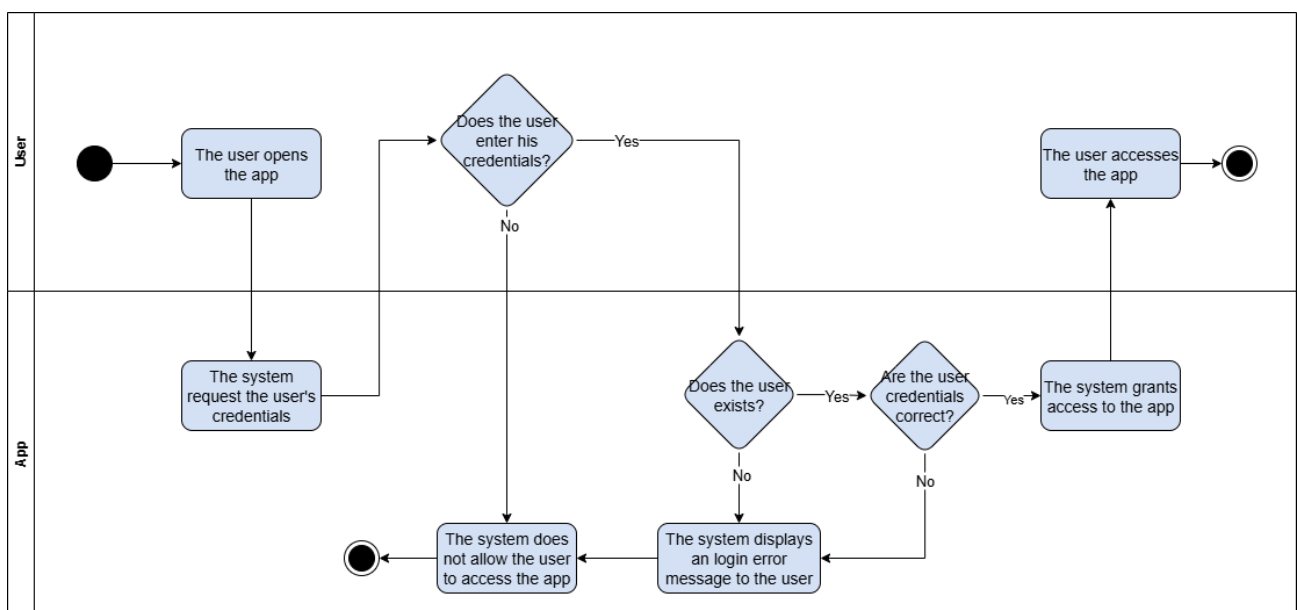


Figure 3.11 Activity diagram – log in

```

graph TD
    Start([Start]) --> WantAccess[Wants to access patient information]
    WantAccess --> SearchPatient[Searches for a patient]
    SearchPatient --> WantSearchAnother{Does the user wants to search for another patient?}
    WantSearchAnother -- No --> SearchPatient
    WantSearchAnother -- Yes --> ProvidesJustification{Does the user provides justification?}
    ProvidesJustification -- No --> SearchPatient
    ProvidesJustification -- Yes --> IsHealthcareProfessional{Is the user a healthcare professional?}
    IsHealthcareProfessional -- No --> DisplayNotFound[The system displays a message informing the user that the patient was not found]
    DisplayNotFound --> QueryOtherSystems[Queries for the patient in other systems]
    QueryOtherSystems --> ReturnedInfoOther{Returned information regarding the patient?}
    ReturnedInfoOther -- Yes --> ReturnInfoOther[Returns information found/no information]
    ReturnInfoOther -- No --> SearchEHR[Searches for the patient in the EHR]
    SearchEHR --> QueryEHR[Queries for the patient in the EHR]
    QueryEHR --> SearchPatientEHR[Searches for the patient]
    SearchPatientEHR --> ReturnInfoEHR[Returns information found/no information]
    ReturnInfoEHR --> ReturnedInfoOther
    IsHealthcareProfessional -- Yes --> HasPermissionSummary{Does the user has permission to access the patient's summary?}
    HasPermissionSummary -- No --> DisplaySummary[The system displays the Patient's Summary]
    DisplaySummary --> UserWantsMoreInfo{Does the user wants to access more information?}
    UserWantsMoreInfo -- No --> SearchPatient
    UserWantsMoreInfo -- Yes --> HasPermissionDetailed{Does the user has permission to view more detailed patient's information?}
    HasPermissionDetailed -- No --> DisplayNoPermission[The system displays a message informing the user that does not have permission to view that patient's information]
    DisplayNoPermission --> UserWantsDifferentInfo{Does the user wants to access different information regarding the patient?}
    UserWantsDifferentInfo -- No --> SearchPatient
    UserWantsDifferentInfo -- Yes --> LogAccess[The system logs user ID, timestamp, patient(s), information accessed and justification, if that is the case]
    HasPermissionDetailed -- Yes --> DisplayMoreDetailed[The system displays more detailed patient's information]
    DisplayMoreDetailed --> LogAccess
    HasPermissionSummary -- Yes --> QueryInternal[Queries for information regarding the patient internally]
    QueryInternal --> RequestIntegrationBUS[Request the Integration BUS to query about the patient externally]
    RequestIntegrationBUS --> QueryOtherSystems2[Queries for the patient's information in other systems]
    QueryOtherSystems2 --> SearchPatient2[Searches for the patient's information]
    SearchPatient2 --> ReturnInfo2[Returns information found/no information]
    ReturnInfo2 --> ReturnedInfoOther2{Returned information regarding the patient?}
    ReturnedInfoOther2 -- Yes --> DisplaySummary2[The system displays a message informing the user that there was no information found]
    DisplaySummary2 --> UserWantsMoreInfo2{Does the user wants to access more information?}
    UserWantsMoreInfo2 -- No --> SearchPatient
    UserWantsMoreInfo2 -- Yes --> LogAccess2[The system logs user ID, timestamp, patient(s), information accessed and justification, if that is the case]
    ReturnedInfoOther2 -- No --> SearchEHR2[Searches for the patient's information in the EHR]
    SearchEHR2 --> SearchPatient3[Searches for the patient's information]
    SearchPatient3 --> ReturnInfo3[Returns information found/no information]
    ReturnInfo3 --> ReturnedInfoOther2
  
```

Figure 1.12 Activity diagram – view patient's information

This diagram describes the exceptional workflow in which healthcare professionals may override standard restrictions in emergency contexts. By requiring justification, the “Break the Glass” process balances the need for immediate access in emergencies with the principles of accountability and data protection.

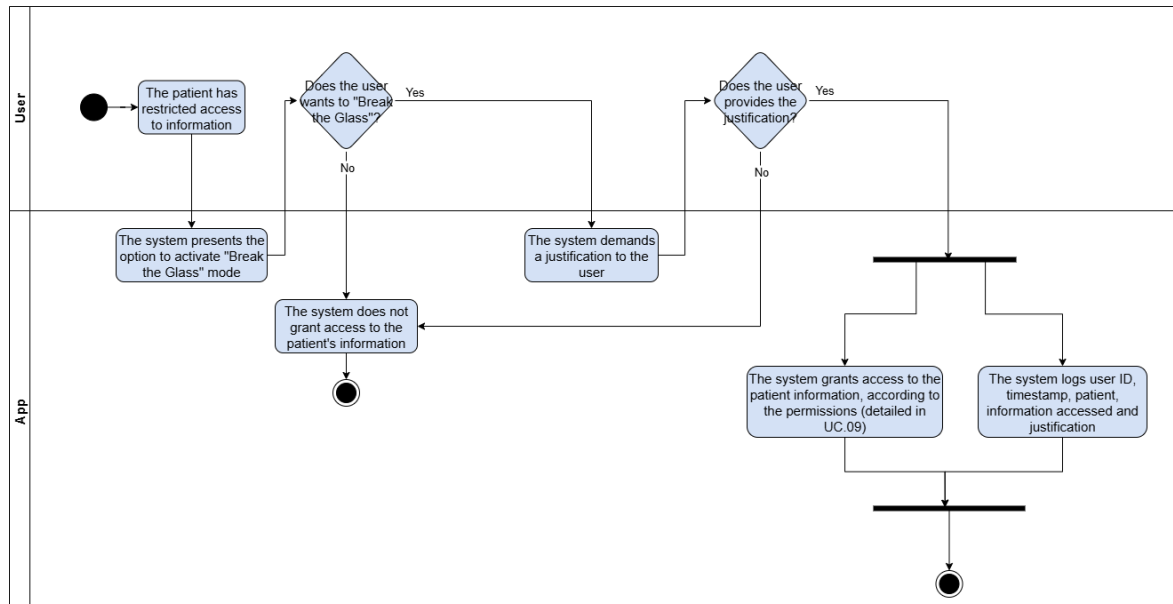


Figure 3.13 Activity diagram – break the glass mode

The following activity diagram demonstrates the process of registering or editing patient health data. The workflow ensures that data updates are validated, logged, and synchronised with external systems, thereby maintaining both traceability and interoperability.

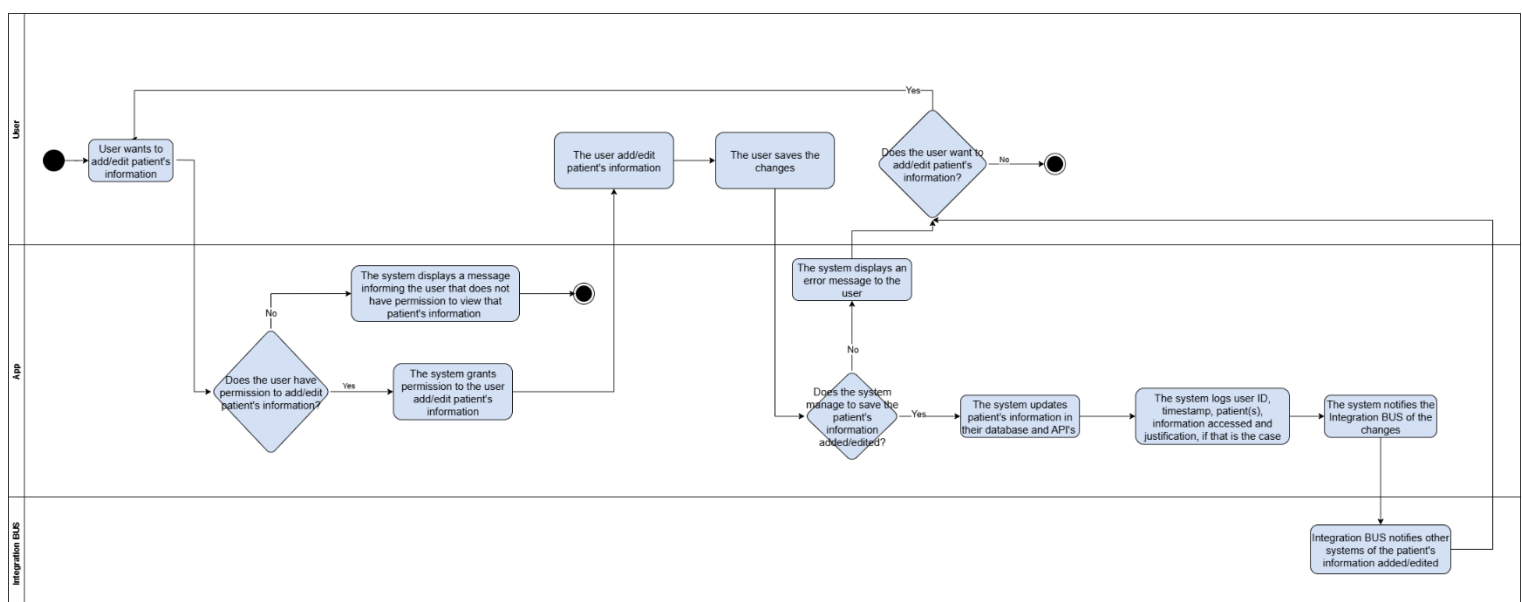


Figure 3.14 Activity diagram – manage patient's information

This diagram outlines how healthcare professionals can upload, edit, or cancel documents associated with a patient's record. By enabling document management, the system ensures that relevant information is available for clinical decision-making while preserving an auditable history of changes.

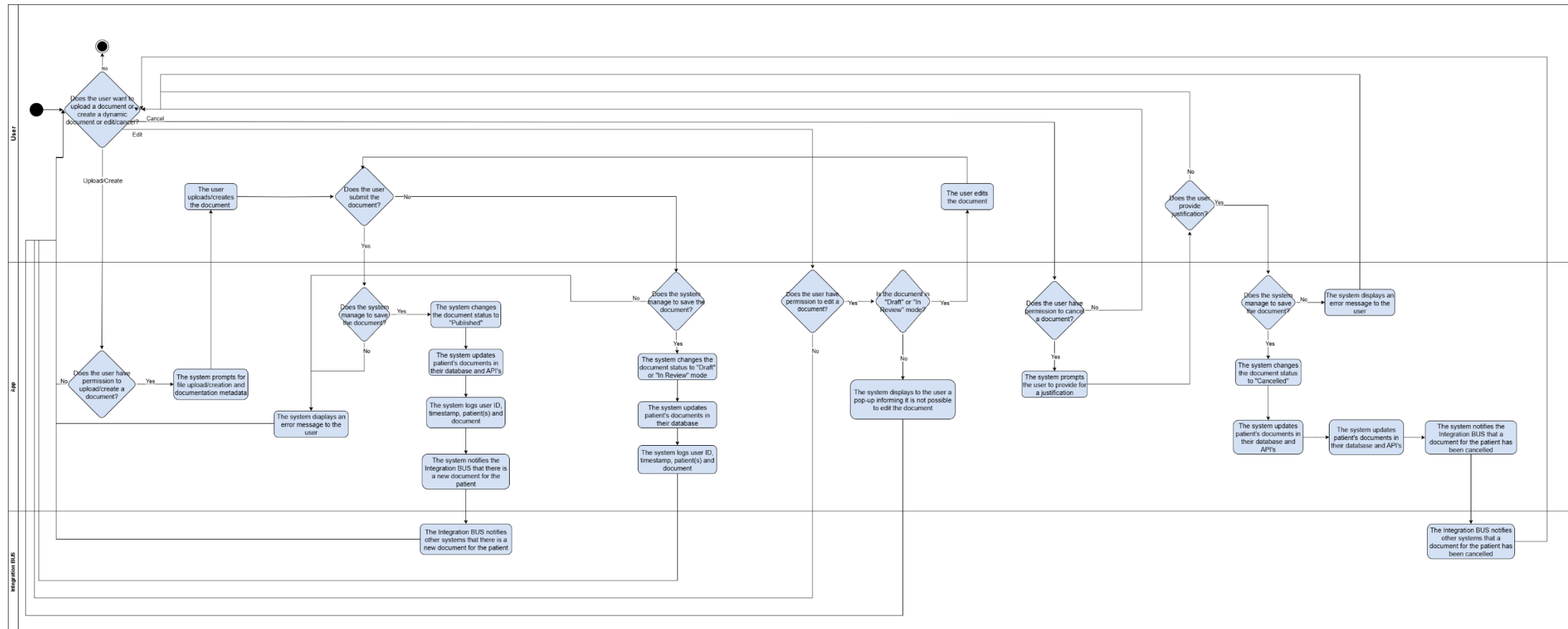


Figure 3.15 Activity diagram – manage patient's document

The diagram describes the exchange of messages between healthcare professionals, a functionality that supports multidisciplinary collaboration and care coordination.

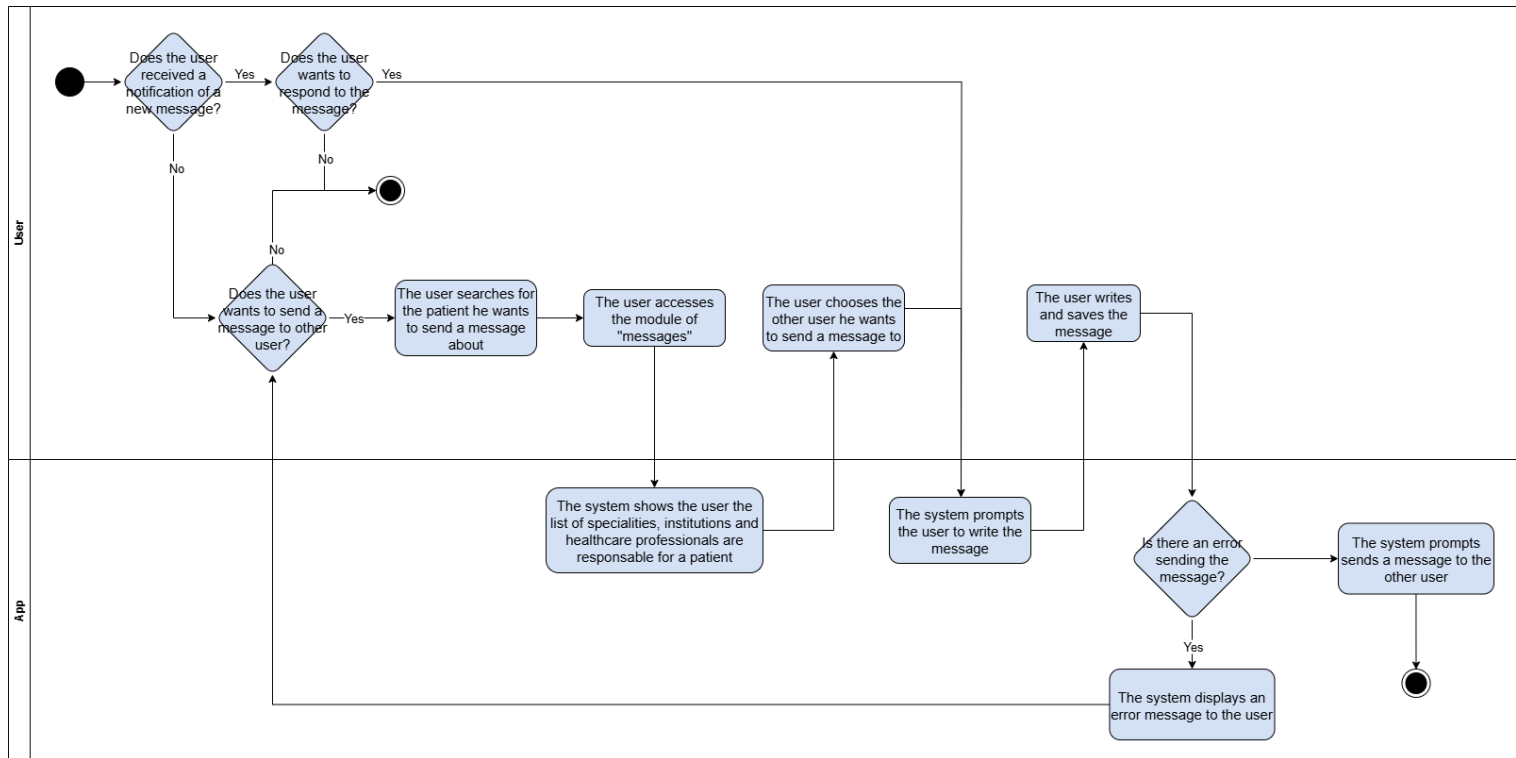


Figure 3.16 Activity diagram – send messages to other users

This activity diagram illustrates the process by which administrators and the DPO can consult audit logs to review data access and system use.

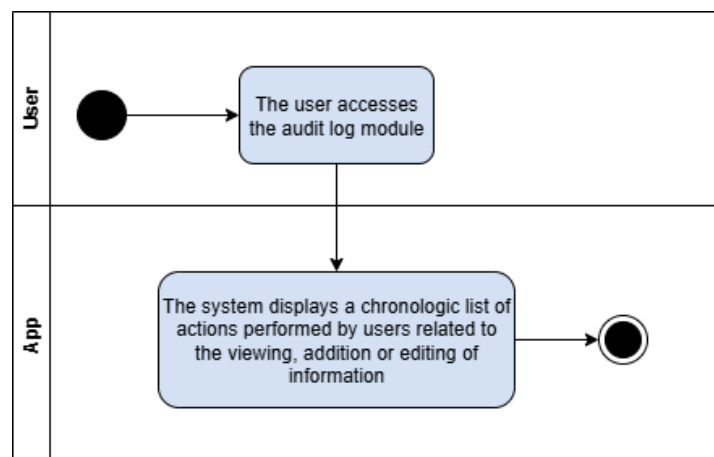


Figure 3.17 Activity diagram – view audit logs

The following diagram depicts how administrators define and manage users' permissions. By implementing granular access controls, the system ensures that sensitive patient data are only accessible to authorised users, supporting both security and GDPR compliance.

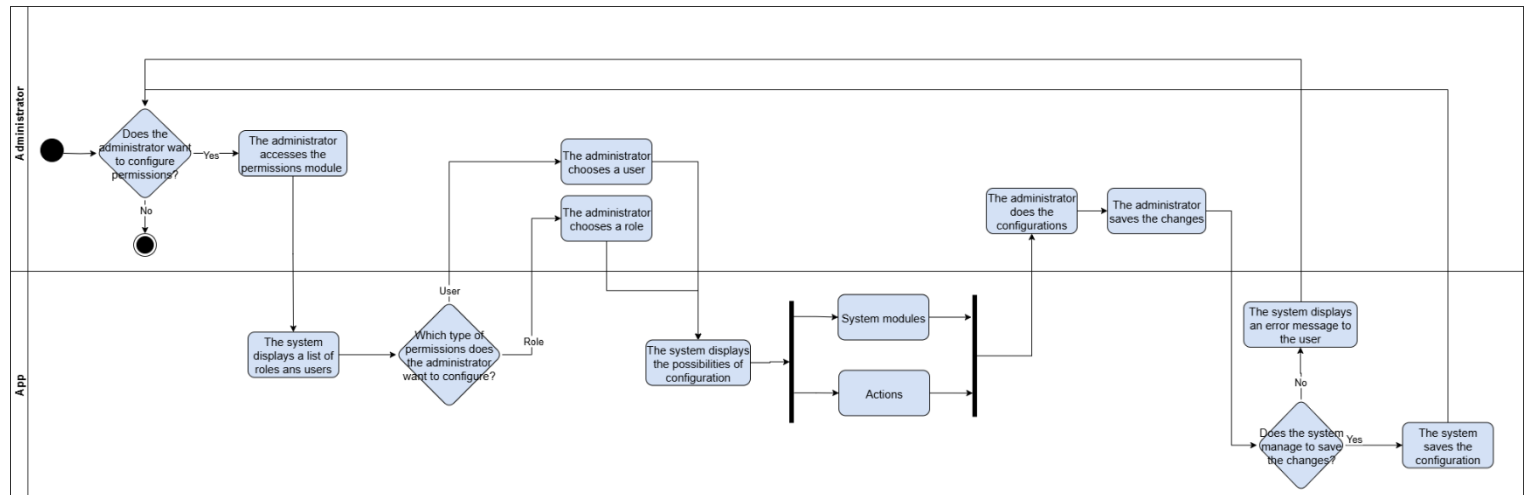


Figure 3.18 Activity diagram – manage access permissions

This activity diagram shows the process of ending a user session, either manually or automatically due to inactivity.

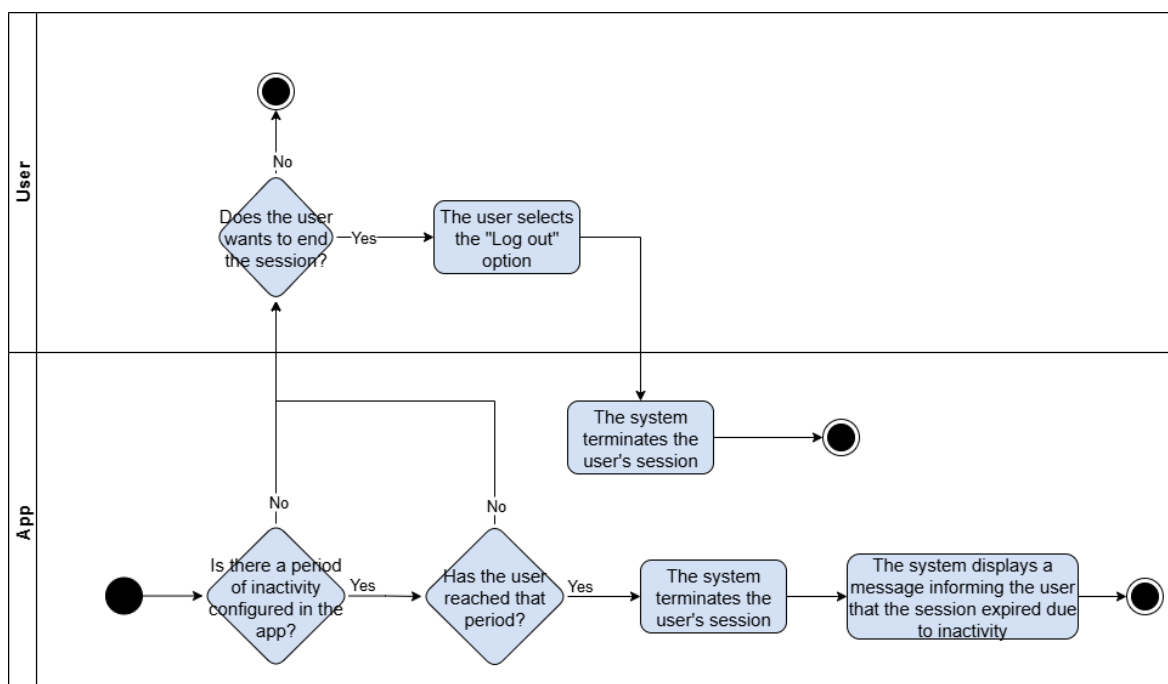


Figure 3.19 Activity diagram – log out

A sequence diagram is required to illustrate the lifecycle of an object and the interactions between actors within a given use case. Sequence diagrams have been created for all the use cases mentioned in the previous sub-chapter [68].

The sequence diagram for the login process shows the interactions between the user, the system interface, and the authentication service.

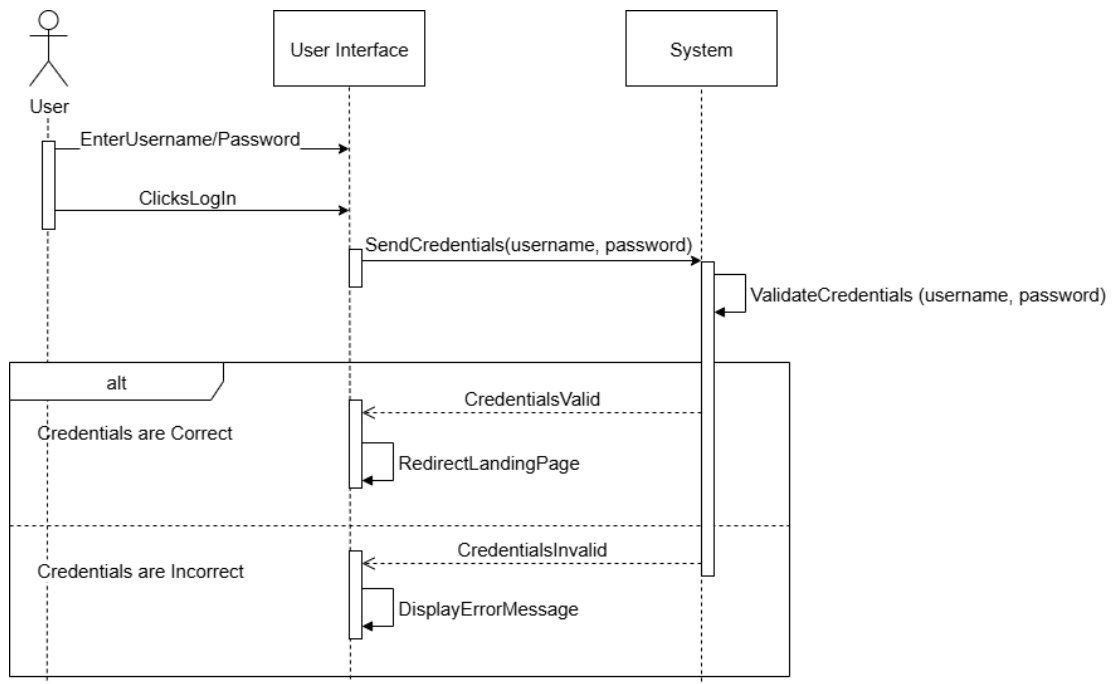


Figure 3.20 Sequence diagram – log in

The following sequence diagram illustrates how a healthcare professional retrieves patient data. It highlights interactions with the integration bus to query internal and external systems.

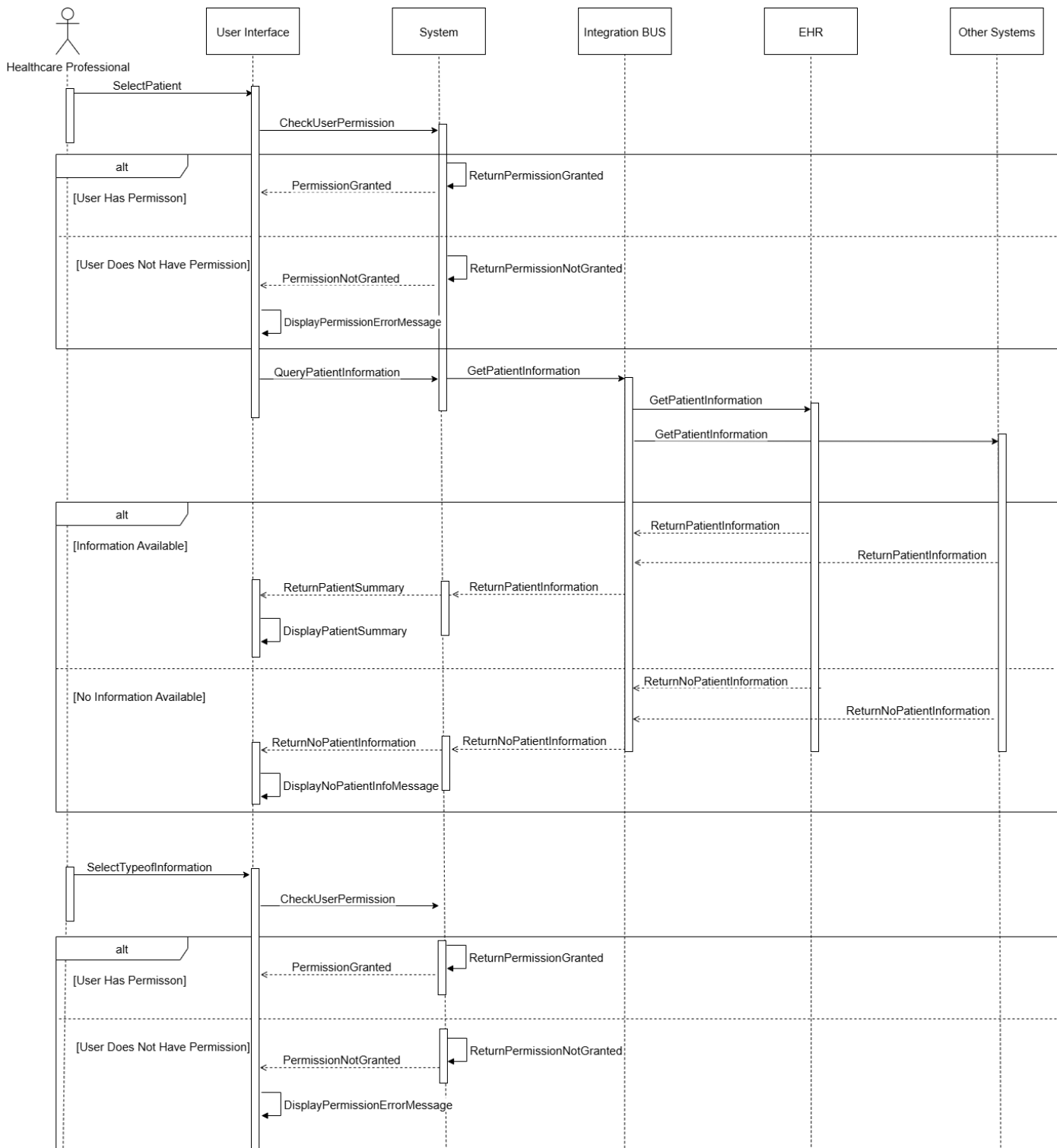


Figure 3.21 Sequence diagram – view patient's information (healthcare professional)

The next diagram focuses on the retrieval of patient data by administrators and the DPO.

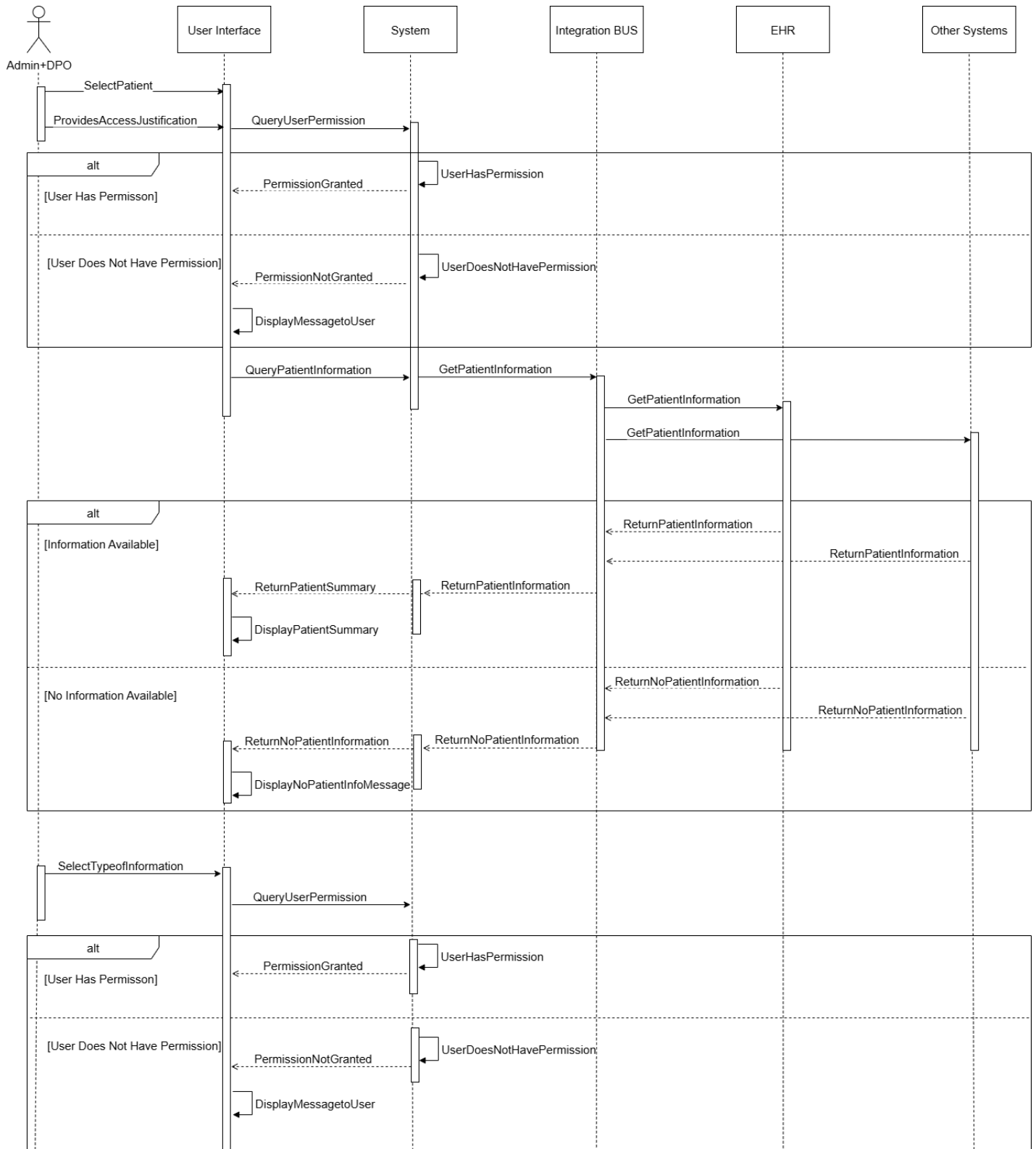


Figure 3.22 Sequence diagram – view patient's information (administrator and DPO)

The sequence diagram depicts how a user overrides privacy restrictions in emergencies by activating “Break the Glass” mode, which highlights the interplay between user justification, access provision, and audit logging, ensuring that emergency access is both effective and accountable.

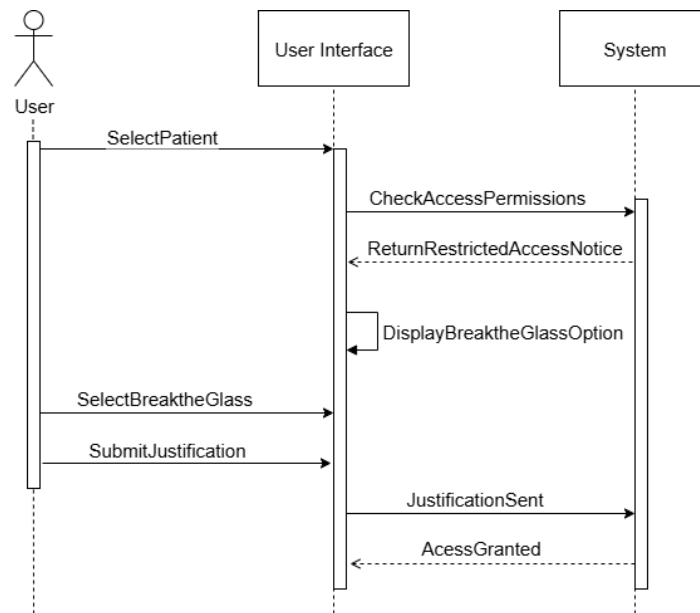


Figure 3.23 Sequence diagram – break the glass

This sequence diagram represents the process of adding or updating patient health data, and it illustrates how information entered by healthcare professionals is validated, saved, and synchronised across systems, ensuring both integrity and interoperability.

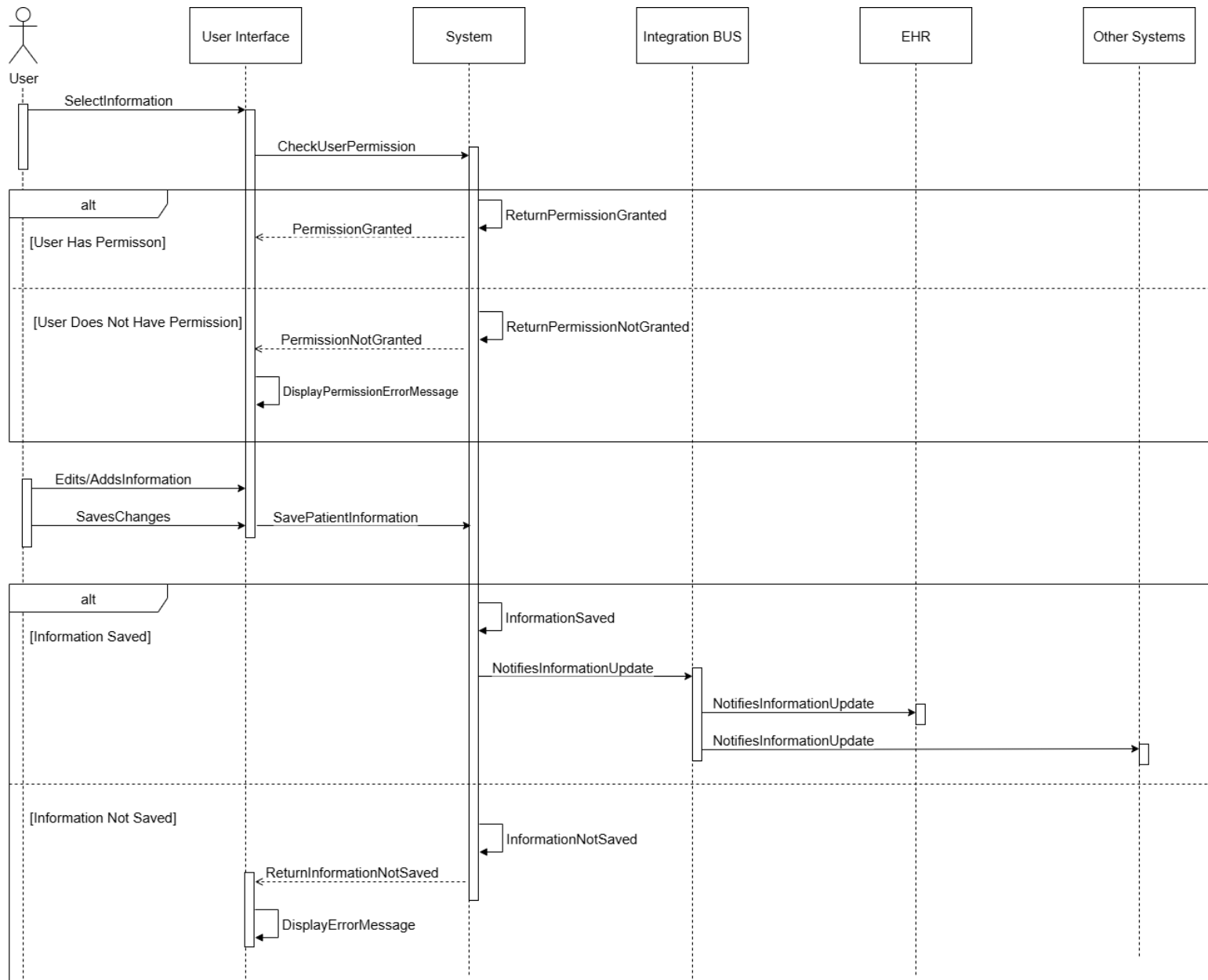


Figure 3.24 Sequence diagram – manage patient information

The following three diagrams demonstrate the workflows for creating, editing, and cancelling documents. The sequences portray the traceability of documentation processes, ensuring that all modifications are logged and reflected in the patient record.

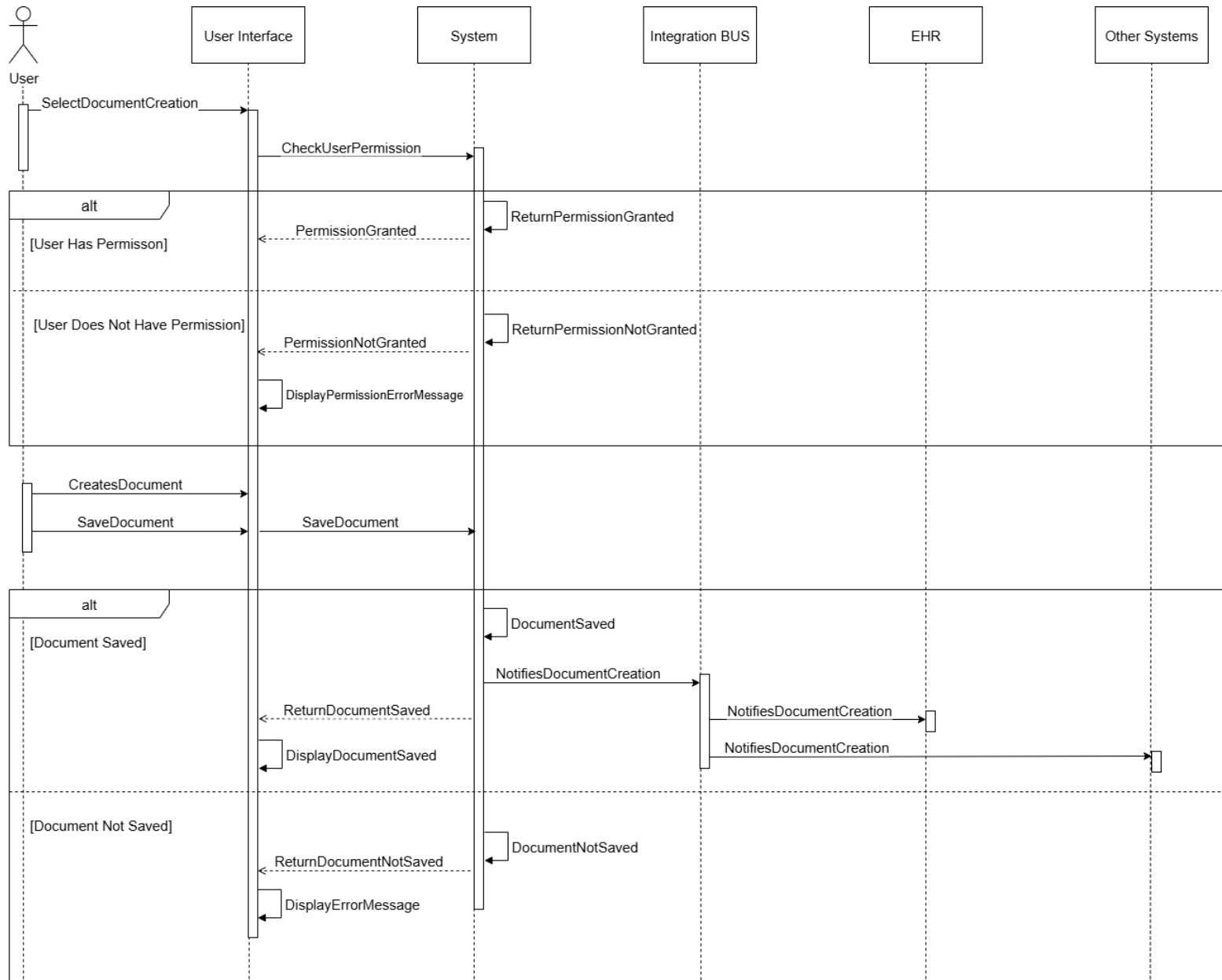


Figure 3.25 Sequence diagram – manage patient's documents (create document)

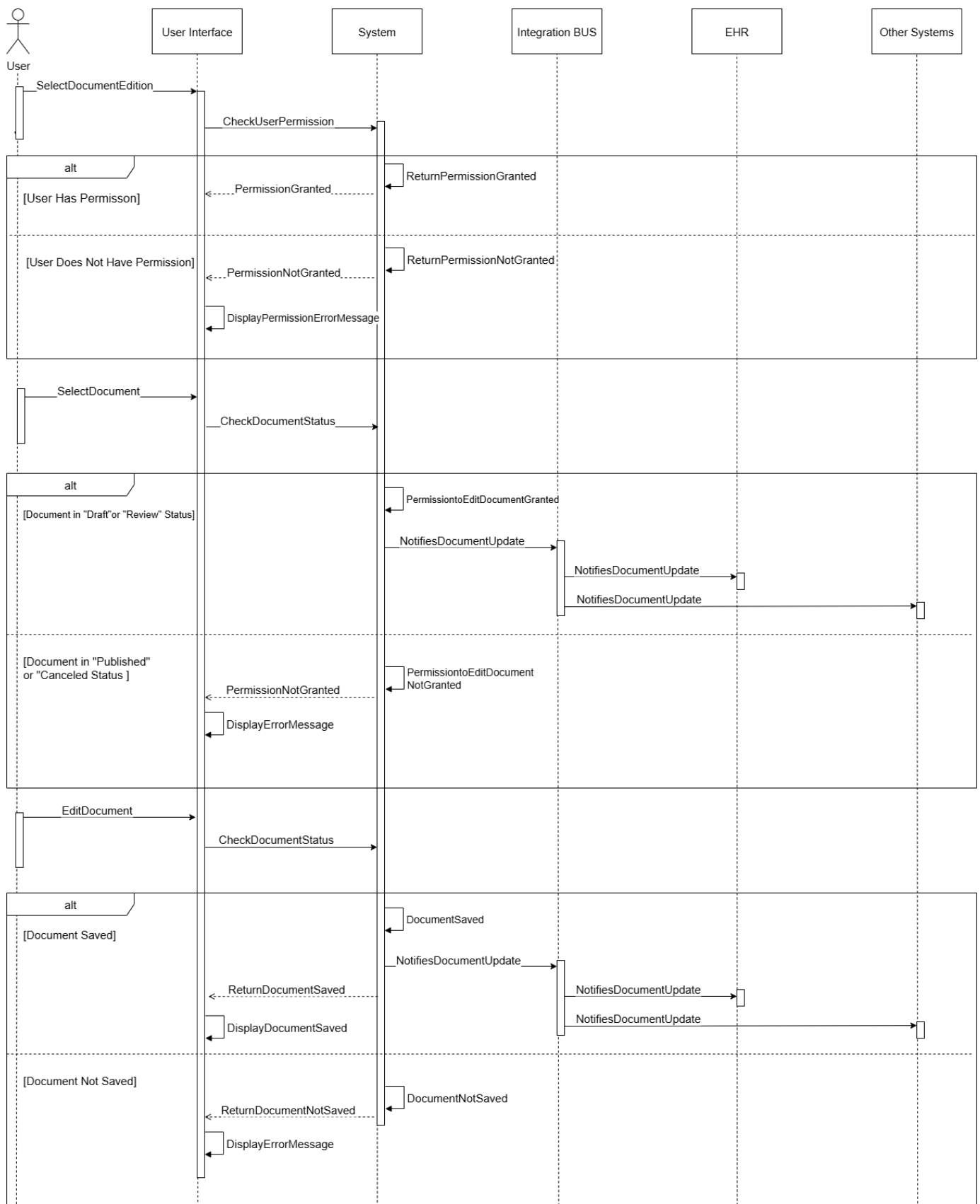


Figure 3.26 Sequence diagram – manage patient's documents (edit document)

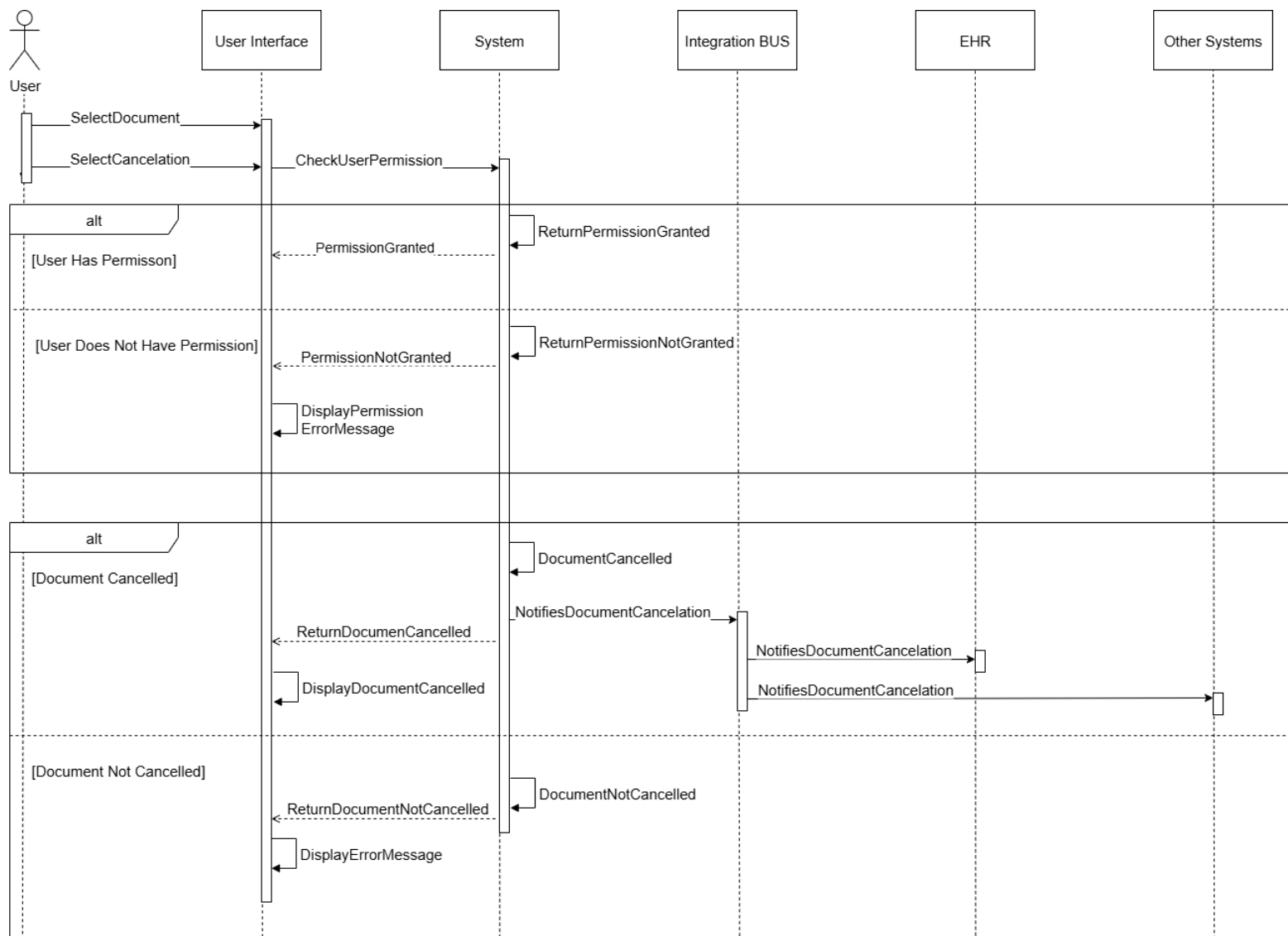


Figure 3.27 Sequence diagram – manage patient's documents (cancel document)

The diagram describes the exchange of messages between healthcare professionals, illustrating the interaction between the user, the user interface and the system.

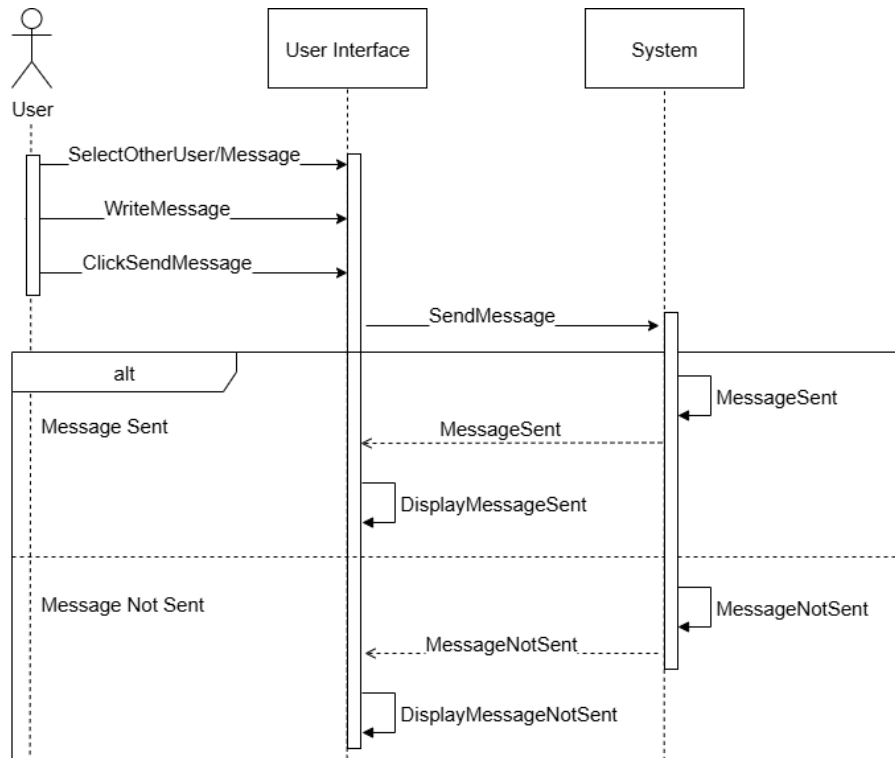


Figure 3.28 Sequence diagram – send messages to other users

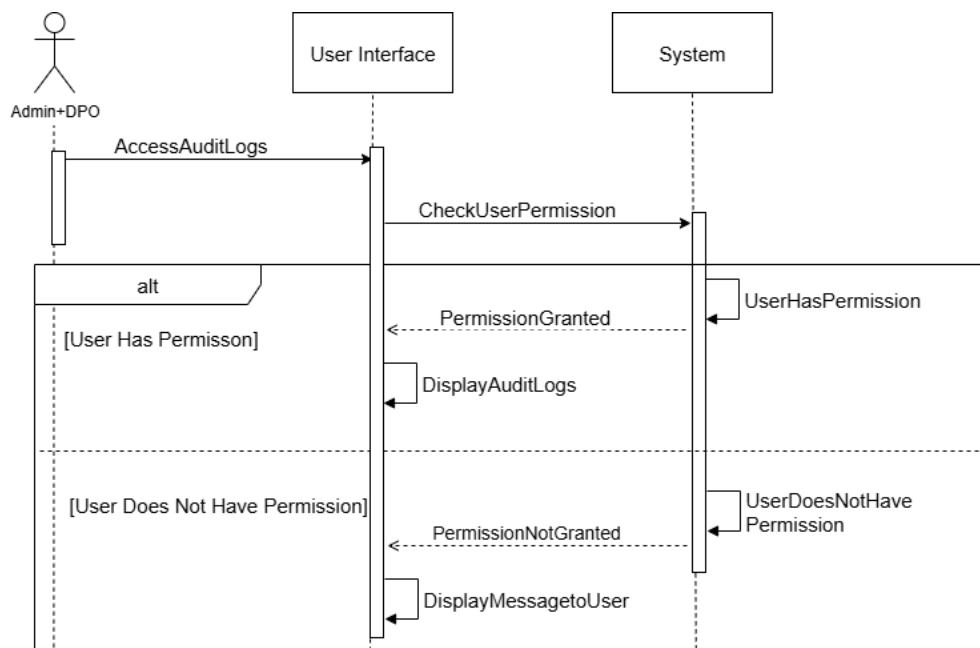


Figure 3.29 Sequence diagram – view audit logs

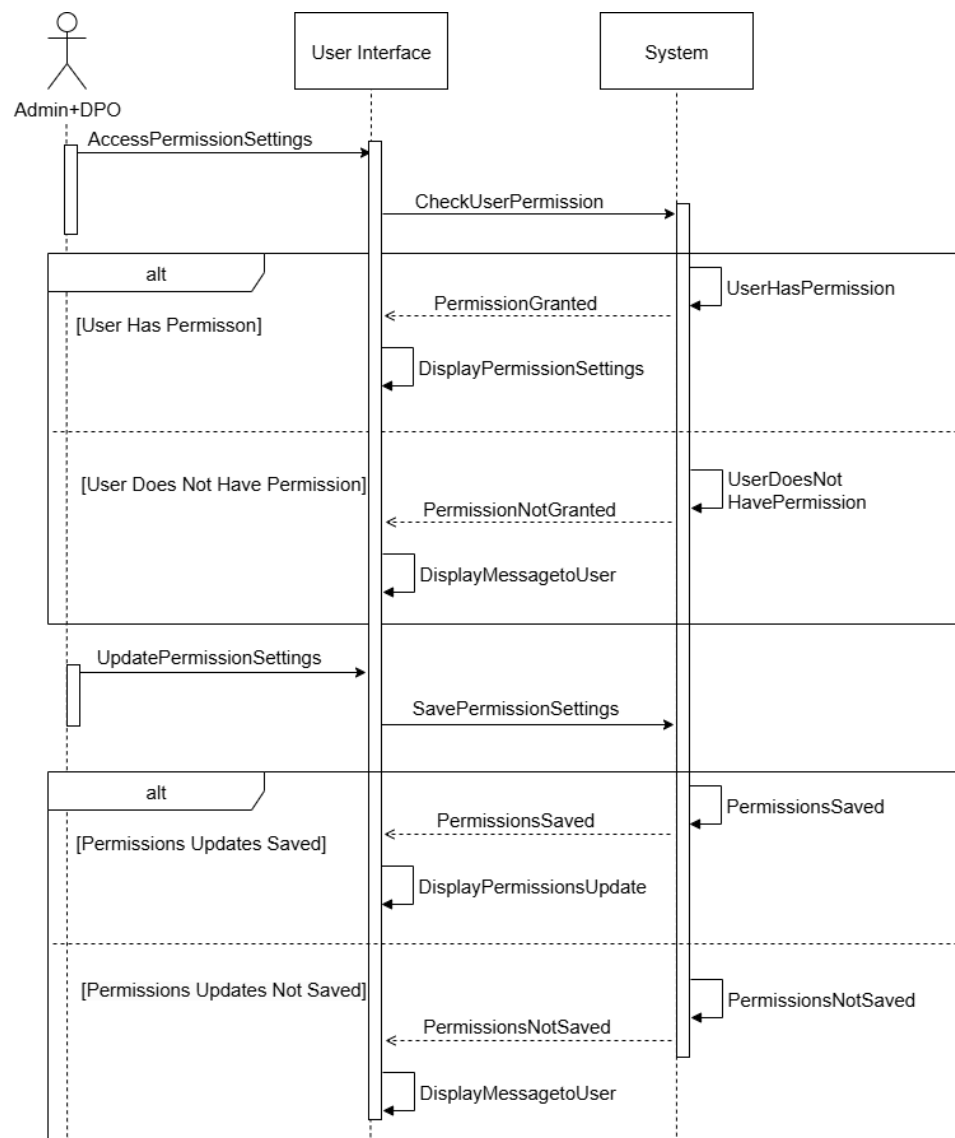


Figure 3.30 Sequence diagram – manage access permissions

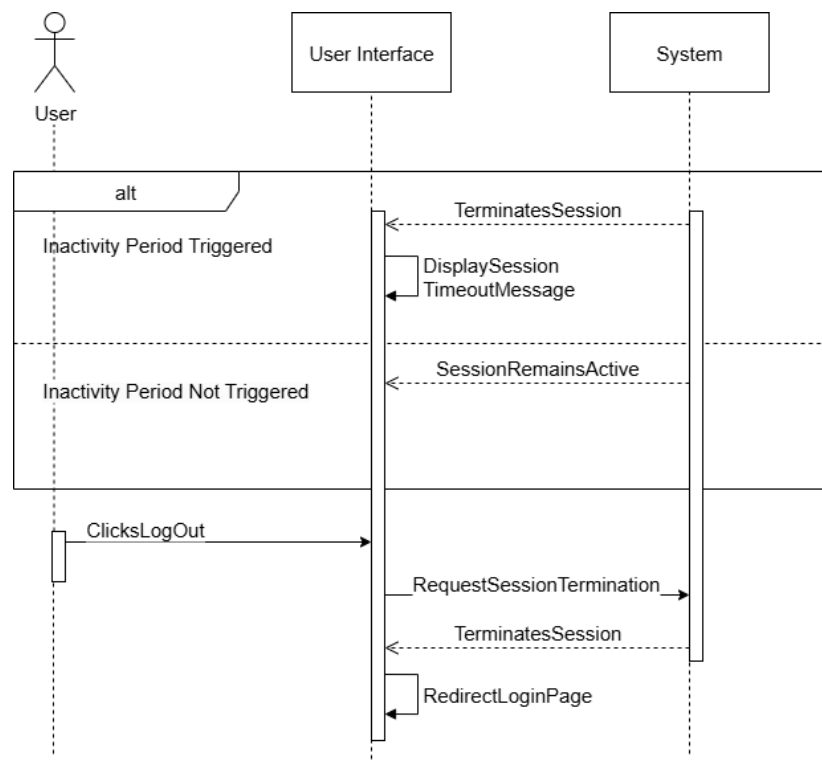


Figure 3.31 Sequence diagram – log out

3.5.3 Non-functional requirements

Non-functional requirements specify how a system should behave and provide functional limitations, ensuring the system is efficient and useful [62]. The following table outlines the non-functional requirements.

Table 3.2: Non-functional requirements

Requirements
The system shall comply with data protection regulations, ensuring proper access control, data anonymization where applicable, and audit logs for data access [69].
The system shall provide a responsive design, ensuring proper usability on desktops and/or tablets.
The system shall display error messages or warnings when data retrieval fails or when the user does not have permission to view certain patient data.
The system shall support easy recovery from user errors by providing options to edit or cancel information [57]
Icons and visual elements shall be used consistently throughout the application [57].
The system must support concurrent access by multiple users without performance degradation.
The system should support flexible data visualization by enabling users to view the same clinical information through multiple formats such as flowsheets, graphs, summaries, and dynamic search [13].
The system shall provide pertinent patient information proactively, rather than requiring manual retrieval [65].
The system shall minimize cognitive load by presenting information in a clear and concise way [65].
The system should provide problem-based connectors as a strategy to reduce cognitive load [65].
The system shall display previously recorded patient information, minimizing the need for healthcare

professionals to document duplicate data [16].
The system shall facilitate accurate data collection by providing intuitive input interfaces, predefined value sets and validation mechanisms [16].
The system should follow the Nielsen's 10 Usability Heuristics for user interface design (system state visibility, match between system and real world, use control and freedom, consistency and standard, error prevention, recognition rather than recall, flexibility and efficiency of use, aesthetic and minimalist design, help users recognize, diagnose and recover from errors, help and documentation) [70].
The system shall use FHIR for data exchange [4].
There shall be adopted international interoperability standards to represent Patient Summary contents in a structured and coded format [36].
The system shall import IPS documents received from external systems.
The system shall generate an IPS document conforming to the Implementation Guide of Portuguese Use Case [4].
Terminology used in IPS must be based on recognized value sets, following the Guidelines of the CTC or other value sets described in the FHIR IPS Implementation Guide [4].

3.5.4 Functional requirements

Functional requirements describe the purpose of a system and the actions it needs to perform to meet user needs. [69]. The following table shows the functional requirements based on the results of interviews and surveys, the bibliography and the IPS guidelines.

Table 3.3: Functional requirements

Dashboard	Requirement
	The system must process data by mapping it to multiple terminology standards, such as SNOMED, LOINC, etc [69].
	The system should enable users to filter information.
Patients Lists	The system shall display a list of all registered patients.
Patients Lists	The system shall allow the user to customize different patient lists, including the selection and order of columns, simple filters, and advanced filters.
Patients Lists	The system shall allow the user to define favourite patient lists and provide quick access to those lists.
Patients Lists	The system shall allow the user to choose the columns that are presented: Name, DOB, Age, Sex, Unique Identifier, Status (Inpatient, Ambulatory, Deceased), Location (Facility, Ward/Bed), Picture, Isolation Status, Length of Stay, Medical Record Number, Date of Admission, Reason for Visit, General Practice Physician, General Practice Nurse, Responsible Physician, Responsible Nurse, Responsible Physician for Admission, Responsible Nurse for Admission, Notes, Patient Summary, Alerts, Allergies, Address, Telephone, E-mail, Next of Kin, Next Appointment.
Patients Lists	The system shall allow the user to apply filters to all columns in the patient list.
Patients Lists	The system shall allow the user to reorder the columns in the patient list according to their preferences.
Patient Summary	Healthcare professionals can manually create and digitally sign a Patient Summary [36].
Patient Summary	The system shall allow the automatic generation of a Patient Summary based on updated patient data [36].
Patient Summary	The system shall enable healthcare professionals to view the IPS content in a structured and human-readable interface.
Patient Summary	The system shall auto-populate IPS sections from existing EHR data where possible.
Patient Summary	The system shall support the creation and update of IPS sections, including Allergies and Intolerances, Medication Summary, Problem List, Immunization, History of Procedures,

	Medical Devices, Diagnostic Results, Functional Status, Past History of Illness, Plan of Care, Pregnancy, Advance Directives, Social History [4].
Allergies and Intolerances	The system shall have the capacity to record the Onset Date, Agent or Allergen, Type of Propensity, Allergy manifestation, Status, End Date, Speciality and Healthcare Professional [5], [36], [71].
Medication Summary	The system shall have the capacity to record the Date of onset of treatment, Active ingredient, Route of administration, Dosage Regimen, Strength, Medication reason, Status, End Date, Speciality and Healthcare Professional
Problems	The system shall have the capacity to record the Onset date, Problem description, Problem Code, End date, Status, Speciality and Healthcare Professional [36], [45].
Immunizations	The system shall have the capacity to record the Date of Vaccination, Vaccine, Disease or agent targeted, Number in a series of vaccinations/doses, Batch/lot number, Type of Record, Status, Speciality and Healthcare Professional [4], [45].
Exams and Results	The system shall have the capacity to record the Date, Type, Priority, Exam, Result, Motive, Date of Execution, State, Speciality and Healthcare Professional [45], [72].
Medical Devices	The system shall have the capacity to record the Implant date, Device and implant description, Body site, End Date, Status, Speciality and Healthcare Professional [36], [45].
Procedures	The system shall have the capacity to record the Procedure date, Procedure description, Procedure Code, Body site, Category, Result, Motive, Status, Speciality and Healthcare Professional [36], [45].
Alerts	The system shall have the capacity to record the Date, Alert, Status, Speciality and Healthcare Professional [36], [44], [45].
Functional Status	The system shall have the capacity to record the Onset Date, Description, Status, Speciality and Healthcare Professional [36], [44], [45], [73].
Clinical Notes	The system shall have the capacity to record the Date, Note, Speciality and Healthcare Professional [36], [44], [45].
Social History	The system shall have the capacity to record the Date, Description, End Date, State, Speciality and Healthcare Professional [36], [44], [45], [74].
Plan of Care	The system shall have the capacity to record the Date, Description, Type, Motive, End Date, Speciality and Healthcare Professional [44], [45].
Evaluation	The system shall have the capacity to record the Date, Type, Evaluation, Speciality and Healthcare Professional [44], [45], [74].
Advance Directives	The system shall have the capacity to record the Date, Type, State, Advance Directive, Speciality and Healthcare Professional [44], [45], [75].
Pregnancy Status and History	The system shall have the capacity to record the Date, State, Details regarding the pregnancy status and history (e.g. number of pregnancies, number of abortions) [44], [45].
Timeline	The system should provide users with an easily accessible timeline of previous and future appointments for each patient.
Nursing	The system shall enable users to add nursing records in accordance with the nursing ontology.
Documents	The system shall allow the user to create, edit, cancel and consult documents.

3.6 Mockups and Prototype

After defining the functional and non-functional requirements, mockups and prototypes were developed. A prototype is a preliminary version of a product designed to obtain initial user feedback, facilitating the collection of insights at an early stage of development [63]. The prototype can be accessed via the following link <https://tinyurl.com/4r48h93z>.

Several mockups were created, and a brief explanation of some of them is provided below.

Patients' Lists

Upon accessing the application, the initial dashboard displayed is the "Patient List". This dashboard allows

the user to view patient lists they have created, as well as the patients contained within those lists.

Lista de Doentes

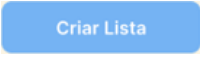
Os Meus Doentes

Doentes Internados



Identificação	Sexo	Isolamento	Localização	Méd. Responsável	Motivo Admissão	Data Admissão	Duração Int.	Resumo	Timeline
Ana Maria Silva Ferreira Nº Uteute 999999999	♀	 Contacto	 Medicina A1, C2	 Mário Silva	Insuficiência cardíaca descompensada	21/04/2025 16h30	1 dia(s)		 
Maria Ana Silva Barbosa Nº Uteute 111111111	♀		 Medicina A1, C4	 Mário Silva	Insuficiência cardíaca descompensada	21/03/2025 00h30	32 dia(s)		 
João Manuel Silva Rocha Nº Uteute 888888888	♂		 Cirurgia B, C1	 Artur Borges	Hemorragia digestiva alta	13/03/2025 02h30	40 dia(s)		 
Inês Sousa Ferreira Nº Uteute 333333333	♀		 Pediatria C, C1	 Ana Maria Martins	Bronquiolite	14/03/2025 12h30	8 dia(s)		 
José Silva Cardoso Nº Uteute 555555555	♂	 Contacto	 Cirurgia C, C1	 Artur Borges	Apendicite	10/03/2025 08h30	43 dia(s)		 
Ana Oliveira Silva Nº Uteute 777777777	♀		 Cirurgia C, C2	 Artur Borges	Hemorragia digestiva alta	14/04/2025 12h30	8 dia(s)		 
José Oliveira Gomes Nº Uteute 222222222	♂		 Neurocirurgia, C1	 Carlos Marques	Outras hemorragias subaracnóideas	10/03/2026 08h30	43 dia(s)		 
Joana Maria Castro Silva Nº Uteute 444444444	♀	 Contacto	 Pediatria B, C1	 Ana Maria Martins	Gastroenterite	13/03/2025 02h30	40 dia(s)		 
Manuel Sousa Silva Nº Uteute 666666666	♂	 Contacto	 Pediatria B, C2	 Ana Maria Martins	Gastroenterite	13/03/2025 02h30	40 dia(s)		 
José António Castro Barbosa Nº Uteute 123456789	♂		 Pediatria A, C1	 Ana Maria Martins	Bronquiolite	21/04/2025 16h30	1 dia(s)		 
Rodrigo Oliveira Martins Nº Uteute 987654321	♂		 Cirurgia C, C3	 Artur Borges	Diverticulite aguda complicada	10/12/2025 08h30	133 dia(s)		 
António Manuel Silva Almeida Nº Uteute 111111119	♂		 Cirurgia B, C2	 Artur Borges	Hemorragia digestiva alta	17/02/2025 05h00	64 dia(s)		 
Maria Carolina Oliveira Ferreira Nº Uteute 111111118	♀	 Góticula	 Medicina A1, C7	 Andreia Carmo	Pneumonia	14/04/2025 12h30	8 dia(s)		 
Ana Catarina Leite Silva Nº Uteute 111111117	♀		 Pediatria A, C2	 Ana Maria Martins	Bronquiolite	10/03/2025 08h30	43 dia(s)		 

Figure 3.32 Mockup - Patients' Lists

Within this dashboard, users can create customised patient lists, select which columns are displayed, arrange their order, apply filters and access individual patient records. These actions are performed by clicking on the . Multiple lists can be created by clicking on  and favourite lists can be defined by clicking on the icon . By doing so, those lists are directly accessible from the “Patient List” dashboard.

Users are also able to configure the visibility of columns through toggle controls , with the exception of the patient identification column, which is always visible. The order of columns can be adjusted by selecting the icon  and dragging it to the desired position. In addition, filters may be applied by default to each list , ensuring that every time the Patient List dashboard is accessed, the information is automatically displayed according to the user’s predefined criteria. When a filter is active, the filter icon changes colour to indicate its application .

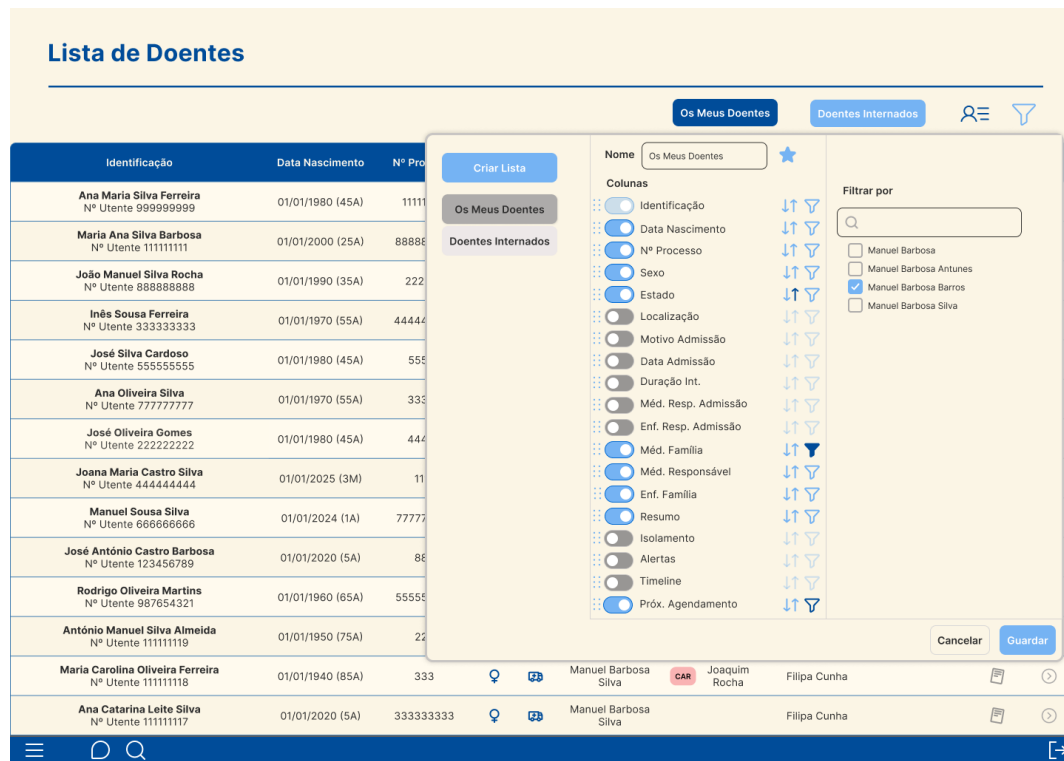


Figure 3.33 Mockup - Patients' Lists with filter

Through the Patient List, it is possible to access patient information, such as the Patient Summary  and the Patient Timeline , thereby enabling users to obtain an overview of key data in a quick and straightforward manner.

Lista de Doentes

Os Meus Doentes Doentes Internados

Identificação	Sexo	Isolamento	Localização	Méd. Responsável	Motivo Admissão	Data Admissão	Duração Int.	Resumo	Timeline
Ana Maria Silva Ferreira Nº Utente 9999999									
Maria Ana Silva Barbosa Nº Utente 1111111									
João Manuel Silva Rocha Nº Utente 8888888									
Inês Sousa Ferreira Nº Utente 3333333									
José Silva Cardoso Nº Utente 5555555									
Ana Oliveira Silva Nº Utente 7777777									
José Oliveira Gomes Nº Utente 2222222									
Joana Maria Castro Silva Nº Utente 4444444									
Manuel Sousa Silva Nº Utente 6666666									
José António Castro Barbosa Nº Utente 1234567									
Rodrigo Oliveira Martins Nº Utente 9876543									
António Manuel Silva Almeida Nº Utente 1111111									
Maria Carolina Oliveira Ferreira Nº Utente 1111111									
Ana Catarina Leite Silva Nº Utente 1111111									

Alergias e Reações Adversas

Alergénio	Tipo	Manifestação	Gravidade	Estado
Paracetamol	Alergia	Ecema	Moderada	Ativo

Problemas

Problema	Código (ICD10)	Data Início	Estado
Apneia do sono, SOE	G4731	2021	Ativo
Hipertensão essencial (primária)	I10	2020	Ativo

Medicação

Medicação	Via	Dose	Frequência	Tipo	Estado
Amlodipina	Oral	5mg	1x dia	Comunidade	Em Pausa
Ringer lactato	IV	1000ml	Contínuo	Internamento	Ativo

Dispositivos Médicos

Dispositivo	Localização	Data de Início
CPAP		2021

MCDT

MCDT	Prioridade	Resultado	Data Pretendida	Estado
Creatinina	STAT	0.8 mg/dL	14/05/2025	Concluído
Hematócrito	STAT	27%	14/05/2025	Concluído

Procedimentos

Procedimento	Localização	Categoria	Data de Realização	Estado
Endoscopia			15/05/2025	Realizado
Ressecção do apêndice por via endoscópica percutânea	Apêndice	Cirúrgico	06/11/2020	Realizado

Vacinação

Vacina	Dose	Data	Estado
--------	------	------	--------

Histórico de Problemas

Problema	Código (ICD10)	Data Início	Estado
Bronquite		08h30	43 dia(s)

Pequena A, C2, PED, Ana Maria Martins, Bronquite, 10/04/2025 08h30, 43 dia(s)

Figure 3.34 Mockup - Patients' Lists with Patient's Summary

Lista de Doentes

Os Meus Doentes Doentes Internados

Identificação	Sexo	Isolamento	Localização	Méd. Responsável	Motivo Admissão	Data Admissão	Duração Int.	Resumo	Timeline
Ana Maria Silva Ferreira Nº Utente 999999999									
Maria Ana Silva Barbosa Nº Utente 111111111									
João Manuel Silva Rocha Nº Utente 888888888									
Inês Sousa Ferreira Nº Utente 333333333									
José Silva Cardoso Nº Utente 555555555									
Ana Oliveira Silva Nº Utente 777777777									
José Oliveira Gomes Nº Utente 222222222									
Joana Maria Castro Silva Nº Utente 444444444									
Manuel Sousa Silva Nº Utente 666666666									
José António Castro Barbosa Nº Utente 123456789									
Rodrigo Oliveira Martins Nº Utente 987654321									
António Manuel Silva Almeida Nº Utente 111111119									
Maria Carolina Oliveira Ferreira Nº Utente 111111118									
Ana Catarina Leite Silva Nº Utente 111111117									

Timeline

- 14/04/2025, 16h30: Internamento Cirurgia Geral Hemorragia digestiva alta ULS São João A decorrer
- 25/11/2023, 16h00: Consulta Pneumologia ULS São João Concluído
- 06/11/2020, 11h00: Internamento Cirurgia Geral Apêndice ULS São João Concluído
- 06/11/2020, 06h00: Urgência Cirurgia Geral Dor Abdominal ULS São João Concluído
- 15/09/2025, 15h30: Consulta Médica Geral e Familiar USF Covelo Agendado
- 28/04/2024, 11h00: Consulta Médica Geral e Familiar USF Covelo Concluído
- 10/11/2023, 11h00: Consulta Enfermagem USF Covelo Concluído
- 06/11/2020, 09h00: Bloco Cirurgia Geral Ressecção do apêndice por via endoscópica percutânea ULS São João Concluído
- 06/08/2020, 11h00: Consulta Pneumologia ULS São João Concluído

Pequena A, C2, PED, Ana Maria Martins, Bronquite, 10/04/2025 08h30, 43 dia(s)

Figure 3.35 Mockup - Patients' Lists with Patient's Timeline

Break the Glass

As mentioned previously, patient information can be accessed through the “Patient List”. In cases where a patient has chosen to protect their data, a “Break the Glass” mechanism is applied. When attempting to access such information, the user must either confirm that they have the patient’s permission or provide a justification for the access. All access attempts and justifications are recorded in the system logs, which can be reviewed via a dedicated dashboard accessible to the DPO.

Lista de Doentes									
Os Meus Doentes Doentes Internados									
Identificação	Data Nascimento	Nº Processo	Sexo	Estado	Méd. Família	Méd. Responsável	Enf. Família	Próx. Agendamento	Resumo
Ana Maria Silva Ferreira Nº Utente 999999999	01/01/1980 (45A)	111111111	♀		Manuel Barbosa Silva	PNEU João Silva	Filipa Cunha	30/07/2025 16h30	
Maria Ana Silva Barbosa Nº Utente 111111111	01/01/2000 (25A)	888888888	♀		Manuel Barbosa Silva		Filipa Cunha		
João Manuel Silva Rocha Nº Utente 888888888	01/01/1990 (35A)	222222	♂		Manuel Barbosa Silva		Filipa Cunha		
Inês Sousa Ferreira Nº Utente 333333333	01/01/1970 (55A)	444444444	♀		Manuel Barbosa Silva		Filipa Cunha	14/08/2025 16h30	
José Silva Cardoso Nº Utente 555555555	01/01/1980 (45A)	55555	♂		Manuel Barbosa Silva	PNEU Carla Barbosa	Filipa Cunha	10/03/2026 08h30	
Ana Oliveira Silva Nº Utente 777777777	01/01/1970 (55A)	Está a aceder a dados protegidos. Indique se tem o consentimento explícito do utente: ☐ Sim, tenho consentimento do doente ☐ Não, não tenho consentimento / não foi possível obtê-lo					Filipa Cunha		
José Oliveira Gomes Nº Utente 222222222	01/01/1980 (45A)						Filipa Cunha		
Joana Maria Castro Silva Nº Utente 444444444	01/01/2025 (3M)						Filipa Cunha	09/05/2025 10h00	
Manuel Sousa Silva Nº Utente 666666666	01/01/2024 (1A)	777777777	♂		Manuel Barbosa Silva		Filipa Cunha		
José António Castro Barbosa Nº Utente 123456789	01/01/2020 (5A)	888	♂		Manuel Barbosa Silva		Filipa Cunha	19/06/2025 10h00	
Rodrigo Oliveira Martins Nº Utente 987654321	01/01/1960 (65A)	555555555	♂		Manuel Barbosa Silva	CAR Joaquim Rocha	Filipa Cunha	10/03/2026 08h30	
António Manuel Silva Almeida Nº Utente 111111119	01/01/1950 (75A)	222	♂		Manuel Barbosa Silva	CAR Mário Silva	Filipa Cunha	30/07/2025 16h30	
Maria Carolina Oliveira Ferreira Nº Utente 111111118	01/01/1940 (85A)	333	♀		Manuel Barbosa Silva	CAR Joaquim Rocha	Filipa Cunha		
Ana Catarina Leite Silva Nº Utente 111111117	01/01/2020 (5A)	333333333	♀		Manuel Barbosa Silva		Filipa Cunha		

Figure 3.36 Mockup - Patients' Lists with break the glass mode justification (1)

Lista de Doentes									
Os Meus Doentes Doentes Internados									
Identificação	Data Nascimento	Nº Processo	Sexo	Estado	Méd. Família	Méd. Responsável	Enf. Família	Próx. Agendamento	Resumo
Ana Maria Silva Ferreira Nº Utente 999999999	01/01/1980 (45A)	111111111	♀		Manuel Barbosa Silva	PNEU João Silva	Filipa Cunha	30/07/2025 16h30	
Maria Ana Silva Barbosa Nº Utente 111111111	01/01/2000 (25A)	888888888	♀		Manuel Barbosa Silva		Filipa Cunha		
João Manuel Silva Rocha Nº Utente 888888888	01/01/1990 (35A)	222222	♂		Manuel Barbosa Silva		Filipa Cunha		
Inês Sousa Ferreira Nº Utente 333333333	01/01/1970 (55A)						Filipa Cunha	14/08/2025 16h30	
José Silva Cardoso Nº Utente 555555555	01/01/1980 (45A)						Filipa Cunha	10/03/2026 08h30	
Ana Oliveira Silva Nº Utente 777777777	01/01/1970 (55A)						Filipa Cunha		
José Oliveira Gomes Nº Utente 222222222	01/01/1980 (45A)						Filipa Cunha		
Joana Maria Castro Silva Nº Utente 444444444	01/01/2025 (3M)						Filipa Cunha	09/05/2025 10h00	
Manuel Sousa Silva Nº Utente 666666666	01/01/2024 (1A)						Filipa Cunha		
José António Castro Barbosa Nº Utente 123456789	01/01/2020 (5A)	888	♂		Manuel Barbosa Silva		Filipa Cunha	19/06/2025 10h00	
Rodrigo Oliveira Martins Nº Utente 987654321	01/01/1960 (65A)	555555555	♂		Manuel Barbosa Silva	CAR Joaquim Rocha	Filipa Cunha	10/03/2026 08h30	
António Manuel Silva Almeida Nº Utente 111111119	01/01/1950 (75A)	222	♂		Manuel Barbosa Silva	CAR Mário Silva	Filipa Cunha	30/07/2025 16h30	
Maria Carolina Oliveira Ferreira Nº Utente 111111118	01/01/1940 (85A)	333	♀		Manuel Barbosa Silva	CAR Joaquim Rocha	Filipa Cunha		
Ana Catarina Leite Silva Nº Utente 111111117	01/01/2020 (5A)	333333333	♀		Manuel Barbosa Silva		Filipa Cunha		

Figure 3.37 Mockup - Patients' Lists with break the glass mode justification (2)

Resumo do Doente

After accessing a patient's record, an International Patient Summary is displayed. The upper bar of the dashboard allows the user to identify the patient whose information is being consulted, as it contains demographic details and clinical data such as allergies. Beneath this, a navigation bar provides access to the different menus of the application.

The main body of the dashboard is organised into modular panels, each corresponding to a specific section of the IPS, including *Problemas*, *Dispositivos Médicos*, *Alertas*, and *História Social*. The Patient Summary enables users to view a wide range of patient information at once. In addition, users can add new information to each section using the icon , or edit existing entries through the icon . In both cases, a side panel opens, allowing data to be added or modified.

Ana Oliveira Silva

Nº Utente 777777777

01/01/1970 (55A) ♀

Alergias

Paracetamol

Alertas

Perda de peso inesperada

Médico de Família

Manuel Silva Barbosa

Localização

ULS São João, Cirurgia C

Motivo de Admissão

Úlcera gástrica aguda com hemorragia

Resumo

Timeline

Documentos

Enfermagem

Alergias

Problemas

Medicação

Disp. Médicos

MCDT

Procedimentos

Vacinação

Alergias e Reações Adversas

Alergénio	Tipo	Manifestação	Gravidade	Estado
Paracetamol	Alergia	Eczema	Moderada	Ativo

Problemas

Problema	Código (ICD10)	Data Início	Estado
Apneia do sono, SOE	G4731	2021	Ativo
Hipertensão essencial (primária)	I10	2020	Ativo

Medicação

Medicação	Via	Dose	Frequência	Tipo	Estado
Amlodipina	Oral	5mg	1x dia	Comunidade	Em Pausa
Ringer lactato	IV	1000ml	Contínuo	Internamento	Ativo

Dispositivos Médicos

Dispositivo	Localização	Data de Início
CPAP		2021

MCDT

MCDT	Prioridade	Resultado	Data Pretendida	Estado
Creatinina	STAT	0.8 mg/dL	14/05/2025	Concluído
Hematócrito	STAT	27%	14/05/2025	Concluído

Procedimentos

Procedimento	Localização	Categoria	Data de Realização	Estado
Endoscopia			15/05/2025	Realizado
Ressecção do apêndice por via endoscópica percutânea	Apêndice	Cirúrgico	06/11/2020	Realizado

Vacinação

Vacina	Dose	Data	Estado
Covid19Pfizer	3/3	10/11/2023	Realizada

Histórico de Problemas

Problema	Código (ICD10)	Data Início	Estado
Apêndice aguda	K35	2020	Resolvido

Alertas

Alerta	Data	Estado
Perda de peso inesperada	14/04/2025	Ativo

Estado Funcional

Estado Funcional	Data de Início	Estado
Mobilidade reduzida	14/05/2025	Ativo

Notas

Tipo	Especialidade	Profissional	Data
Enfermagem	Enfermagem	Ana Silva	17/05/2025

História Social

Descrição	Data Início	Estado
Ex-fumador	10/11/2023	Ativo

Figure 3.38 Mockup - Patient's Summary

Ana Oliveira Silva

Nº Utente 777777777

01/01/1970 (55A) ♀

Alergias

Paracetamol

Alertas

Perda de peso inesperada

Médico de Família

Manuel Silva Barbosa

Localização

ULS São João, Cirurgia C

Motivo de Admissão

Úlcera gástrica aguda com hemorragia

Resumo

Timeline

Documentos

Enfermagem

Alergias

Problemas

Medicação

Disp. Médicos

Alergias e Reações Adversas

Alergénio	Tipo	Manifestação	Gravidade	Estado
Paracetamol	Alergia	Eczema	Moderada	Ativo

Problemas

Problema	Código (ICD10)	Data Início	Estado
Apneia do sono, SOE	G4731	2021	Ativo
Hipertensão essencial (primária)	I10	2020	Ativo

Medicação

Medicação	Via	Dose	Frequência	Tipo	Estado
Amlodipina	Oral	5mg	1x dia	Comunidade	Em Pausa
Ringer lactato	IV	1000ml	Contínuo	Internamento	Ativo

Dispositivos Médicos

Dispositivo	Localização	Data de Início
CPAP		2021

MCDT

MCDT	Prioridade	Resultado	Data Pretendida	Estado
Creatinina	STAT	0.8 mg/dL	14/05/2025	Concluído
Hematócrito	STAT	27%	14/05/2025	Concluído

Procedimentos

Procedimento	Localização	Categoria	Data de Realização	Estado
Endoscopia			15/05/2025	Realizado
Ressecção do apêndice por via endoscópica percutânea	Apêndice	Cirúrgico	06/11/2020	Realizado

Vacinação

Vacina	Dose	Data	Estado
Covid19Pfizer	3/3	10/11/2023	Realizada

Histórico de Problemas

Problema	Código (ICD10)	Data Início	Estado
Apêndice aguda	K35	2020	Resolvido

Alertas

Alerta	Data	Estado
Perda de peso inesperada	14/04/2025	Ativo

Estado Funcional

Condição	Data de Início	Estado
Mobilidade reduzida	14/05/2025	Ativo

Notas

Tipo	Especialidade	Profissional	Data
Enfermagem	Enfermagem	Ana Silva	17/05/2025

História Social

Descrição	Data Início	Estado
Ex-fumador	10/11/2023	Ativo

Dispositivo Médico

Concluir

Data Início

2021

Dispositivo Médico

CPAP

Localização

Selecionar

Data Fim

Data

*Estado

Ativo

Figure 3.39 Mockup - Patient Summary with a form allowing information to be edited

Navigation Bar

As mentioned previously, there is a navigation bar available within the patient record, allowing the user to move between different menus containing the patient's information. In addition to the menus related to the IPS, other menus have been designed and incorporated into the navigation bar. These include the *Enfermagem*, *Timeline* and *Documentos*.

The inclusion of these additional menus was due to the findings of the interviews and survey. Participants emphasised the importance of accessing nursing records, chronological views of patient data, and supporting documentation as essential for continuity of care and clinical decision-making.

Menus

Most of the menus work in a similar manner, enabling the user to view information, edit existing entries or add new data via a sidebar. In all menus, the menu bar remains permanently visible to ensure ease of access and facilitate seamless navigation across the patient's information. Furthermore, all menus include filtering capabilities, allowing the user to refine and display only the information that meets specific criteria.

Regarding the information required to complete a data entry, this depends on the type of entry being made. For example, in the menus where the Portuguese Implementation Guide is applied, the mandatory fields correspond to those defined by the specification. In other menus, the selection of fields was based on the FHIR specification and the Guideline on the Electronic Exchange of Health Data under the Cross-Border Directive 2011/24/EU.

Ana Oliveira Silva
Nº Utente 777777777

Alergias | Alertas | Médico de Família | Localização | Motivo de Admissão

Paracetamol | Perda de peso inesperada | Manuel Silva Barbosa | ULS São João, Cirurgia C | Úlcera gástrica aguda com hemorragia

Resumo | Timeline | Documentos | Enfermagem | **Alergias** | Problemas | Medicação | Disp. Médicos | MCDT | Procedimentos | Vacinação

+ Alergias

Data início	Alergénio	Tipo	Manifestação	Gravidade	Data fim	Especialidade	Prof. Responsáveis	Estado
15/04/2025, 15h30	Paracetamol	Alergia	Eczema	Moderada		ca	Artur Borges	Ativo

Figure 3.40 Mockup - Allergies menu

Ana Oliveira Silva
Nº Utente 777777777

Alergias | Alertas | Médico de Família | Localização | Motivo de Admissão

Paracetamol | Perda de peso inesperada | Manuel Silva Barbosa | ULS São João, Cirurgia C | Úlcera gástrica aguda com hemorragia

Resumo | Timeline | Documentos | Enfermagem | **Alergias** | Problemas | Medicação | Disp. Médicos

+ Alergias

Data início	Alergénio	Tipo	Manifestação	Gravidade	Data fim
15/04/2025, 15h30	Paracetamol	Alergia	Eczema	Moderada	

Alergias e Reações Adversas Concluir

Data início: 17/05/2025

Alergénio: Amêndoa

Tipo: Alergia

Manifestação: Eczema

Gravidade: Moderada

*Estado: Ativo

Data fim: Data

Figure 3.41 Mockup - Allergies menu with a form allowing information to be edited

In addition to the option of viewing information in a table format, certain menus offer alternative forms of visualisation, such as graphical representations (used in the *Avaliações* section) or timelines (used in the *Problemas* section and in the patient's list of episodes).

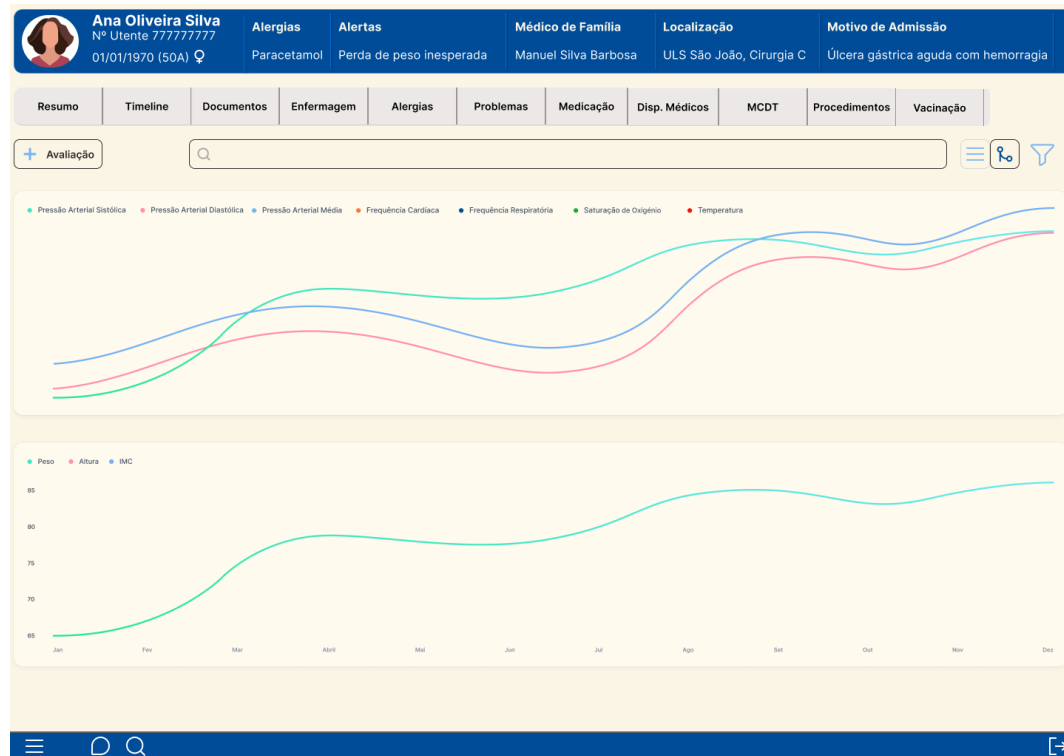


Figure 3.42 Mockup - Evaluations menu

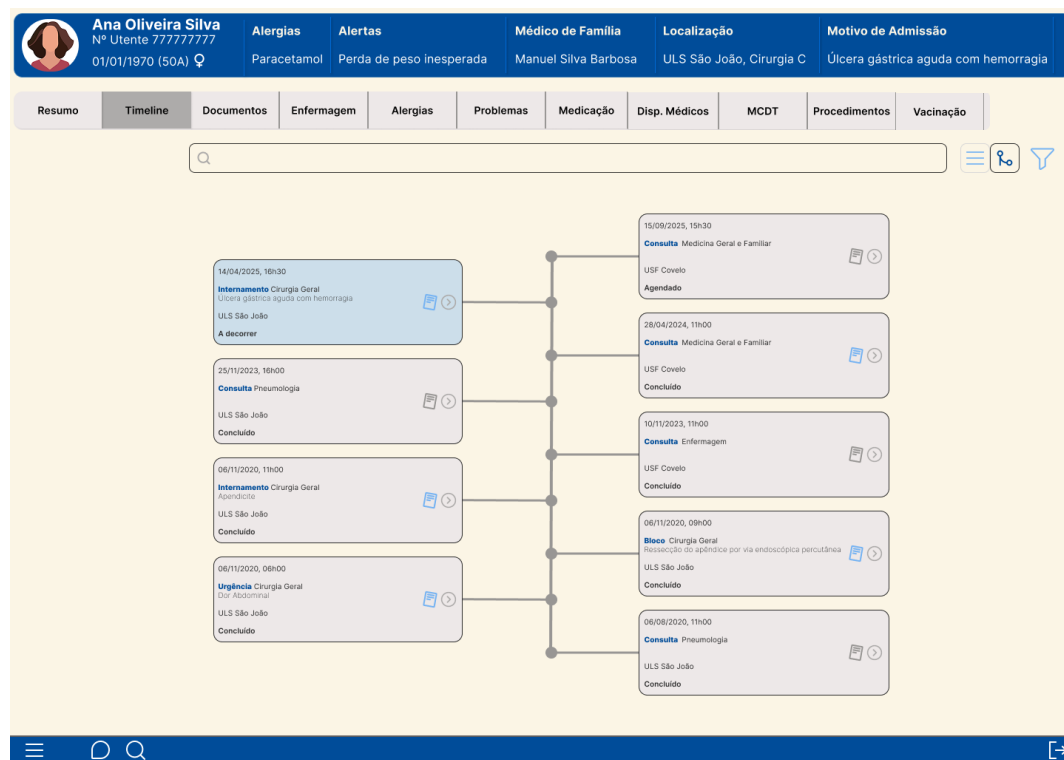


Figure 3.43 Mockup - Timeline menu

Footer

In all dashboards, a footer is available. Through this footer, users can return to the *Lista de Doentes* , access the messaging module, search for a patient and log out of the application .

Messages

Furthermore, the application includes a module specifically designed to enable the exchange of messages between healthcare professionals. This module, accessible via the footer through the icon , allows users to send messages as well as respond to those received.

This functionality was included because, during the interviews, several participants reported difficulties in contacting colleagues involved in the care of the same patient. They emphasised the importance of having a direct communication channel to clarify doubts or to share updates regarding changes in the patient's clinical status. By incorporating this feature, the system aims to strengthen care coordination and support timely information exchange within multidisciplinary teams.

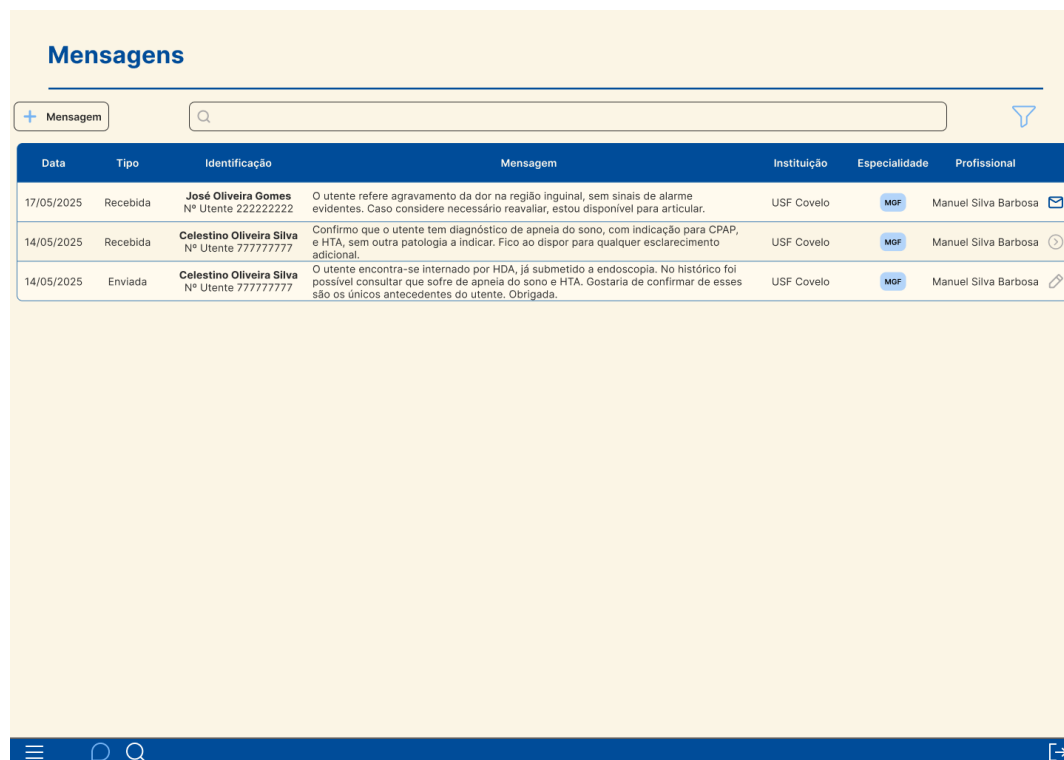


Figure 3.44 Mockup - Messages menu

Pesquisa de Doentes

Another functionality is the ability to search for patients. By selecting the icon , users can search for a patient using either their name or *Número de Utente* (national health number) and subsequently access the patient's record.

Lista de Doentes

Os Meus Doentes Doentes Internados

Identificação	Data Nascimento	Nº Processo	Sexo	Estado	Méd. Família	Méd. Responsável	Enf. Família	Próx. Agendamento	Resumo
Ana Maria Silva Ferreira Nº Utente 999999999	01/01/1980 (45A)	111111111	♀	🏠	Manuel Barbosa Silva	PNEU João Silva	Filipa Cunha	30/07/2025 16h30	📄 ↻
Maria Ana Silva Barbosa Nº Utente 111111111	01/01/1980 (45A)	888888888	♀	🏠	Manuel Barbosa Silva		pa Cunha		📄 ↻
João Manuel Silva Rocha Nº Utente 888888888	01/01/1980 (45A)	888888888	♂	🏠	Manuel Barbosa Silva		pa Cunha		📄 ↻
Inês Sousa Ferreira Nº Utente 333333333	01/01/1970 (55A)	333333333	♀	🏠	Manuel Barbosa Silva		pa Cunha	14/08/2025 16h30	📄 ↻
José Silva Cardoso Nº Utente 555555555	01/01/1980 (45A)	555555555	♂	🏠	Manuel Barbosa Silva		pa Cunha	10/03/2026 09h30	📄 ↻
Ana Oliveira Silva Nº Utente 777777777	01/01/1980 (45A)	777777777	♀	🏠	Manuel Barbosa Silva		pa Cunha		📄 ↻
José Oliveira Gomes Nº Utente 222222222	01/01/1980 (45A)	222222222	♂	🏠	Manuel Barbosa Silva	João Maria Silva	pa Cunha		📄 ↻
Joana Maria Castro Silva Nº Utente 444444444	01/01/2015 (10A)	444444444	♀	🏠	Manuel Barbosa Silva		pa Cunha	09/05/2025 10h00	📄 ↻
Manuel Sousa Silva Nº Utente 666666666	01/01/2024 (1A)	666666666	♂	🏠	Manuel Barbosa Silva		pa Cunha		📄 ↻
José António Castro Barbosa Nº Utente 123456789	01/01/2020 (5A)	123456789	♂	🏠	Manuel Barbosa Silva		pa Cunha	19/06/2025 10h00	📄 ↻
Rodrigo Oliveira Martins Nº Utente 987654321	01/01/1980 (45A)	987654321	♂	🏠	Manuel Barbosa Silva	João Rocha	pa Cunha	10/03/2026 08h30	📄 ↻
António Manuel Silva Almeida Nº Utente 111111119	01/01/1980 (45A)	111111119	♂	🏠	Manuel Barbosa Silva	João Maria Silva	pa Cunha	30/07/2025 16h30	📄 ↻
Maria Carolina Oliveira Ferreira Nº Utente 111111118	01/01/1940 (85A)	111111118	♀	🏠	Manuel Barbosa Silva	João Rocha	Filipa Cunha		📄 ↻
Ana Catarina Leite Silva Nº Utente 111111117	01/01/2020 (5A)	333333333	♀	🏠	Manuel Barbosa Silva		Filipa Cunha		📄 ↻

Figure 3.45 Mockup - Search functionality

3.7 Usability Testing

After the development of the mockups and prototype, usability testing was conducted with the aim of identifying potential usability issues at an early stage and addressing them prior to the application's development.

Two methods were employed for the user evaluation: the Cognitive Walkthrough and Heuristic Evaluation. These methods are complementary, as the Cognitive Walkthrough focuses on assessing whether new users are able to successfully perform tasks within the system, while the Heuristic Evaluation provides a more holistic appraisal of the system's overall usability [76].

There were six participants in the usability tests, with an effort made to ensure diversity among users. The group consisted of four nurses, one cardiopneumologist technician, and one doctor, all of whom had not participated in the interview process.

3.7.1 Cognitive Walkthrough

As mentioned previously, the Cognitive Walkthrough is used to assess a system's learnability. Accordingly, this test was conducted with the aim of evaluating whether new users could navigate and interact with the system effectively without prior training.

These tests were performed to three participants – one doctor and two nurses – each of whom was assigned four tasks in order to assess whether they could complete them without any prior explanation.

For the doctor, the following tasks were assigned:

- **Task 1: Register a food allergy (almond)**
 - Scenario: During an interaction with a patient, a doctor learns that the patient has a known allergy to almonds. The doctor records this information in the system.
- **Task 2: Register a clinical note**
 - Scenario: A doctor needs to register a clinical note documenting the patient's ongoing encounter.
- **Task 3: Add a document (statement)**
 - Scenario: A doctor wants to add a document related to the patient.
- **Task 4: Respond to a message sent by another healthcare professional**
 - Scenario: A doctor receives a message from another healthcare professional regarding a patient.

For the nurses, the following tasks were assigned:

- **Task 1: Record a vital sign (blood pressure)**
 - Scenario: A nurse needs to record a patient's blood pressure measurement as part of routine monitoring.
- **Task 2: Document a nursing record (nursing diagnosis of “Cuidar da higiene pessoal comprometido”)**
 - Scenario: A nurse observes that the patient shows signs of impaired personal hygiene and needs to register this nursing diagnosis.
- **Task 3: Add a document (statement)**
 - Scenario: A healthcare professional wants to add a document related to the patient.
- **Task 4: Respond to a message sent by another healthcare professional**

- Scenario: A healthcare professional receives a message from another healthcare professional regarding a patient.

In order to evaluate each task performed, a system of colours was used:

- Green: the user completed the task without difficulty.
- Yellow: the user had difficulties in completing the task.
- Red: the user was unable to complete the task.

Following, there is a table that shows the results of the Cognitive Walkthrough.

Table 3.4: Cognitive walkthrough results

	Nurse 1	Nurse 2	Doctor
Task 1	Yellow	Yellow	Green
Task 2	Green	Yellow	Green
Task 3	Green	Green	Green
Task 4	Green	Green	Green

Both nurses experienced difficulties with the first task, particularly with the step involving access to the menu via the navigation bar. This likely indicates that it is not immediately apparent to users that the navigation bar includes a horizontal scroll. . In the second task, one of the nurses also encountered some difficulty when documenting a nursing record. Apart from these two challenges, all other tasks were completed without difficulty, and the doctor was able to complete all assigned tasks with ease.

3.7.2 Heuristic Evaluation

As mentioned previously, the Heuristic Evaluation provides a more holistic appraisal of the system's overall usability. This evaluation consists of applying the 10 heuristics, defined by Jacob Nielsen [70]:

1. **Visibility of System Status:** the system should always keep users informed of what is happening, through appropriate feedback in a reasonable time.
2. **Match Between the System and the Real World:** the system should speak the user's language, with words, phrases and concepts that are familiar to the user.
3. **User Control and Freedom:** users often select system functions by accident and will need a clearly marked "emergency exit" to leave unwanted states without having to go through extended dialogs.
4. **Consistency and Standard:** users don't have to wonder if different words, situations, or actions mean the same thing.

5. **Error Prevention:** good error messages are important, but the best designs carefully prevent problems from occurring in the first place.
6. **Recognition Rather than Recall:** make objects, actions, and options visible. The user does not have to memorize information from one section of the dialog to another.
7. **Flexibility and Efficiency of Use:** accelerators invisible to novice users - may often speed up interaction for expert users so that the system can cater to both experienced and inexperienced users. Allow users to customize frequently performed actions
8. **Aesthetic and Minimalist Design:** dialogue should not contain irrelevant or rarely needed information.
9. **Users Recognize, Diagnose and Recover from Errors:** error messages should be stated in plain language.
10. **Help and Documentation:** ideally the system can be used without documentation but it may be necessary to provide assistance and documentation. Any such information should be easy to find and should be focused on the user's task.

The Heuristic Evaluation was performed by three participants – one cardiopneumology technician and two nurses. Initially, a 20 minute meeting was held during which the procedure and each heuristic were explained. Following this, a document (available in the annex 6.4.1) was provided to the participants, allowing them to record, for each heuristic, the problems identified, to rate their severity on a scale from 0 to 4, and to propose potential improvements.

The following table summarises the results of the heuristic evaluation:

Table 3.5: Heuristic Evaluation

Heuristic	Problem	Severity	Suggestion
1	Lack of clear error message descriptions.	3	Error notification with a clear description.
1	No notification appears to indicate that there is an unread message.	2	A notification should be displayed indicating that there is an unread message.
1	There are icons that suggest the presence of additional information; however, when hovered over no tooltip is displayed, and when clicked no further information is provided.	3	Icons should consistently provide tooltips or relevant content when hovered over or clicked.
3	In most menus, there is no option available to delete records.	4	An option should be added to allow the user to delete records.
4	The exit button is not consistent across the application; in some areas it is represented by an “X”, while in others it appears as “Cancel”.	2	Consistency should be maintained by adopting a single option throughout the application.

4	The identification of the responsible healthcare professional is not consistent across the application; in some areas it is labelled as “ <i>médico responsável</i> ” and in others as “ <i>profissional responsável</i> ”.	2	Consistency should be maintained by adopting a single option throughout the application.
5	Not all fields required for form submission and/or modifications are marked as mandatory.	3	Representation of all fields that are mandatory.
5	In the <i>Documents</i> menu, it was possible to delete a document without providing a reason, even though the field was marked as mandatory.	2	Block the action until the mandatory field has been completed.
6	There is no visible scroll bar, which prevents the user from perceiving that it is possible to scroll and access additional information.	3	Add a visible scroll bar.
10	Some of the icons used are not clear in indicating the type of data/action they represent.	3	When hovering over the icons, a tooltip should be displayed.

This evaluation revealed violations in heuristics 1, 3, 4, 5, 6, and 10. The majority of the issues identified were associated with the absence of clear tooltips and insufficient documentation, while others were related to inconsistencies in labelling, terminology, and interface design.

One participant also observed that the summary section did not display any information, which could lead to uncertainty regarding the data already recorded. In practice, there is a functionality in the prototype that allows the user to expand and view the information. However, the fact that this comment was made indicates that the design is not sufficiently intuitive and should be reviewed.

Another participant reported an issue whereby fields appeared pre-filled when attempting to add a new record. This was not a design flaw but rather a limitation of the non-functional prototype which, in the absence of a database to store user input, relied on pre-filled forms to ensure consistency across modules.

Several participants further noted that although certain fields were marked as mandatory, it was possible to save the form without completing them. This issue likewise is due to the constraints of a non-functional prototype. Similarly, while filter options could be modified, they did not affect the information displayed to the user, again due to prototype limitations.

The issues identified in relation to the heuristics should be resolved prior to the development of the application. The other problems reported by participants are not expected to occur in the final system, as they resulted from the limitations of a non-functional prototype. Moreover, this evaluation underscores the importance of ensuring clarity, consistency, and adherence to usability principles in order to enhance user experience and reduce the likelihood of errors.

3.8 Summary

This chapter presented the methodology and results of developing the conceptual design for a module aimed at allowing the registration and visualisation of patient information, as well as enabling the generation of an IPS. The process began with the identification of stakeholders, followed by mixed-method user research.

User personas were then developed and a benchmarking analysis of existing EHR solutions allowing the identification of established functionalities and design patterns. Based on these findings, use cases, user stories,

and UML diagrams were constructed, leading to the specification of requirements and the development of mockups and prototypes.

The prototype was evaluated through usability testing, using both Cognitive Walkthrough and Heuristic Evaluation. The results highlighted identified usability issues, particularly related to labelling, consistency, and insufficient tooltips. These findings underscore the importance of refining the design prior to initiating the development of the application. Furthermore, some of the issues highlighted during the usability tests were due to constraints inherent in the prototype design, such as the inability to enforce mandatory fields before allowing forms to be saved.

In summary, this chapter demonstrates how the integration of stakeholder perspectives, user-centred research, benchmarking insights and usability evaluation contributed to the development of an interoperable and user-friendly EHR that allows the healthcare professionals to have a repository of patient information and uses it to generate an IPS.



Conclusion

4. Conclusion

4.1 Conclusions

This dissertation aimed to develop a conceptual design for a module to be integrated into an EHR, with the purpose of enabling the registration and visualisation of patient information independently of healthcare encounters and to generate an IPS that aligns with the national and international requirements. The module was conceived to provide healthcare professionals with a holistic and continuous view of a patient's health information, while also supporting the generation of an IPS in compliance with both national and international interoperability standards.

The findings of this research, derived from semi-structured interviews, surveys, and benchmarking of existing EHR systems, confirmed the existence of significant challenges such as information fragmentation, duplication of records and limited data sharing between institutions. These challenges not only compromise the efficiency of clinical workflows but also makes continuity of care difficult and may negatively affect patient safety.

The proposed conceptual design addresses these limitations by consolidating patient information into a unified interface and supporting functionalities such as timelines, structured summaries, secure messaging, and audit logs. The inclusion of mechanisms such as “Break the Glass” ensures that patient safety is prioritised in emergency situations, while reinforcing compliance with GDPR.

Usability testing was conducted through Cognitive Walkthrough and Heuristic Evaluation. The results demonstrated that there are areas in the design that should be addressed before the development of the software, ensuring a module that is aligned with the key principles of usability and learnability.

Overall, this dissertation contributes to the discourse on health data interoperability and patient-centred care by proposing a conceptual foundation for an EHR module capable of reducing information silos, enhancing clinical decision-making, and supporting continuity of care. Furthermore, this conceptual Foundation is aligned with the principles of the EHDS and international IPS standards, representing a step towards the development of a unified, interoperable, and patient-centred digital health ecosystem.

4.2 Future Work

This dissertation contributed for the development of a conceptual design for an EHR module that provides a longitudinal and holistic view of patient health information, enhancing continuity of care and supporting evidence-based clinical decision-making. Additionally, mockups and a prototype were developed and subjected to user testing.

Beyond the contributions brought by this dissertation, additional validation is required. The usability testing conducted in this dissertation was limited to a small number of healthcare professionals and expanding the evaluation to a more diverse group of users, including professionals from different care contexts, will provide more comprehensive insights.

Second, technical implementation and integration must be analysed and pursued. Future studies should advance beyond conceptual prototypes to test interoperability with existing infrastructures, such as the RSEu and MyHealth@EU. This would involve simulating data exchange, validating compliance with FHIR IPS Implementation Guides, and assessing system scalability, reliability, and security under real-world conditions.

Finally, enhancements in functionality could be explored. Incorporating advanced data visualisation, clinical decision support tools, and predictive analytics could transform the module from a passive data repository into an active contributor to clinical reasoning and workflow optimisation. Additionally, the integration of medical devices and patient-generated health data would extend the scope of the module and promote continuity of care beyond institutional boundaries.

By pursuing these directions, the conceptual design presented in this dissertation may evolve into a practical and interoperable solution, supporting the long-term vision of a unified, efficient, and patient-centred health information system in Portugal and across Europe.



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Annexes

6. Annexes

6.1 Software

Table 1.1: List of software mentioned in the semi-structure interviews and survey

Application	Objective
SClinico	SClinico is the primary EHR system used across the Portuguese National Health Service, encompassing both hospital and primary-care environments.
JustCare	Software used to refer patients and monitor their progress within the framework of the <i>Rede Nacional de Cuidados Continuados</i> .
Glintt	EHR system.
ByMe	Software that enables the registration and management of exams.
Alert	Software used for the registration and management of patient encounters in emergency departments.
PatientCare	Software used for the registration and management of patient encounters in intensive care, neonatology, operating theatres, outpatient appointments, and emergency departments.
Registo de Saúde Eletrónico (RSE)	Software that allows patients to access part of their clinical information and to perform certain actions, such as scheduling appointments.
Visão Clínica Integrada (VCI)	Project that enables the consultation of clinical information recorded in SClinico, allowing data to be viewed either in a chronological timeline or as a list of episodes. It also provides access to a clinical summary of the patient.
Processo Clínico Eletrónico (PCE)	A system of the Portuguese National Health Service that centralises patients' health information.
B-ICU Care	Software used for the registration and management of patient encounters in intensive care and neonatology.
ObsCare	Software used for the registration and management of patient encounters in obstetric care.
I'mThom	EHR system.
Siima	Platform for the management of examinations across multiple clinical specialties.
GHAf	Software used for the management of pharmacies.
GestCare	Software used for the registration and management of patient encounters in obstetric care.
Cerner	EHR system.
Novigest	Software used for the registration and management of patient encounters in dental care.
jOne	Software that enables the registration and consultation of clinical information for all patients, used primarily in the context of emergency departments at ULS São João.

6.2 Semi-Structured Interviews

6.2.1 Healthcare Professionals' Interviews

Introduction

- Introduce myself and the purpose of the interview.
- Mention the estimated duration of the discussion (30 to 45 mins).
- Asking for consent.

Questions

- Que aplicações utilizas para a realização de registos/consulta de dados dos doentes?
- Como é que os sistemas de Registo de Saúde Electrónico (RSE) que utiliza apoiam ou dificultam as suas tarefas diárias?
- Durante o seu dia de trabalho, tem frequentemente necessidade de aceder a dados clínicos que estão indisponíveis ou que são difíceis de encontrar?
 - Que desafios enfrenta em relação à visualização de dados ou à partilha de informação entre diferentes prestadores de cuidados ou aplicações?
 - Os dados de que necessita diariamente para tomar decisões encontram-se disponíveis numa única aplicação ou tem, frequentemente, de consultar aplicações diferentes para os obter?
 - Ao aceder aos dados de saúde de um doente, que desafios enfrenta para ter uma visão completa da sua história clínica ou do seu estado de saúde atual?
 - Quais as funcionalidades que necessita num sistema de RSE de forma a conseguir realizar as suas tarefas de forma eficiente?
- Que tipos de dados clínicos são mais importantes para o seu trabalho?
- Pensa que a possibilidade de adicionar e actualizar registos clínicos de doentes de forma independente de episódios/visitas (por exemplo, independente de uma consulta médica ou uma visita hospitalar) seria útil?
 - Se sim, de que forma isso melhoraria o seu fluxo de trabalho ou a qualidade dos cuidados que presta?
- Pode descrever com que frequência precisaria de aceder ou actualizar as informações neste módulo durante o seu dia de trabalho?
 - Além disso, que tipos de dados clínicos considera que deveria ter disponíveis de forma imediata neste módulo?
- Que funcionalidades deste módulo melhorariam a sua experiência e a sua capacidade de tomar decisões?
- Existem riscos ou desafios que antecipa na utilização deste módulo?

Conclusion

- Thank the participants for their insights.

- Asking the participants if they have additional thoughts or suggestions.

6.2.2 IT Professionals' Interviews

Introduction

- Introduce myself and the purpose of the interview.
- Mention the estimated duration of the discussion (30 to 45 mins).
- Asking for consent.

Questions

- Pode descrever o seu cargo e as suas principais responsabilidades na gestão de sistemas de informação em saúde?
- Como é o seu dia de trabalho típico relativamente à supervisão ou implementação de sistemas de Registo de Saúde Electrónico (RSE)?
- Quais são os maiores desafios que a sua equipa ou organização enfrenta relativamente à visualização e partilha de dados entre sistemas de RSE?
 - Com que frequência surgem problemas de interoperabilidade e de que forma estes afectam a eficiência organizacional ou a prestação de cuidados aos utentes?
- Quais as funcionalidades e características técnicas que deve ter um módulo de RSE para permitir actualizações contínuas de dados clínicos e possibilitar uma visão abrangente e em tempo real das informações do doente?
 - Que capacidades técnicas (por exemplo, interoperabilidade, desempenho do sistema) considera essenciais para alcançar este objetivo?
- Seria importante para a sua organização ter um módulo de RSE que permitisse actualizações contínuas ao processo clínico dos doentes, independentes de episódios/visitas específicos? Porquê? Porque não?
- Como pensa que este módulo se iria inserir na infraestrutura de TI da sua organização?
- Existem riscos ou desafios que antecipa na utilização deste módulo?

Conclusion

- Thank the participants for their insights.
- Asking the participants if they have additional thoughts or suggestions.

6.3 Survey

Questions

- Na Q1, se Médico(a)
 - responde à Q2
- Se Enfermeiro(a)
 - responde à Q3
- Se Farmacêutico(a)
 - responde à Q4
- Restantes questões respondidas por todos os profissionais de saúde.

Perfil do Participante

As próximas questões têm como objetivo caracterizar o perfil dos participantes deste estudo. As respostas são anónimas e servirão apenas para contextualizar os resultados da investigação.

1 – Qual é a sua profissão? (*Escolha única*)

- Médico(a)
- Enfermeiro(a)
- Fisioterapeuta
- Psicólogo(a)
- Farmacêutico(a)
- Nutricionista
- Outra

2 – Qual a sua especialidade? (*Especialidades médicas - escolha múltipla*)

- Anatomia Patológica
- Anestesiologia
- Angiologia e Cirurgia Vascular
- Cardiologia
- Cardiologia Pediátrica
- Cirurgia Cardio-Torácica
- Cirurgia Geral
- Cirurgia Maxilo-facial
- Cirurgia Pediátrica
- Cirurgia Plástica e Reconstructiva e Estética
- Dermato-venereologia
- Doenças Infecciosas
- Endocrinologia-Nutrição
- Estomatologia
- Farmacologia Clínica
- Gastrenterologia
- Genética Médica

- Ginecologia-Obstetrícia
- Hematologia Clínica
- Imuno-alergologia
- Imuno-hemoterapia
- Medicina Desportiva
- Medicina do Trabalho
- Medicina Física e de Reabilitação
- Medicina Geral e Família
- Medicina Interna
- Medicina Legal
- Medicina Nuclear
- Medicina Tropical
- Nefrologia
- Neuro-Cirurgia
- Neurologia
- Neuro-Radiologia
- Oftalmologia
- Oncologia Médica
- Ortopedia
- Otorrinolaringologia
- Patologia Clínica
- Pediatria
- Pneumologia
- Psiquiatria
- Psiquiatria da Infância e da Adolescência
- Radiodiagnóstico
- Radioterapia
- Reumatologia
- Saúde Pública
- Urologia
- Outra
- N/a

3 - Qual a sua especialidade? (*Especialidades de enfermagem - escolha múltipla*)

- Enfermagem Comunitária
- Enfermagem Médico-Cirúrgica
- Enfermagem de Reabilitação
- Enfermagem de Saúde Infantil e Pediátrica
- Enfermagem de Saúde Materna e Obstétrica

- Enfermagem de Saúde Mental e Psiquiátrica
- Enfermagem de Saúde Comunitária e de Saúde Pública
- Enfermagem de Saúde Familiar
- Enfermagem à Pessoa em Situação Crítica
- Enfermagem à Pessoa em Situação Crónica
- Enfermagem à Pessoa em Situação Paliativa
- Enfermagem à Pessoa em Situação Perioperatória
- Outra
- N/a

4 - Qual a sua especialidade? (*Especialidades farmacêuticas- escolha múltipla*)

- Análises Clínicas
- Assuntos Regulamentares
- Distribuição Farmacêutica
- Farmácia Hospitalar
- Genética Humana
- Indústria Farmacêutica
- Farmácia Comunitária
- Outra
- N/a

5 – Qual o contexto onde exerce a sua função? (*Escolha múltipla*)

- Internamento
- Bloco Operatório
- Urgência/Atendimento permanente
- Rede nacional de cuidados continuados integrados
- Cuidados de saúde primários
- Consulta externa
- Hospitalização domiciliária
- Hospital de dia
- Outro

6 - Há quanto tempo exerce a sua função? (*Escolha única*)

- Menos de 1 ano
- 1 a 3 anos
- 4 a 10 anos
- Mais de 10 anos

Objetivo 1 – Identificar as necessidades, desafios e preferências dos profissionais de saúde relativamente ao acesso e gestão da informação dos utentes

7 – Com que frequência utiliza um sistema de registos clínicos? (*Escolha única*)

- Diariamente
- Semanalmente

- Mensalmente
- Raramente
- Nunca

8 – Quantas aplicações utiliza diariamente para realizar registos clínicos/consultar informação clínica acerca dos utentes? (*Escolha única*)

- 0 aplicações
- 1 aplicação
- 2 a 3 aplicações
- 4 a 5 aplicações
- Mais de 5 aplicações

9 – Que aplicações utiliza diariamente para realizar registos clínicos/consultar informação clínica acerca dos utentes? (*Escolha múltipla*)

- SClínico
- Glintt
- Alert
- JustCare
- PatientCare
- B-ICU Care
- JOne
- Clinidata
- ObsCare
- ByMe
- Outra

10 – De seguida são apresentadas afirmações relacionadas com o acesso à informação clínica dos cidadãos. Por favor, indique o seu nível de concordância ou discordância. (*Utilização da escala de Likert em que 1 representa Discordo Totalmente e 5 representa Concordo Totalmente.*)

- Para obter o historial clínico de um utente tenho de consultar várias aplicações.
- Consigo encontrar toda a informação que necessito acerca de um utente.
- Tenho dificuldade em localizar rapidamente a informação mais relevante acerca de um utente.
- Existem informações registadas sobre o utente noutros sistemas, mas não consigo aceder às mesmas.
- Os sistemas que utilizo apresentam redundância de informação.
- A informação clínica está frequentemente dispersa, dificultando a minha tomada de decisão.
- Tenho dificuldade em consultar a informação registada por outras categorias profissionais.
- Tenho dificuldade em consultar a informação registada por outras especialidades.
- Tenho dificuldade em aceder a informações clínicas registadas noutras instituições de saúde (fora da minha ULS ou instituição privada).
- Tenho dificuldade em aceder a informações clínicas registadas noutras instituições de saúde (dentro da minha ULS ou instituição privada).

- O Registo de Saúde Eletrónico (RSE) disponibiliza todas as informações relevantes acerca do histórico clínica do utente.
- O Processo Clínico Eletrónico (PCE) disponibiliza todas as informações relevantes acerca do histórico clínica do utente.
- A Visão Clínica Integrada (VCI) disponibiliza todas as informações relevantes acerca do histórico clínica do utente.
- A utilização combinada do RSE, PCE e VCI suprimem as minhas necessidades em termos de consulta do histórico do utente.

11 – De seguida são apresentadas afirmações relacionadas com a utilização de sistemas de informação e o seu impacto na prática clínica e na qualidade dos cuidados prestados. Por favor, indique o seu nível de concordância ou discordância. (*Utilização da escala de Likert em que 1 representa Discordo Totalmente e 5 representa Concordo Totalmente.*)

- Tenho tempo suficiente para consultar toda a informação clínica relevante de um utente antes de tomar decisões.
- Frequentemente, encontro erros ou inconsistências nos registos clínicos do utente.
- A falta de um acesso centralizado ao histórico clínico do utente compromete a segurança do mesmo.
- A fragmentação dos registos clínicos leva, frequentemente, à repetição desnecessária de exames e procedimentos.
- Uma melhor organização dos dados clínicos ajudaria a reduzir erros na prática clínica.
- O histórico clínico do utente está bem organizado e estruturado no(s) sistema(s) que utilizo.
- Gostaria que existisse uma forma mais eficiente de visualizar a trajetória clínica completa do utente.
- Tenho necessidade de duplicar os registos do utente em várias aplicações.
- Tenho necessidade de duplicar os registos do utente em aplicações eletrónicas e em papel.

12 - Qual a informação clínica que necessita de consultar com mais frequência no seu dia a dia de trabalho? (pode selecionar mais do que uma opção, se aplicável) (*Escolha múltipla*)

- Antecedentes pessoais
- Medicação habitual
- Grau de dependência (anteriores e atual)
- Contexto social
- Informação acerca do cuidador ou outros apoios (por exemplo Serviços de Apoio Domiciliário)
- Prescrição Externa Medicamentosa (PEM)
- Informação registada por outras especialidades, tanto a nível dos hospitais públicos, nível privado e centros de saúde
- MCDT
- Vacinação
- Registos realizados em contexto de consulta
- História clínica do doente
- Diário médico

- Padrões de sinais vitais
- Registos de enfermagem
- Medicação administrada em contexto de internamento
- Outros.

Objetivo 2 – Determinar as funcionalidades que os profissionais de saúde consideram relevantes para a aplicação.

13 - Que informação clínica deveria estar disponível num resumo do historial clínico geral do utente? (pode seleccionar mais do que uma opção, se aplicável) (*Escolha múltipla*)

- Problemas ativos
- Medicação atual (ambulatório e medicação recorrente do utente, por exemplo administrada em contexto de hospital de dia)
- Alergias e Intolerâncias
- Vacinação
- Procedimentos cirúrgicos
- Dispositivos médicos
- MCDT prescritos e respetivos resultados
- Sinais vitais
- Antecedentes pessoais
- Historial de gravidez
- Contexto social
- Grau de dependência
- Diretiva antecipada de vontade (testamento vital)
- Outros.

14 - Que informação clínica do utente deveria estar disponível num resumo de um episódio gerado no seu contexto de trabalho? (pode seleccionar mais do que uma opção, se aplicável) (*Escolha múltipla*)

- Problemas ativos
- Motivo de admissão
- Medicação atual
- Alergias e Intolerâncias
- Vacinação
- MCDT prescritos e respetivos resultados
- Últimos diários registados (médico, enfermagem ou outros profissionais)
- Diagnósticos de enfermagem ativos
- Intervenções de enfermagem ativas (e data da última realização)
- Procedimentos cirúrgicos
- Via aérea
- Técnicas anestésicas (quais, data de realização e resultado)
- Relatos cirúrgicos
- Dispositivos médicos

- Triagens (data de realização, cor e discriminador)
- Diretiva antecipada de vontade (testamento vital)
- Antecedentes pessoais
- Historial de gravidez
- Sinais vitais
- Contexto social
- Grau de dependência
- Outra

15 – Quais as funcionalidades que gostaria de ter numa aplicação que lhe permitisse aceder ao historial clínico do utente? (pode seleccionar mais do que uma opção, se aplicável) (*Escolha múltipla*)

- Visualizar informação clínica agrupada por especialidade.
- Visualizar informação clínica agrupada por tipologia de registo (por exemplo, ver todos os diários médicos registados para aquele utente, independentemente do episódio onde foram registados).
- Visualizar informação clínica agrupada por episódio.
- Consultar quais os profissionais responsáveis pelo cuidado do utente noutras especialidades ou noutros contextos clínicos.
- Troca de mensagens com profissionais de outras especialidades.
- Visualizar uma timeline com os episódios do utente.
- Visualizar uma timeline com os diagnósticos, antecedentes pessoais e problemas do utente.
- Visualizar uma timeline de MCDT, com informação acerca da data de prescrição, realização e respetivos resultados.
- Possibilidade dos utentes registarem informação (por exemplo, dados administrativos, contacto de referência, informação acerca do estilo de vida).
- Integração de informação de dispositivos médicos ou wearables do utente (ex. bombas de insulina, smartwatches).
- Validar ou atualizar informação acerca do utente (por exemplo, inserir um novo diagnóstico).
- Consultar informação clínica do utente, independentemente de ter sido registada ao nível do setor público ou privado.
- Consultar um resumo do historial clínico do utente.
- Consultar o estado atual do utente (por exemplo, caso este se encontre internado).
- Consultar informação através de trends (por exemplo, análises clínicas, sinais vitais...).
- Repositório de controlo de acesso, onde é possível saber quais os profissionais acederam ao processo clínico do utente e em que momento.
- Possibilidade dos profissionais de saúde, quando acedem ao processo clínico do utente, registarem o motivo pelo qual o estão a consultar.
- Utente poder escolher ser notificado quando um profissional de saúde acede ao seu processo clínico.
- Existência de alertas (criados pelo próprio utilizador)
- Existência de alertas universais (não passíveis de serem escolhidos pelo utilizador).

- Interface customizável, na qual o utilizador pode escolher qual a informação que deseja visualizar.

6.4 Use Cases and User Stories

Following, there are the user stories developed for the application under design, along with their associated use cases.

Log in

User Stories

As a healthcare professional,

I want to log into the system,

So that I can access and edit patient health data.

As an administrator,

I want to log into the system,

So that I can manage permissions for healthcare professionals, configure the system, and support users with any issues.

As a data protection officer

I want to log into the system,

So that I can audit accesses to patient's health records and ensure data privacy compliance.

Use Case - UC.01 Log in

Goal: Enable users to authenticate into the system using valid credentials.

Actor: Healthcare Professional, Administrator, Data Protection Officer

UC.01.01 Successful Login

- 1.The user opens the application.
- 2.The system requests the user's credentials.
- 3.The user enters their authentication credentials.
- 4.The user clicks on the log in button.
- 5.The system verifies if the authentication credentials are correct.
- 6.If the credentials are correct, the user gains access to the application.

UC.01.02 Incorrect Credentials

- 1.In step 4. of UC.01.01, if the credentials are incorrect, the system displays a login error message to the user.
- 2.The system does not grant access to the user.

View patient's informationUser Story

As a healthcare professional,
I want to view patient's health data,
So that I can make informed clinical decisions.

As an administrator,
I want to view patient's health data,
So that I can support users with any issues.

As a data protection officer,
I want to view patient's health data,
So that I can investigate a data breach or complaint and conduct audits.

Use Case - UC.02 View patient's information

Goal: Enable the users to view the patient's information, including medical history, allergies, current medications, and other relevant clinical data.

Actor: Healthcare Professional, Administrator, Data Protection Officer

Assumptions: The user searched for a patient, the patient exists in the system and the patient did not restrict the access to their health data.

UC.02.01 Successful information retrieval – healthcare professional

- 1.The system checks if the user has permission to view the patient's information.
- 2.The system searches internally for the patient's information.
- 3.The system requests the Integration BUS to query the EHR and/or external systems for updated patient information.
- 4.If there is information in the EHR and/or external systems, the Integration BUS returns information to the system.
- 5.The system retrieves the patient's International Patient Summary (IPS).
- 6.If the user wants to view more detailed information, they choose which additional data they want to access, organized into the following categories:
 - a. Summary
 - b. Timeline
 - c. Documents
 - d. Nursing
 - e. Allergies and Intolerances
 - f. Problems
 - g. Medication
 - h. Medical Devices
 - i. Exams

- j. Procedures
- k. Immunizations
- l. Alerts
- m. Functional Status
- n. Clinical Notes
- o. Social History
- p. Plan of Care
- q. Vital Signs
- r. Advance Directives
- s. Pregnancy Status and History

7.The system checks if the user has permission to view the patient's detailed information.

8.The system logs user ID, timestamp, patient and information accessed.

UC.02.02 Successful information retrieval – administrator, data protection officer

1.The system checks if the user has permission to view the patient's information.

2.The user provides a mandatory justification to access the patient's information.

3.The system searches internally for the patient's information.

4.The system requests the Integration BUS to query the EHR and/or external systems for updated patient information.

5.If there is information in the EHR and/or external systems, the Integration BUS returns information to the system.

6.The system retrieves the patient's International Patient Summary (IPS).

7.If the user wants to view more detailed information, they choose which additional data they want to access, organized into the following categories:

- a. Summary
- b. Timeline
- c. Documents
- d. Nursing
- e. Allergies and Intolerances
- f. Problems
- g. Medication
- h. Medical Devices
- i. Exams
- j. Procedures
- k. Immunizations
- l. Alerts
- m. Functional Status
- n. Clinical Notes
- o. Social History
- p. Plan of Care
- q. Vital Signs
- r. Advance Directives

s. Pregnancy Status and History

8.The system checks if the user has permission to view the patient's detailed information.

9.The system logs user ID, timestamp, patient, information accessed and justification.

UC.02.03 Access denied by administrator policy – healthcare professional

1.In step 1. and step 7. of UC.02.01 and in step 1. and 9. of UC.02.02 and if the user does not have permission because access was not granted by an administrator, the system displays an informative message indicating the lack of permissions.

UC.02.04 No information available – healthcare professional, administrator and data protection officer

1.In step 2. and 3. of UC.01.01, if there is no patient information available (either locally or from external systems), the system displays an informative message to the user.

Break the Glass mode

User Story

As a healthcare professional in an emergency situation,

I want to access patient's restricted information,

So that I can provide care even if normal permissions would not allow it.

As an administrator,

I want to view patient's health data,

So that I can support users with any issues.

As a data protection officer,

I want to view patient's health data,

So that I can investigate a data breach or complaint and conduct audits.

Use Case - UC.03 Break the Glass mode

Goal: Enable user to override patient privacy restrictions in emergency situations and access restricted patient data.

Actor: Healthcare Professional, Administrator, Data Protection Officer

Assumptions: The patient exists in the system and there is information available. The user attempted to access patient data that is restricted by patient-defined privacy settings.

UC.03.01 Successful Activation of “Break the Glass” Mode

1.The user attempts to access patient information and is notified that access is restricted due to the patient's privacy settings.

2.The system presents the option to activate “Break the Glass” mode.

3.The user confirms the access to the patient's information through “Break the Glass” mode.

4.The user provides a mandatory justification to access the patient's information.

5.The system grants access to the patient's restricted information, according to the permissions granted by the Administrator (detailed in UC.09)

6.The user can view the patient's information.

7.The system logs user ID, timestamp, patient, information accessed and justification.

UC.03.02 Cancel Break the Glass Activation

1.In step 3. of UC.03.01, if the user chooses not to proceed with “Break the Glass,” the system returns to the previous state without granting access.

UC.03.03 Missing Justification

1.In step 4. of UC.03.01, if the user attempts to activate “Break the Glass” mode without entering a justification, the system prevents access and displays an error message requesting justification.

Manage patient’s information

User Story

As a healthcare professional,

I want to register or edit patient’s health data,

So that the healthcare record accurately reflects the patient’s current clinical status.

As an administrator,

I want to register or edit a test patient's health data,

So that I can perform software tests when a user requests assistance.

Use Case - UC.04 Manage patient’s information

Goal: Enable the users to add or edit clinical data.

Actor: Healthcare Professional, Administrator

Assumptions: The user has already searched for a patient, the patient exists in the system, the user has permission to view information, or the user activated the " Break the Glass" mode.

UC.04.01 Successful addition of new patient’s information

1.The user selects the type of information to add. This may include the following categories:

- a. Summary
- b. Timeline
- c. Documents
- d. Nursing
- e. Allergies and Intolerances
- f. Problems
- g. Medication
- h. Medical Devices
- i. Exams
- j. Procedures
- k. Immunizations
- l. Alerts
- m. Functional Status
- n. Clinical Notes
- o. Social History

- p. Plan of Care
- q. Vital Signs
- r. Advance Directives
- s. Pregnancy Status and History

2.The system verifies that the user has permission to add the selected type of information.

3.The user adds patient's information and metadata related to it (e.g., source, status, can relate documents or associate this information to other type of information that the patient already has registered).

4.The user saves the changes.

5.The system logs user ID, timestamp, patient and information added.

6.The system updates the patient's information in the database and the APIs.

7.The system updates the International Patient Summary.

8.The system informs the Integration BUS that the patient's information has been updated.

9.The Integration BUS notifies external systems that the patient's information has been updated.

10.The Integration BUS notifies external systems that the patient's International Patient Summary has been updated.

UC.04.02 Successful edition of patient's information

1.The user selects the type of information to edit. This may include the following categories:

- a. Summary
- b. Timeline
- c. Documents
- d. Nursing
- e. Allergies and Intolerances
- f. Problems
- g. Medication
- h. Medical Devices
- i. Exams
- j. Procedures
- k. Immunizations
- l. Alerts
- m. Functional Status
- n. Clinical Notes
- o. Social History
- p. Plan of Care
- q. Vital Signs
- r. Advance Directives
- s. Pregnancy Status and History

2.The system verifies that the user has permission to edit the selected type of information.

3.The user edits patient's information and metadata related to it (e.g., source, status, can relate documents or associate this information to other type of information that the patient already has registered).

4.The user saves the changes.

5.The system logs user ID, timestamp, patient and information edited.

- 6.The system updates the patient's information in the database and the API's.
- 7.The system updates the International Patient Summary.
- 8.The system informs the Integration BUS that the patient's information has been updated.
- 9.The Integration BUS notifies external systems that the patient's information has been updated.
- 10.The Integration BUS notifies external systems that the patient's International Patient Summary has been updated.

UC.04.03 Unsuccessful addition of patient's information

1.In step 4. of UC.04.01, if the system has an error while adding patient's information, the system displays an error message to the user.

UC.04.04 Unsuccessful edition of patient's information

1.In step 4. of UC.04.02, if the system has an error while adding patient's information, the system displays an error message to the user.

Manage patient's documents

User Story

As a healthcare professional,

I want to upload, create, edit or cancel documents,

So that important documentation is available, and I can correct inaccurate information.

As an administrator,

I want to upload, create, edit or cancel documents regarding a test patient,

So that I can perform software tests when a user requests assistance.

Use Case - UC.05 Manage patient's documents

Goal: Enable the user to upload, create, edit, or cancel clinical documents associated with a patient.

Actor: Healthcare Professional, Administrator

Assumptions: The user has already searched for a patient, the patient exists in the system, the user has permission to view information, or the user activated the " Break the Glass" mode and the user has permission to upload, create, edit and cancel documents.

UC.05.01 Successful document upload

- 1.The user selects the option to upload a document.
- 2.The system verifies that the user has permission to upload documents.
- 3.The system prompts for file upload and documentation metadata (e.g., type of document, description, if the document is related to other clinical entry, etc.)
- 4.The user registers the document metadata.
- 5.The user uploads the files and submits.
- 6.The system logs user ID, timestamp, patient and document uploaded.
- 7.The system updates the patient's documents in the database and the API's.
- 8.The system informs the Integration BUS that the patient's documentation has been updated.
- 9.The Integration BUS notifies external systems that the patient's documentation has been updated.

UC.05.02 Successful dynamic document creation

- 1.The user selects the option to create a new dynamic document
- 2.The system verifies that the user has permission to create new dynamic documents
- 3.The user chooses which type of dynamic document wants to create
- 4.The system prompts for documentation metadata (e.g., description, content, if the document is related to other clinical entry, etc.)
- 5.The user registers the document metadata.
- 6.The user submits the document.
- 7.The system logs user ID, timestamp, patient and dynamic document created.
- 8.The system updates the patient's documents in the database and the API's.
- 9.The system informs the Integration BUS that the patient's documentation has been updated.
- 10.The Integration BUS notifies external systems that the patient's documentation has been updated.

UC.05.03 Successful document edition

- 1.The user selects the document that wants to edit.
- 2.The system verifies that the user has permission to edit documents.
- 3.The system verifies that the document chosen by the user is still on "Draft" or "In Review" status.
- 4.The user edits and submits the document.
- 5.The system logs user ID, timestamp, patient and the document edited.
- 6.The system updates the patient's documents in the database and the API's.
- 7.The system informs the Integration BUS that the patient's documentation has been updated.
- 8.The Integration BUS notifies external systems that the patient's documentation has been updated.

UC.05.04 Successful documentation cancellation

- 1.The user selects the document that wants to cancel.
- 2.The system verifies that the user has permission to cancel documents.
- 3.The system prompts for a justification for the cancelation.
- 4.The user registers the justification and saves.
- 5.The system shows in the patient's list of documents that that document is cancelled.
- 6.The system logs user ID, timestamp, patient and dynamic document edited.
- 7.The system updates the patient's documents in the database and the API's.
- 8.The system informs the Integration BUS that the patient's documentation has been updated.
- 9.The Integration BUS notifies external systems that the patient's documentation has been updated.

UC.05.05 Unsuccessful document upload

- 1.In step 6. of UC.05.01, if there is an error uploading the document, the system displays an error message to the user.

UC.05.06 Unsuccessful dynamic document creation

- 1.In step 6. of UC.05.02, if there is an error creating the document, the system displays an error message to the user.

UC.05.07 Unsuccessful document edition

- 1.In step 3. of UC.05.03, if the document is in "Published" status, the system does not allow the cancellation of the document.
- 2.In step 4. of UC.05.03, if there is an error editing the document, the system displays an error message to the user.

UC.05.08 Unsuccessful document cancellation

1. In step 4. of UC.05.04, if there is an error cancelling the document, the system displays an error message to the user.

2. In step 4. of UC.05.04, if the user attempts to cancel a document without entering a justification, the system prevents that cancellation and displays an explanatory message.

Send Messages to Other UsersUser Story

As a healthcare professional,

I want to send messages related to a patient to other healthcare professionals,

So that it is possible to coordinate care and ensure continuity across different healthcare settings.

As an administrator,

I want to send messages related to a test patient to other healthcare professionals/administrators,

So that I can perform software tests when a user requests assistance.

Use Case - UC.06 Send Messages to Other Users

Goal: Enable the user to send secure messages to other professionals within the same institution or network regarding patient care.

Actor: Healthcare Professional, Administrator

Assumptions: The user has already searched for a patient, the patient exists in the system, the user has permission to view and edit the patient's information or the user activated the "Break the Glass" mode and has permission to send messages.

UC.06.01 Successful message sending

1. The user accesses the module "messages" of the application.

2. The user can see which specialities, institutions and healthcare professionals are responsible for that patient.

3. The user chooses which user wants to contact.

4. The user writes and sends the message.

5. The system sends the message to the corresponding user.

6. The other user, when accessing the application, receives a notification.

7. The other user can reply to the message.

UC.06.02 Unsuccessful message sending

1. In step 5. of UC.05.01, if there is an error in sending the message, the system displays an error message to the user.

View Audit LogsUser Stories

As an administrator,

I want to view detailed audit logs of who accessed or modified patient data,

So that I can support users with any issues.

As a data protection officer,

I want to view detailed audit logs of who accessed or modified patient data,

So that I can ensure compliance with data privacy regulations.

Use Case - US.08 View Audit Logs

Goal: Enable the user to view system activity logs, including data access, modifications, and actions performed.

Actor: Administrator, Data Protection Officer

Assumptions: The patient exists in the system; the user has permission to view and/or edit the patient's information and has special access to the Audit Logs module.

UC.08.01 View Audit Logs Related to a Patient

- 1.The user accesses the audit logs section.
- 2.The system displays a chronological list of actions, including:
 - a. User ID
 - b. Timestamp
 - c. Affected patient
 - d. Justification entered by the user (is that is the case)
 - e. Module or function accessed
 - f. Type of action performed (view, modify, etc.)
 - g. If the information was accessed in relation to “Break the Glass” mode activation

UC.08.02 Unsuccessful Audit Log Access – Insufficient Permissions

- 1.In step 2. of US.07.01 and in step 3. of US.07.02, if the user does not have permission to view audit logs for the selected patient or system area, the system displays an informative access denied message.

Manage access permissions

User Story

As an administrator,

I want to manage access levels to different types of patient information and for different healthcare professionals,

So that users only access or edit the data they are authorized to.

Use Case - UC.09 Manage access permissions

Goal: Enable the administrator to configure access permissions to different system features and data, ensuring compliance with security policies.

Actor: Administrator

Assumptions: The administrator is authenticated in the system and has access to the permission management module.

UC.09.01 Configure Role-Based Access Permissions

- 1.The administrator accesses the permissions module.
- 2.The system displays a list of predefined user roles (e.g., Doctor, Nurse, Data Protection Officer...).
- 3.The administrator selects a role and configures access rights to specific:
 - a. System modules (e.g., Audit Logs, Notification Management, Break the Glass logs).
 - b. Actions (e.g., view, edit).
- 4.The system saves the updated permissions and applies them to all users associated with that role.

UC.09.02 Assign Custom Permissions to an Individual User

- 1.The administrator searches for and selects a specific user.
- 2.The system displays the user's current role and inherited permissions.
- 3.The administrator customizes access settings for that specific user.
- 4.The system saves the changes and updates the user's effective permissions.

UC.09.03 Unsuccessful Permission Update

1.In step 4. of UC.09.01 and US.09.02, if the administrator attempts to save permission changes but encounters a system error, the system displays an error message, and the changes are not applied. The administrator is prompted to retry.

Log out

User Story

As a user,

I want to log out of the system,

So that I can ensure the security and confidentiality of patient health data when I'm no longer using the system.

Use Case - US.10 Log out

Goal: Enable the user to end the session.

Actor: Healthcare Professional, Administrator, Data Protection Officer

UC.10.01 Successful Log out

- 1.The user selects the "Log out" option.
- 2.The system terminates the user's session.
- 3.The user is redirected to the login page.

UC.10.02 Automatic Session Termination Due to Inactivity

- 1.The user remains inactive for a predefined period.
- 2.The system automatically logs the user out.
- 3.The system displays a message informing the user that the session has expired due to inactivity.
- 4.The user is redirected to the login page.

UC.10.03 Log Out Failure

1.In step 2 of UC.10.01, if a system error prevents the session from ending properly, the system displays an error message to the user.

6.5 Usability Testing

6.5.1 Heuristic Evaluation

Objetivo

Identificar problemas de usabilidade na interface, com base nos princípios heurísticos de Nielsen.

Instruções

Este formulário destina-se a registar os problemas de usabilidade encontrados durante a avaliação do protótipo não funcional disponível no link <https://www.figma.com/proto/MKOIHTxuq01LCjC4uN36G/Processo-do-Doente?node-id=54-18948&p=f&t=nqBjODvo3dI9HxVA-1&scaling=min-zoom&content-scaling=fixed&page-id=54%3A7333&starting-point-node-id=54%3A18948&show-proto-sidebar=1>.

Primeiro passo: aceder ao link fornecido e explorar o protótipo não funcional.

Segundo passo: para cada heurística, descreva os problemas identificados, atribua um nível de severidade e, se possível, sugira melhorias.

Escala de Severidade

- 0 – Não é um problema de usabilidade
- 1 – Problema estético (não necessita ser corrigido a menos que exista tempo disponível)
- 2 – Problema menor (pode ser corrigido com prioridade baixa)
- 3 – Problema maior (deve ser corrigido com prioridade alta)
- 4 – Problema crítico (imperativo corrigir antes da entrega)

Tabelas de Avaliação

Heurística nº 1: Visibilidade do estado do sistema

O sistema deve manter os utilizadores informados sobre o que está a acontecer através de feedback apropriado.

Problemas Identificados	Severidade (0 a 4)	Sugestão de Melhorias

Heurística nº 2: Correspondência entre o sistema e o mundo real

O sistema deve conter a linguagem do utilizador, com palavras, frases e conceitos familiares.

Problemas Identificados	Severidade (0 a 4)	Sugestão de Melhorias

Heurística nº 3: Controlo e liberdade do utilizador

Os utilizadores devem conseguir desfazer e refazer ações facilmente, com opções de saída claras.

Problemas Identificados	Severidade (0 a 4)	Sugestão de Melhorias

Heurística nº 4: Consistência e padrões

O sistema deve manter a consistência de conceitos e significados.

Problemas Identificados	Severidade (0 a 4)	Sugestão de Melhorias

Heurística nº 5: Prevenção de erros

O sistema deve evitar erros antes que eles ocorram, com confirmações e restrições quando necessário.

Problemas Identificados	Severidade (0 a 4)	Sugestão de Melhorias

Heurística nº 6: Reconhecimento em vez de memorização

O sistema deve minimizar a carga de memória e cognitiva dos utilizadores tornando visíveis objetos, ações e opções.

Problemas Identificados	Severidade (0 a 4)	Sugestão de Melhorias

Heurística nº 7: Flexibilidade e eficiência de uso

O sistema deve conter atalhos e métodos que permitam acelerar a interação para utilizadores mais experientes.

Problemas Identificados	Severidade (0 a 4)	Sugestão de Melhorias

Heurística nº 8: Design estético e minimalista

A interface não deve conter informações que não são relevantes ou raramente necessárias.

Problemas Identificados	Severidade (0 a 4)	Sugestão de Melhorias

Heurística nº 9: Ajudar a reconhecer, diagnosticar e corrigir erros

As mensagens de erro devem ser expressas de forma clara e oferecer soluções.

Problemas Identificados	Severidade (0 a 4)	Sugestão de Melhorias

Heurística nº 10: Ajuda e documentação

Apesar de, idealmente, o design não necessitar de explicações adicionais, pode ser necessário providenciar ajuda ao utilizar para completar uma tarefa.

Problemas Identificados	Severidade (0 a 4)	Sugestão de Melhorias

Outras Sugestões

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