Universidade do Minho
Escola de Engenharia

Francini Abdul Hak

Effective Clinical Decision Support Systems by Means of Open Data, Intelligence and Interoperability

November, 2024

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Francini Hak
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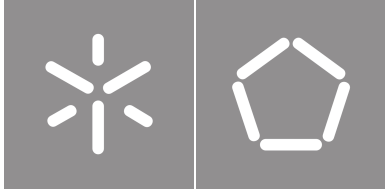

Universidade do Minho
Escola de Engenharia

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Effective Clinical Decision Support Systems by Means of Open Data, Intelligence and Interoperability

Doctorate Thesis
Doctoral Program in Information Systems and Technologies

Work developed under the supervision of:
Professor Doctor Manuel Filipe Torres dos Santos

November, 2024

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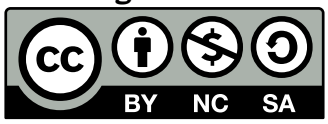

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STATEMENT OF INTEGRITY

I hereby declare having conducted this academic work with integrity. I confirm that I have not used plagiarism or any form of undue use of information or falsification of results along the process leading to its elaboration.

I further declare that I have fully acknowledged the Code of Ethical Conduct of the Universidade do Minho.

_____, _____

(Place) (Date)

_____

(Francini Abdul Hak)

”

“*Who has a why*
can bear any how”

— Viktor Frankl, Man’s search for meaning
(Neuropsychiatrist, Psychoanalyst)

Resumo

Sistemas de Apoio à Decisão Clínica Eficazes por Meio de Dados Abertos, Inteligência e Interoperabilidade

Tomar decisões faz parte do nosso quotidiano, mesmo que ocorra de forma simples e indireta. O sector da saúde, sendo um ambiente complexo e em constante evolução, exige cada vez mais suporte tanto para as tarefas de rotina como para os processos de tomada de decisão. Os Sistemas de Apoio à Decisão Clínica (SADC) desempenham um papel crucial neste contexto, auxiliando a tomada de decisões, reduzindo as taxas de erro, melhorando a coordenação das atividades diárias, e, em última análise, melhorando a qualidade da prestação de cuidados de saúde. Apesar dos potenciais benefícios, a atual adoção de SADC continua a ser insatisfatória. Uma análise sistemática da literatura identificou uma lacuna na eficácia dos SADC, uma vez que os sistemas analisados ainda não atingiram o nível de maturidade desejado na sua implementação. Abrindo uma oportunidade de investigação, este trabalho de doutoramento tem por objetivo explorar a forma como as abordagens abertas normalizadas podem aumentar a eficácia dos SADC. As normas de dados abertos são uma estratégia promissora, facilitando a extração e representação estruturada e interoperável do conhecimento clínico. Entre as opções disponíveis, a linguagem de decisão (DL) da norma openEHR revelou-se a mais completa, fornecendo suporte tanto para processos de fluxo de trabalho como para formulários estruturados. A utilização da DL resultou no desenvolvimento de um artefacto SADC baseado num motor lógico, capaz de processar regras e orientações através de modelos lógicos de decisão. Para demonstrar o sistema proposto, foram realizados quatro casos de utilização num Centro Hospitalar Português, centrados no serviço de imagiologia médica, transplante de córnea, avaliação do risco nutricional, e obstetrícia. Através de análises quantitativas e qualitativas, o artefacto revelou-se versátil e flexível para todos os casos de utilização. Para aferir a eficácia do artefacto proposto, foi formulado um Modelo de Estágios de Maturidade (MSM), alinhado com as fases da teoria da tomada de decisão de Herbert Simon. Utilizando os critérios definidos para cada fase de maturidade, concluiu-se que a abordagem proposta permite que um SADC atinja a eficácia desejada. Permanece o incentivo para continuar a explorar as técnicas adequadas e melhorar o artefacto proposto, contribuindo assim com conhecimento valioso para a comunidade científica.

Palavras-chave: Decisão lógica, Eficácia, Interoperabilidade, OpenEHR, Sistemas de apoio à decisão clínica

Abstract

Effective Clinical Decision Support Systems by Means of Open Data, Intelligence and Interoperability

Decision-making is an integral part of our daily lives, even if occurring in simple and indirect ways. The healthcare sector, being a complex and constantly evolving environment, increasingly demands support for both routine tasks and decision-making processes. Clinical Decision Support Systems (CDSS) play a crucial role in this context by aiding decision-making, reducing error rates, enhancing the coordination of daily activities, and ultimately improving the quality of healthcare delivery. Despite the potential benefits, the current adoption of CDSS remains unsatisfactory. A systematic analysis of the literature identified a gap in the effectiveness of CDSS, as the reviewed systems have not yet achieved the desired level of maturity in their implementation. Opening up a research opportunity, this doctoral work aims to explore how standardised open approaches can enhance the effectiveness of CDSS. Open data standards are a promising strategy, facilitating the structured and interoperable extraction and representation of clinical knowledge. Among the available options, the Decision Language (DL) of the openEHR standard proved to be the most complete, providing support for both workflow processes and structured forms. Utilising DL led to the development of a CDSS artefact based on a logic engine, capable of processing rules and guidelines through logical decision models. To demonstrate the proposed system, four use cases were conducted at a Portuguese Hospital Centre, focusing on the medical imaging service, corneal transplantation, nutritional risk assessment, and obstetric care. Through quantitative and qualitative analysis, the artefact proved to be versatile and flexible for all use cases. To gauge the effectiveness of the proposed artefact, a Maturity Staging Model (MSM) was formulated, aligned with the phases of the Herbert Simon's decision-making theory. Using the defined criteria for each maturity stage, it was concluded that the proposed approach allows a CDSS to achieve the desired effectiveness. An incentive remains to continue exploring suitable techniques and improving the proposed artefact, thereby contributing valuable knowledge to the scientific community.

Keywords: Clinical decision support systems, Decision logic, Effectiveness, Interoperability, OpenEHR

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Acronyms

AD Archetype Designer *(pp. 91, 103, 113–116, 124)*
ADL Archetype Definition Language *(p. 33)*
AI Artificial Intelligence *(pp. 15, 26, 27, 56, 177)*
API Application Programming Interface *(pp. 34, 69, 71, 75, 76, 88, 128, 141)*
AVGREQ Average Number of Requests *(pp. 95, 109, 129, 139)*
AVGRT Average Response Time *(pp. 95, 109, 129, 138, 139)*

BMI Body Mass Index *(pp. 75, 84, 118–120, 122, 125)*
BPM Business Process Model *(pp. 37, 43)*

CDS Clinical Decision Support *(pp. 3, 24, 26, 27, 36, 38, 50, 61, 66, 67, 87–89, 107)*
CDSS Clinical Decision Support Systems *(pp. 3–6, 8, 23–27, 29, 42, 43, 47–53, 55–68, 80, 81, 84–89, 92, 99, 110, 111, 122, 135–138, 140, 142–144, 146, 148–150, 152, 176)*
CKM Clinical Knowledge Manager *(pp. 33, 91, 101, 113, 114, 124)*
CPOE Computerized Provider Order Entry *(pp. 56, 176)*
CT Computed Tomography *(p. 91)*

DL Decision Language *(pp. 4–6, 40–45, 68, 72–76, 84, 85, 89, 107, 111, 120, 138, 144, 149, 150)*
DLE Decision Logic Engine *(pp. 69–78, 81, 83–85, 90, 92–95, 103, 105, 107, 109, 115, 116, 120, 127, 129, 139–141, 143, 145, 149, 150)*
DLM Decision Logic Module *(pp. 40–42, 68, 72–75, 80, 82, 85, 93–96, 98, 105–109, 111, 116, 120–122, 125, 127–129, 144, 145)*
DMN Decision Model and Notation *(pp. 37, 38, 42–45)*
DSR Design Science Research *(pp. 6–8)*
DSS Decision Support Systems *(pp. 2, 3, 9, 15–17, 24–26, 51, 52, 135, 146)*

EDD Expected Date of Delivery *(pp. 125, 127)*

EHR Electronic Health Records *(pp. 3, 4, 23, 24, 26–33, 36, 39, 40, 42–44, 49, 50, 56, 57, 61, 62, 66–69, 73, 75, 76, 80, 85, 87, 88, 92, 97–99, 103, 107, 111, 123, 135, 144–146, 176)*

EL Expression Language *(p. 88)*

EMR Electronic Medical Records *(pp. 56, 176)*

ES Expert Systems *(pp. 16, 17, 66, 67)*

FE Form Engine *(pp. 70–72, 90, 92–94, 101, 103, 105, 115, 117, 140)*

GDL Guideline Definition Language *(pp. 38–40, 42–45, 73)*

GEHR Good European Health Record *(p. 31)*

GLIF Guideline Interchange Format *(pp. 36, 37, 42–44)*

GLIM Global Leadership Initiative on Malnutrition *(pp. 110, 112, 114–116, 119, 121)*

HIS Health Information System *(pp. 2–5, 23, 24, 27, 29–31, 36, 43, 50, 51, 53, 56–58, 61, 62, 64, 66, 68, 69, 73, 76, 85, 92, 94, 100, 112, 123, 135, 144, 176)*

HL7 Health Level Seven International *(pp. 35–37, 40, 55)*

ICU Intensive Care Unit *(p. 26)*

IS Information System *(pp. 2, 5, 6, 8, 11, 14, 15, 17, 24, 29, 35, 47, 48, 52, 93, 100, 146, 150)*

ISO International Organisation of Standardization *(pp. 29, 31)*

IT Information Technology *(pp. 15, 31, 48, 85, 100, 105, 108, 112, 124, 133, 140, 141, 145, 146)*

JDT JSON Data Template *(pp. 92, 103, 117)*

JSON JavaScript Object Notation *(pp. 39, 73, 74, 78, 91, 116, 117, 120)*

KR Knowledge Representation *(pp. 17, 18, 24, 25, 42, 43, 51, 53, 55, 66)*

LCIM Level Conceptual Interoperability Model *(pp. 28, 29)*

MIS Management Information Systems *(p. 15)*

ML Machine Learning *(pp. 15, 16, 56, 58, 60, 80, 81, 129, 130, 150)*

MLM Medical Logic Modules *(pp. 35, 36, 44)*

MRI Magnetic Resonance Imaging *(pp. 91, 92, 96)*

MSM Maturity Staging Model *(pp. 59–63, 135, 138, 142–144, 146, 148, 149, 152)*

NRS Nutritional Risk Screening *(pp. 110, 112, 113, 115–117, 119, 120, 122)*

ODIN Object Data Instance Notation *(pp. 39, 120)*
OPT Operational Template *(pp. 71, 91, 103, 115, 117)*

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-Analysis *(pp. 7, 51, 53, 54)*
PROC Process and Clinical Decision Support *(p. 40)*

RE Resource Engine *(p. 70)*
RM Reference Model *(pp. 32–34, 41)*
RQ Research Question *(pp. 4, 6, 51, 59, 61, 62, 144, 149)*

SLR Systematic Literature Review *(pp. 6, 7, 50–53, 55, 59, 61–65, 68, 144, 148, 149)*
SM Service Model *(p. 34)*
SPO Subject Data Proxy *(pp. 41, 44, 69, 75, 120, 122, 125, 141)*

TP Task Planning *(pp. 40, 70, 89, 93, 94, 104, 106, 116)*
TP-VML Task Plan Visual Modelling Language *(pp. 40, 91)*
TRL Technology Readiness Levels *(pp. 8, 9)*

WAVG Weighted Average *(p. 63)*
WE Workflow Engine *(pp. 70–72, 90–94, 103–105, 115, 116, 120, 140)*
WHO World Health Organization *(p. 23)*
WP Work Plan *(pp. 71, 97, 98, 106, 108, 115, 119)*

XML Extensible Markup Language *(p. 129)*

Part I

Introduction and Research Design

1

Introduction

In this inaugural chapter, the scope of this doctoral thesis is introduced, revealing the motivation behind this work. In identifying the problems related to the topic, a research opportunity emerges covering the effectiveness of decision support systems in healthcare. Guided by a set of well-defined research objectives, a main research question is defined to delineate a path towards understanding and clarifying the topic addressed. Next follows the presentation of the chosen research methodology and the research process conducted, to form the basis on which the research efforts are defined. Finally, the organisation of the document is explained through a structure of chapters and sections, which will outline the purpose of this work.

1.1 Contextualisation

Friedman (2009) boasted a theorem stating that an individual or group working with the contribution of a technological information resource has a better performance compared to a job without such assistance. An information resource is understood by any mechanism, usually computer-based, capable of providing information or knowledge to support the accomplishment of a task (Friedman, 2009).

As far as is known, the decision support activity started to be represented in a computerised system in the mid-60s, giving rise to Decision Support Systems (DSS) (D. J. Power, 2007). Despite there is no formulated definition, to Keen (1980) a DSS represents the role of computers within the decision-making process, being “relevant to situations where a final system can be developed only through an adaptive process of learning and evolution”. Notwithstanding, Turban et al. (2005) demonstrates the basis of a DSS, focusing on its central purpose as ”to support and improve decision-making”.

In the healthcare field, many needs arise with the exponential growth of data, encouraging the adoption of Information System (IS). A Health Information System (HIS) is one of the building blocks of a health organisation, tailored to address the information needs within the health sector (Lemma et al., 2020). However, other components are needed to complement the HIS function. With a continuous decision-making at all levels of healthcare, resources capable of transforming unstructured records into knowledge are required, in order to support the decision-making activity.

Fundamentally, Clinical Decision Support (CDS) is responsible for the decision support activity in the healthcare domain, where HIMSS (2016) defines it as a "process for enhancing health-related decisions and actions with pertinent, organised clinical knowledge and patient information to improve health and healthcare delivery". By replicating this activity in computerised systems, Clinical Decision Support Systems (CDSS) emerged, fulfilling the objectives of DSS with a focus on healthcare processes.

Extracting and acquiring clinical knowledge from Electronic Health Records (EHR) is one of the challenges present in CDSS design. Finding relevant data is a long and arduous process if the data sources are not compatible or interoperable with the source system. Once the data has been identified, there is still an extensive process on how to collect and prepare it for analysis, which also becomes a challenge given that the health system has many scattered data sources, often isolated and used for specific purposes (Feldman et al., 2018). Furthermore, once the data has been collected, a significant effort is required to ensure consistency between all sources (Feldman et al., 2018).

Currently, CDSS have been increasingly sought after and it is already considered a requirement for a health system to be considered mature (HIMSS, 2017). However, it is necessary to ensure its correct functioning in order to achieve its effectiveness. The motivation behind this work is to design a ubiquitous approach that is common to various clinical purposes, meeting the diverse needs and perspectives of stakeholders, to achieve a greater chance of success.

1.2 Research problem and opportunity

Technological advances have allowed the representation of cognitive activities of health professionals in a computable form, capable of collecting, storing, and processing EHR (Vasconcelos et al., 2004). Previous studies claim that the implementation of an effective CDSS is a tough process that involves different purposes, technologies, and organisations, where Sarkar and Samal (2020) reflect that "the current performance of a CDSS is disappointing, we should change direction".

Improving the quality of healthcare delivery is one of the most promising expected outcomes that encourage the CDSS adoption, as well as providing better management in the workflow tasks to lighten the workload of healthcare professionals, reducing errors and malpractices in services (Sutton et al., 2020). With the rise of EHR, the adoption of CDSS is increasingly encouraged. However, potential pitfalls and harms remain a concern that prevent CDSS from achieving its proper functioning and desired purpose (Sutton et al., 2020).

Interoperability and integration between heterogeneous systems are concepts that continue to fail. Since a CDSS has to share data with others HIS and different healthcare organisations, there needs to be no loss of data or misinterpretations, otherwise this will hinder the dissemination of ineffective systems. Another key point for the CDSS effectiveness lies in its knowledge base, which must be reliable and structured, to combine heterogeneous sources of information (McCullough and Rangarathnam, 2019; Purcell, 2005). Notwithstanding, Middleton et al. (2016) affirms that the lack of clinical terminologies

and standardised approaches is a limitation identified in recent decades, and, despite its evolution, it still needs to be addressed.

Standardisation techniques are recognised as an asset in structuring clinical data to overcome barriers to data sharing and interpretation (Jao & Hier, 2010; Sulley, 2018). Data standardisation generates attention for other problems that can be directly or indirectly linked to it, with interoperability, legacy systems and lack of data structuring standing out as obstacles to evidence in clinical practice (HIMSS, 2017, Sutton et al., 2020). Middleton et al. (2016) advocate the open data movement, defending that making the knowledge available inside and outside the organisation provides the ability to examine community, environmental, and other public health data, and accelerate diagnostic and treatment processes. To complement, the use of open data standards allows professionals in the field to share a vast knowledge base to translate clinical evidence into decision support artefacts, improving the quality and variability of clinical data (HIMSS, 2017; Middleton et al., 2016; Sutton et al., 2020).

In the healthcare domain, some standardised open approaches have already been created to solve the problems identified, but they still lack the semantic representation of clinical knowledge, workflow synchronisation and data access binding (Beale & Chen, 2021). The openEHR standard aims to address this flaw by proposing a decision language based on logical modules to support clinical decisions. By processing computerised guidelines through a rule-based, workflow-oriented system, it is possible to achieve an open CDSS that is interoperable and integrated with any HIS or EHR system (Kopanitsa, 2017).

Replacing human error and coordinating work teams are at the centre of the requirements for an effective CDSS, which can be achieved through a system of automatic, self-modifying structured rules based on clinical guidelines (Beale & Chen, 2021; Sutton et al., 2020). The application of standardised approaches aims to address existing and present shortcomings that can increase the effectiveness of CDSS. Therefore, a research opportunity arises to exploit the openEHR Decision Language (DL) in order to build a CDSS based on a logical module, promising to positively affect the effectiveness of a CDSS. With this realisation, it is hoped that one day we will be able to say that "the health of a population is impacted as a result of the effective use of CDSS in their health organisations" (HIMSS, 2017).

1.3 Research question and objectives

Over the years, several CDSS have been developed to meet the needs faced in various healthcare sectors. Despite the evolution in the adoption of these systems, many are not being considered effective in their implementation. A detailed literature review allowed to identify problems that prevent the effective use of the designed decision systems, particularly flaws in interoperability and the representation of clinical knowledge. Open standards are a promising strategy for addressing the challenges encountered in CDSS adoption. As a result, the primary Research Question (RQ) formulated to support this research work is:

- To what extent does the adoption of logical models and open data allow the creation of more effective CDSS?

Overall, this doctoral research aims to explore the use of an open standard for structuring and standardising a CDSS. The central objective is to use the openEHR standard specifications for the design and development of a logical decision engine. It is expected to evaluate whether this approach will allow the implementation of more effective CDSS. Consequently, a set of objectives was defined to guide and simplify the conduct of this work, including:

0.1. Explore the state-of-the-art of CDSS and identify the research gap through literature review;

0.2. Elaboration of a maturity model capable of evaluating the maturity status of CDSS;

0.3. Representation and processing of clinical knowledge in a standardised format, using openEHR specifications;

0.4. Develop a decision logic engine capable of processing computerised guidelines and automatic rules through different models;

0.5. Prototyping of the proposed artefact and application in real healthcare contexts.

0.6. Realisation of an evaluation using the developed maturity model.

In each chapter of this document, the distinct objectives are delineated. Chapter III is dedicated to the fulfilment of specific aims: objectives 0.1. and 0.2. are described within section 4; objectives 0.3. and 0.4. are expounded upon in section 5; the attainment of objective 0.5. is elucidated in section 6. Subsequently, in Chapter IV, the achievement of objective 0.6. is realised.

Aiming to build an effective and interoperable system, the DL of the openEHR standard will be considered to support evidence-based decision-making, which can be integrated into any HIS. Furthermore, improving healthcare delivery and providing best work practices through technological innovation are the main motivations present in this work. As a continuous area of innovation, this work seeks to shed light on the true potential of a CDSS.

1.4 Research design

Research constitutes a systematic process of establishing new scientific knowledge. Therefore, this section describes the process conducted in this research work and the methodology employed. This process involves steps from the conceptualisation of the problem to the validation of the new knowledge created, encapsulating all the components proposed for this work. The research design elucidates the overarching strategy that guides a research through methods and techniques, exposing the scope, objectives, development, and possible limitations of this study, promoting transparency and rigour in the process.

1.4.1 Research methodology

Acquiring knowledge within a specific domain requires a methodological approach as a guide. Given the need to address both theoretical inquiries and practical case analyses, the integration of scientific research within the IS field assumes primary importance (Collins et al., 2004).

Hereupon, the systematic methodology used to conduct this research relies on the Design Science Research (DSR) methodology for IS, proposed by Peffers et al. (2007). As Hevner et al. (2004) states, the DSR "seeks to extend the boundaries of human and organisational capabilities by creating new, innovative and successful artefacts". DSR incorporates principles, practices, and procedures in a six-step structural methodology, ranging from the initial identification of the problem to the subsequent evaluation and communication of the proposed solution, intending to improve the performance of the artefact (Peffers et al., 2007). Therefore, Figure 1 demonstrates the steps performed using the DSR methodology to create a successful artefact.

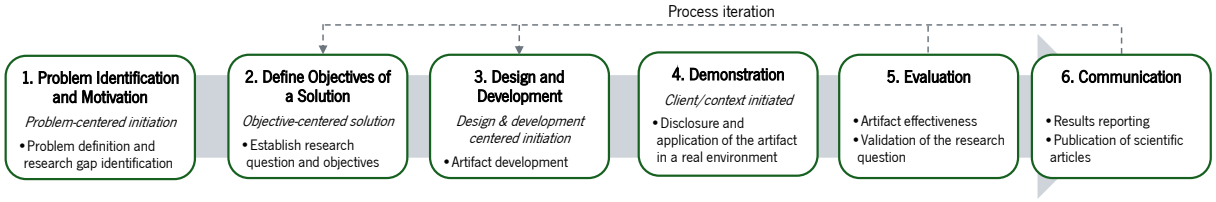


Figure 1: Stages of the DSR methodology (adapted from Peffers et al., 2007).

- Problem identification and motivation: This initial phase aims to define the problem to be addressed, which will result in the development of an artefact designed to solve the problem. To achieve this, resources are needed that include the state of knowledge of the problem and the importance of the solution. For this work, the problem was identified through a Systematic Literature Review (SLR), where it was found that the majority of CDSS are not achieving the desired effectiveness. Therefore, this problem is addressed throughout this document, demonstrating the concerns and the negative impact it will have if the problem persists.

- Objectives: After specifying the problem, objectives will be established for the new solution. This will include an analysis of existing solutions and hitherto unsolved problems, to be supported by the new artefact. Based on the problem description and domain knowledge applied to this work, a RQ was formulated along with a set of objectives to evaluate whether the use of open standards will contribute to the development of more effective CDSS.

- Design and Development: This activity focuses on creating the artefact. The proposed artefact can be of any type, as long as it is designed for a research contribution. For development, the purpose, functionalities, architecture and processing of the artefact will be addressed. In this work, the design and development of the artefact will result in the construction of a logical decision engine based on the DL of the openEHR standard.

- Demonstration: This phase requires demonstrating the use of the artefact involving the resolution of one or more instances of the problem. Various techniques can be explored in this activity, such as experimentation, simulation, case studies, or other appropriate techniques. Thus, the proposed artefact is demonstrated by the application of different use cases carried out in a real

hospital environment. The purpose of this experiment was to verify the viability of the artefact and its ability to solve the identified problems.

- Evaluation: The evaluation activity is responsible for verifying the viability of the proposed artefact as a solution to the problem addressed. A comparison of the initially defined objectives with the results obtained in the demonstration phase is carried out. Relevant models or techniques can be applied for their assessment, both at a quantitative and qualitative level. The artefact proposed in this work will be evaluated in three ways considering: (i) system performance; (ii) mapping of functionalities achieved with the application of use cases; (iii) and the application of a maturity model to evaluate the effectiveness of the artefact. Furthermore, as DSR is an iterative process, if the evaluation result is not satisfactory, researchers can return to the objective definition or the design and development phase to improve the viability of the artefact until it achieves its desired purpose.

- Communication: Communicating the entire process, from problem identification to artifact evaluation, is crucial. This communication typically occurs through scientific publications and academic works. To disseminate the knowledge resulting from this work, communication will be done through the writing of this doctoral thesis and the publication of scientific articles to the appropriate audience. By sharing the results and knowledge acquired in this project, it is possible to obtain feedback on the work conducted, as well as leave opportunities for improvements for subsequent projects.

1.4.2 Research process

In research, the production and establishment of new knowledge, appropriate throughout the research process, must be prioritised. Research encompasses activities contributing to various facets of scientific knowledge, including establishment, expansion, dispute, confirmation, and refutation. The research process is the trajectory leading toward the development and validation of scientific knowledge. This includes considerations from initial problem selection to employing sound research methodologies, to reflecting on findings, and finally to communicating and disseminating research outcomes (Gregor & Hevner, 2013).

Research methods designate the systematic processes employed to establish novel scientific knowledge. In other words, research methods aim to facilitate the validation of the knowledge produced, rather than creating new knowledge (Gregor & Hevner, 2013). These methods offer systematic approaches for conducting activities, while research methodologies serve as means for accessing the phenomena under analysis to validate the generated knowledge. Following the purpose of this work, the research process adopted is demonstrated in Figure 2.

The research process of this work is accompanied by a methodology and a set of methods and techniques, aligned at every step. Starting with the first step of the DSR, the SLR technique is used to identify the problem, which was conducted using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) methodology. With this SLR, a research gap was identified, opening up

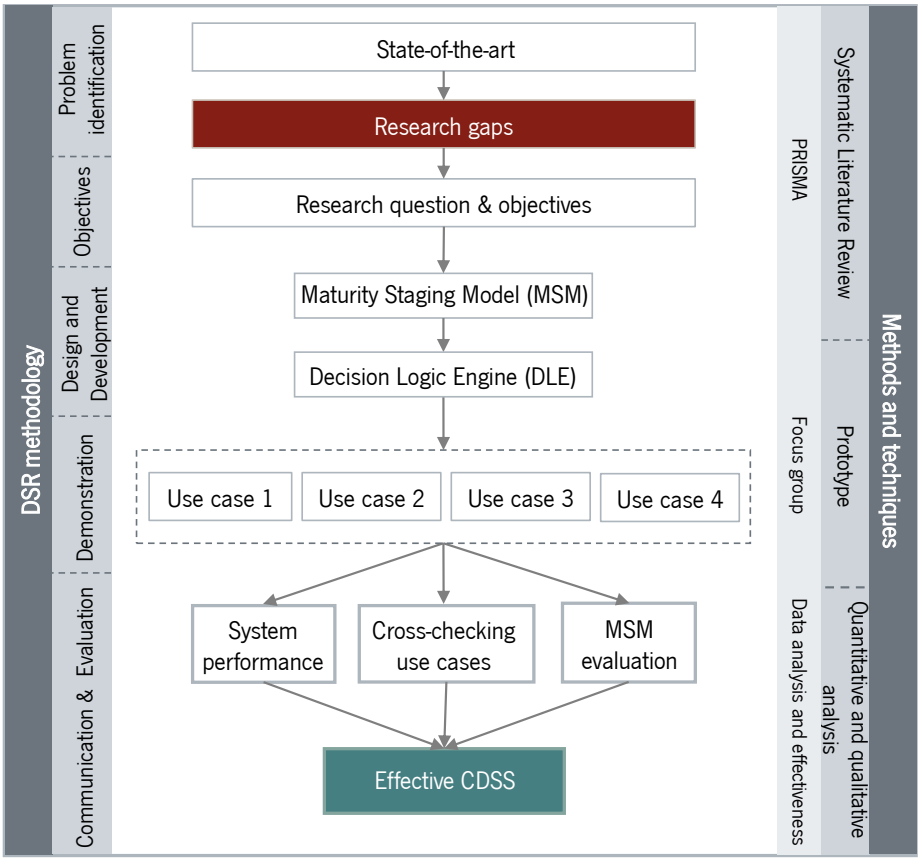


Figure 2: Research process adopted, based on methodology, methods and techniques.

a research opportunity that gave rise to this work. To address the identified gap, a research question was formulated, aligned with a set of objectives, forming step two of the DSR. In accordance with the defined objectives, the development and design step resulted in the development of a maturity model and a logical decision engine. In parallel, this stage focuses on prototyping the artefact, which extends to the demonstration phase. To this end, four use cases were implemented to demonstrate the artefact in a real hospital context. Focus groups, consisting of doctors, nurses, biomedical engineers, and IS engineers, were employed as the research method to gather requirements for each demonstration case.

Once the artefact has been developed and demonstrated in practice, it must be evaluated from different perspectives. The evaluation is carried out considering the system's performance through data analysis. Besides, a mapping of the results achieved between use cases was also carried out, as well as the application of the maturity model previously developed. Finally, the ultimate goal is to verify the effectiveness of the CDSS developed, by communicating and publicising the results obtained.

Notwithstanding, the evaluation process covers various stages of technological development. The Technology Readiness Levels (TRL) is a method composed of levels that define the phases of a system's technological advancement. The TRL starts with basic principles (level 1) and progresses to the formulation of the technological concept (level 2). Level 3 marks applied research and the completion of the first laboratory tests, indicative of proof of concept. From the point of view of technological development,

the technology can be validated in a laboratory environment (level 4), validated in a relevant environment (level 5), and demonstrated in a relevant environment (level 6). Moving on to deployment, level 7 of the TRL corresponds to demonstrating the prototyped system in an operational environment. When the technology has been fully developed, tested and evaluated, it is ready for deployment in the intended operational environment, corresponding to TRL8. Finally, the technology has been successfully deployed and proven in an operational environment (TRL9). In this work, the proposed artefact aims to reach TRL level 8.

Moreover, the present doctoral work is allocated to the ALGORITMI Research Center of the School of Engineering of the University of Minho. Beyond that, the work will consider the needs and requirements proposed in collaboration with a Portuguese Hospital Centre. This organisation has been one of the Portuguese hospitals that pioneered the implementation of open standards, promoting interoperability between systems. From this collaboration, it was possible to carry out the demonstration cases with the application of the system in a real environment, covering different healthcare contexts.

1.5 Document structure

This document is organised in five parts. First, Part I introduces the topic that will be approached, detailing the research problem and the motivation behind this work. Additionally, it outlines the research objectives, methodology, and a description of the research process. The second part (II) consists of two chapters, which provide an overview of decision-making and DSS in healthcare, covering the current state of the art in these areas.

Part III of this thesis encompasses three chapters that highlight the contributions obtained. Chapter four presents a systematic review of the literature, resulting in the formalisation of a maturity staging model. In chapter five, a logical decision component is designed, based on the specifications of the openEHR standard, enabling to process rules and different knowledge representation models. The practical application of the logical model is demonstrated in chapter six through the implementation of real-world use cases.

Aligned with the research process, Part IV initiates with a chapter dedicated to the evaluation and validation of the proposed artefact, using different techniques. This chapter also entails a discussion of the conducted work. Ultimately, Part V draws conclusions based on the contributions achieved and directs future work.

Part II

State-of-the-art

2

Understanding Decision-Making

The present chapter provides an overview of the decision-making process. It is intended to explore the contextual landscape surrounding decision-making, encompassing its theoretical foundations, processes, and models, as well as its practical implementation within the domain of Information System (IS).

2.1 Decision background

Yoghurt or orange juice? Shirt or blouse? Right or left? These are just few of the many decisions that are part of our daily lives. Despite the lack of a precise definition in literature, decision-making is generally understood as the act of selecting one option from various alternatives (Bohanec, 2003; Eilon, 1971). A decision is the final stage of a control process, that encompass the analysis of information and the evaluation of potential actions. Resolving a decision model involves identifying an action strategy with an expected relative value that is at least equal to or greater than any other strategy within a specified set (Eilon, 1971). The optimal strategy, according to a prescriptive criterion, aims to maximise the decision maker's total expected relative value. Additionally, the act of making a decision entails making a judgment about the appropriate course of action after considering different alternatives. Key points of this definition include the presence of multiple choices for the decision maker and the need to compare these options and evaluate their outcomes. Reasoning, conversely, comprises a logical and coherent process that begins with fundamental principles and leads to formally derived conclusions. These steps adhere to all the requirements dictated by formal logic (Eilon, 1971).

Psychology research elucidates how individuals make decisions and what influences their quality. One crucial aspect is the uncertainty surrounding decision-making, as there are numerous potential outcomes for a single decision point, making it challenging to choose the best alternative (Körding, 2007). There is much evidence that structuring decision problems and identifying creative alternatives determines the quality of decisions (Ada & Ghaffarzadeh, 2015). Utility function is known to measure the quality of a possible decision outcome, where an outcome depends on the decision in a probabilistic way, meaning that it is not possible to choose the outcome directly (Körding, 2007). Combining the utility function and the knowledge of how decisions affect potential outcomes is the most beneficial decision. Simple decisions

can be predicted by assuming that individuals employ a decision-making approach that approximates optimally. Consequently, the most favourable decisions will maximise the expected utility. Making decisions appears feasible, choosing the action aligned with the maximum expected utility. However, accurately estimating the likelihood of an outcome and considering a given decision prove to be difficult to estimate (Körding, 2007).

The nervous system is a decision-making device. In our day-to-day routine, the capacity and expertise required to evaluate our decision-making and problem-solving are embedded within the human intellect and various tools and machines (Simon et al., 1987). Consequently, comprehending the cognitive mechanisms of human minds holds the potential to improve the effectiveness of decision systems. Research findings have facilitated the elucidation of the actual procedures employed by individuals in decision-making and problem-solving, with certain studies suggesting superior methods and providing guidance for the enhancement of these processes (Simon et al., 1987). Prescriptive theories in decision-making describe how people make choices, involving problem-solving through data collection using means-ends analysis. Consequentially, it is crucial to represent a knowledge base in a computational architecture to develop decision systems.

Change is the only constant in the world, thereafter an effect system must predict how the situation will change and how any decision would affect it (Körding, 2007). If the constraints of the problem are known, it is defined the best possible outcome. Computer simulations are intended to optimise this process (Körding, 2007). Calculating the probability of outcomes frequently requires revising the pre-existing knowledge (conditions) with new information (values). This knowledge is updated by combining information received from prior experiences. The process combines prior belief and sensory insights (likelihood) to formulate an informed revised belief (outcome) (Körding, 2007). Inverse decision theory allows for the estimations of the used utility functions, priors, and likelihoods, potentially simplifying the effort required for identifying their neural manifestations (Körding, 2007).

Concisely, decision-making constitutes the entire process involved in making choices, comprising problem assessment, information gathering and verification, the identification of alternatives, anticipation of decision consequences, the use of sound judgment and logic based on available information, communicating decisions and their rationale, and the evaluation of decisions (Bohanec, 2003). Decision systems and decision sciences distinctly delineate between machine-based and human decision-making. Consequently, related disciplines are Decision Systems and Decision Sciences. Decision Systems primarily focus on computer-based programs and technologies for routine decision-making, process monitoring and control. Decision Sciences is an interdisciplinary field based in economics, cognitive psychology, and other domains, that investigates how individuals make decisions both theoretically and empirically (Bohanec, 2003). Situated primarily in decision sciences, decision support concerns the improvement of human decision-making processes, to help individuals improve their decision-making capabilities (Ada & Ghaffarzadeh, 2015). Therefore, systems in decision support are interactive computer-based systems designed to assist decision-makers use data and models to identify, analyse and solve problems, as well as to make informed decisions (Bohanec, 2003).

2.2 Decision-making process and theory

Decision-making is an inherent part of our existence and is one of the main processes dealt within an organisation (Turban et al., 2014). This process can be approached using different models and theories. Decision theory examines the mechanisms underlying decision-making, the interplay of multiple choices, and the strategies employed by decision-makers in navigating uncertainties (Eilon, 1971). In situations of uncertainty regarding the optimal course of action, decision theory entails the selection of diverse actions contingent upon the desirability of their immediate outcomes. Conventionally, the decision-making process encompasses several stages: identifying the problem, collecting and validating data, determining different alternatives, predicting the potential outcomes of decisions, employing logic in the choice of available information, communicating the decision, and evaluating the effect of the outcome obtained (Bohanec, 2003).

The decision-making process is outlined as a sequential progression, beginning with analysing information and concluding with resolution, translating into a choice from a set of available alternatives (Eilon, 1971). Subsequently, the information undergoes an examination to validate its authenticity and differentiate between significant and inconsequential components. This process leads to the delineation of performance metrics, serving as a basis for evaluating a specific course of action, and then culminates in the development of a model aimed at characterising the behaviour of the system under consideration (Eilon, 1971). The schematic representation of the decision process portrays it as a series of sequential activities, often in the form of iterative chains with feedback loops. It is imperative to meticulously examine each of these stages to identify the crucial moments in the progression that lead to the final selection of a specific course of action. The absence of a model that elucidates the behaviour of the system, which the decision-maker strives to manage, prevents the consideration of alternative courses of action or strategies (Eilon, 1971).

Over the years, several theories have been formulated to represent the decision-making process. Herbert Simon (1960) was an economist who carried out research involving several areas, such as psychology, computing and management. One of Simon's great contributions to scientific research was the theory of bounded rationality or decision-making theory, where Simon redefines human rationality arguing that people act rationally according to the knowledge and perception they obtain. To formalise his theory, Simon established four phases that define the decision-making process, as shown in Figure 3.

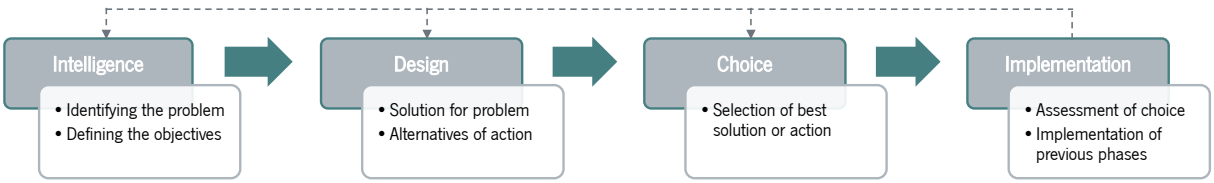


Figure 3: Iterative phases of the decision-making theory (adapted from (Turban et al., 2014)).

- Intelligence - Formalisation of the problem and definition of decision conditions. The decisions to

be made with the help of the proposed system and the benefits it will bring are still unclear and not understood. In this phase, reality is examined to model the existing information for decomposing the problem and determining its properties. The intelligence phase ends with a problem statement.

- Design - At this stage it is necessary to have the problem defined to search for alternatives or available options, where possible courses of action are analysed and validated. Problem-situation models are built to explore alternative solutions. For this, it is necessary to have well-defined and declared selection criteria as a result for the evaluation of potential solutions that will be identified (includes techniques, technologies, format, integration, functionalities, etc). Several possible outcomes can be considered for each alternative, each with a certain probability of occurrence. In cases where decisions are made with uncertainty, there are multiple outcomes for each alternative.

- Choice - In the choice phase, all alternatives are researched, evaluated, and one is defined as the recommended solution. In pursuit of goals, a course of action that is good enough is selected. Computer models or critical success factors can be used as techniques to evaluate the recommended solution. Normative models can use either the analytical model or an exhaustive and complete enumeration model. The solution is tested and once the proposed solution appears viable, a decision can be made.

- Implementation - This phase is the validation of all previous phases. If the adopted solution seems good enough, it can be implemented. Successful implementation results in solving the original problem. In case of failure, it must be returned to the previous phases.

In summary, the Intelligence phase identify the problems and the purpose of action involving the decision. In the Design phase, alternatives are created as possible solutions to the problem. Consequently, in the Choice phase, the alternative that most satisfies the purpose of action will be chosen. Years later, Turban et al. (2014) was responsible for reformulating Simon's theory by adding a fourth phase in order to assess the implementation process. Thus, the Implementation phase results from the joining of the three previous phases put into practice. It should be noted that the decision-making is a sequential and iterative process, which requires the completion of all phases to reach the final phase and an ongoing review of the same.

2.3 Decision support systems

The current era is known as the information age, in which the amount and intricacy of information handled by individuals and organisations has increased significantly (Bonczek et al., 1981). The dependence on and speed of information processing is unparalleled, becoming an important resource for the management of modern organisations, changing the role of IS in decision-making (Ada & Ghaffarzadeh, 2015). Technological advancements in information processing define this information revolution, a significant increase in the number, size, and complexity of groups and organisations, and the use of human-machine

systems for information processing (Bonczek et al., 1981). The current technology revolution is characterised by the processing of various forms of data, such as text, photography, video, and others. The challenge at hand is how to effectively integrate humans and computers as information processors, into a decision-making system that produces 'good' outcomes.

In the backdrop of the early 1960s, organisations were in the beginning stages of computerising operational functions. IS were developed to handle tasks such as order processing, billing, inventory management, payroll, and accounting. The initial objective of Management Information Systems (MIS) was to bridge the gap between transactional data stored in processing systems and the information required by management for decision-making processes (Arnott & Pervan, 2015). The objective of MIS is to provide information to support operations, management and the decision-making function in the organisation (Ada & Ghaffarzadeh, 2015). During the early 1970s, the term 'decision support' emerged as a result of MIS focused on database management systems. Decision support differs from MIS by integrating models into the IS software, providing relevant information to top-level management to help with less structured decision-making and offering easy-to-use problem-solving languages.

Decision support is a term employed in various contexts pertaining to decision-making. However, is a concept that is constantly changing and its interpretation may vary among individuals and different domains. Decision support encompasses all means of assisting individuals in decision-making. The inclusion of the word 'support' in the concept implies a focus on assisting people in making decisions (Bohanec, 2003). Therefore, the decision support activity is concerned with facilitating human decision-making. In the contemporary computational field, decision support is primarily associated with decision systems that are computer-based programs and technologies designed to make routine decisions, monitor processes, and control processes.

Consequently, a Decision Support Systems (DSS) is an integrated Information Technology (IT) tool that allows direct interaction between decision-makers and computers to retrieve information for making semi-structured and unstructured decisions (Ada & Ghaffarzadeh, 2015). The history of DSS began in the mid-1960s, encompassing a range of technologies and concepts designed to improve the decision-making processes of individuals or organisations, from personal device support to knowledge management systems (Mombini & Tulu, 2020; D. Power, 2004). Moreover, computerised DSS are usually categorised into two types:

- **Knowledge-based:** It requires a knowledge base that can produce rule statements, interconnecting with inference and communication mechanisms. Usually have a knowledge base capable of generating rules through the data collected by IS.
- **Non-knowledge based:** Use of data centred on learning algorithms through Machine Learning (ML) and Artificial Intelligence (AI) techniques for predictive decision-making.

In summary, a knowledge-based DSS is a system that integrates the principles of traditional DSS with

the advancements of Expert Systems (ES) (De Kock, 2003). It is designed to assist in strategic decision-making by providing information and interpretations on various alternatives. The knowledge-based DSS uses knowledge-based system development methods to support decisions that require expertise. It incorporates a knowledge base that serves as a repository of rules for domain-specific knowledge, an inference engine that guides the system in making inferences using the knowledge from the knowledge base, development tools that aid in the construction and testing of the knowledge base, and a working memory where partial results of the problem at hand are stored (De Kock, 2003). In summary, a knowledge-based DSS is designed to provide knowledge and specialised assistance to enhance decision-making in complex environments.

On the other hand, non-knowledge based systems are compared as a knowledge-free system, that is a system that combines a knowledge-based approach with a learning-based approach to provide support in situations with missing information. It uses ML algorithms to predict missing values. This type of system is designed to assist professionals involved in decision-making, especially in complex situations with incomplete information. It is able to learn from raw data and perform tasks such as classification, regression, and clustering to provide effective support.

The process of making decisions involves both storing and retrieving data, whether it is done by humans or machines, requiring effective management of databases. In addition, decision-making also involves the use of logical reasoning to determine appropriate information-processing strategies for a given problem, as well as the use of language to communicate the problem and understand the meaning of statements in a particular language (Bonczek et al., 1981).

2.4 Processing decision models

The natural complexity of the world requires complex decision-making processes. Numerous limitations on human rationality underscore this need, encompassing the incompleteness of human knowledge, the existence of inconsistencies, and conflicts between divergent beliefs. These constraints materialise as computational complexities, whereby the use of a series of tools and machines is imperative to effectively face these multiple challenges (Simon et al., 1987).

In circumstances where tasks are excessively complex or the risks involved are of significant importance, individuals frequently encounter uncertainty or a lack of clarity in decision-making, leading to the use of decision support techniques (Bouyssou, 2000). Modelling techniques denote a set of explicit and well-defined protocols designed for the collection, evaluation and processing of information, to facilitate informed recommendations in decision-making processes. According to Bouyssou (2000), formal decision models offer a common language aiming to represent a given problem. The use of formal models requires a substantial commitment from the decision-maker to structure their understanding or representation of the problem, often requiring computational means for implementation.

The perspective on computerised decision systems is that they should be approached as a synthesis

of Knowledge Representation (KR) techniques (Bonczek et al., 1981). When tracing the evolution of data management, there is a discernible trend towards representing increasingly complex types of knowledge. This knowledge typically includes large volumes of facts involved in the decision-making process, which must be represented in an organised and systematic way. The KR method used by a given system can be thought of as a set of rules according to which knowledge is expressed for retention purposes in the DSS (Bonczek et al., 1981).

Consequently, there are many ways to represent decision support activities. KR is crucial to decision-making processes, enabling the representation of decision problems in a format that demonstrates knowledge, the decision maker's preferences and the potential results of different actions. This includes understanding the alternatives, the outcomes associated with each alternative, and the probabilities of those outcomes occurring (Humphreys & Berkeley, 1983).

KR can be related to different techniques that are interconnected, including logic, ontology, and computation (Chandrasegaran et al., 2013). The classification of KR has several perspectives depending on the authors that present this concept. According to Freitas (2014), KR classification can be fit into five types, these being decision tables, classification rules, decision trees, Bayesian Network classification, and Nearest Neighbors algorithm. On the other hand, Chandrasegaran et al. (2013) classify KR into five categories: pictorial, symbolic, linguistic, virtual, and algorithmic.

Knowledge bases offer a spectrum of knowledge that covers various levels of abstraction and expressiveness, from implicit knowledge to fully explicit KR, which extends from natural language to universal logic (Blobel, 2017). Components of knowledge bases can be represented using rules set, boolean logic, probability, bayes rules, or informal logic, depending on the quality of their relations and the strategy of the reasoning engine (Gaman et al., 2023). This action includes the fundamental conceptualisation of intelligent reasoning in the context of representation, the set of inferences sanctioned by the representation and the set of inferences it defends. KR functions as a platform that facilitates computationally efficient thinking and serves as a means of human expression and language to delineate the complexities of the world (Blobel, 2017).

2.4.1 Production rules

An ES is an advanced version of a DSS, being a type of programmed IS that helps users with limited knowledge by capturing and reproducing the knowledge and experience of experts. Rule-based systems are currently the most used type of expert systems, representing knowledge through numerous rules that indicate conclusions for different situations. By analogy with a human cognitive process, rules are a natural way of solving problems (Gaman et al., 2023).

Rule-based systems are an approach to creating a knowledge-based DSS, in which data is represented in a rule format and is evaluated, resulting in a final decision (Sutton et al., 2020). Rule-based DSS are a positive strategy since the result that comes out of the rule can be used as a recommendation or alert so that a user can decide accordingly. When trying to discover the knowledge that experts possess, it is

easier to explain the structure of the knowledge presentation to them, since a simple representation of the rules is used.

Similar to first-order logic, rule-based systems capture knowledge with conditions in logical systems, as can be organised, for example, in 'IF-THEN' statements (Berner & Gong, 2016). Classification rules, structured as 'IF' and 'THEN' classes, provide a logical representation, initially in text form, with the option of incorporating positional information indicating the importance of the attribute (Freitas, 2014). Figure 4 represents a logical structure for production rules.

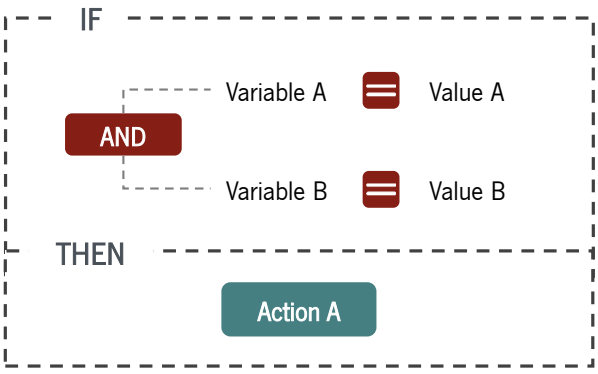


Figure 4: Structure of production rules (adapted from (Brachman and Levesque, 2004)).

A production rule is a two-part structure consisting of an antecedent set of conditions and a consequent set of actions (Brachman & Levesque, 2004). Following the logical structure of 'IF-THEN' statements, rules offer a direct and convenient way to represent these pieces of knowledge. The 'IF' part corresponds to the premise and the 'THEN' part is where the output action is triggered. The first part describes a possible situation formed by one or a set of conditions. The conditions are created by combining a variable, an operator and a value. On the other hand, the second part of the rule is the indication of the actions to be carried out (Gaman et al., 2023). When the conditions defined in the 'IF' part are truly met, the 'THEN' part of the rule is activated, followed by a list of actions to be carried out in rule execution.

This format indicates that if it can be determined that the possible situation exists, then the actions indicated must be carried out for the reasons given. In other words, if the premise is true, then the conclusion is valid. Rule induction algorithms usually expand classification rules incrementally, selecting one attribute value at a time. This ordering helps prioritise conditions based on the relevance estimated by a rule induction algorithm. Not relying on mutually exclusive and exhaustive predictions allows models to include only relevant conditions (Burstein & Holsapple, 2008).

2.4.2 Decision tables

Decision Tables are a form of KR that contains conditions associated with one or more decisions and are therefore considered as a special table (Y. Yao & Zhang, 2017). The table is composed of a set of attributes and conditions that are associated with one or more actions, thus forming decisions (Witt, 2012; Y. Yao & Zhang, 2017) This type of table helps to answer questions for organisations, since these tables

contain knowledge and experience to provide recommendations in the decision-making process (Riaño et al., 2019). Therefore, processes can be represented by Decision Tables and can appear in different structures (Riaño et al., 2017). Figure 5 presents an example of a Decision Table structure.

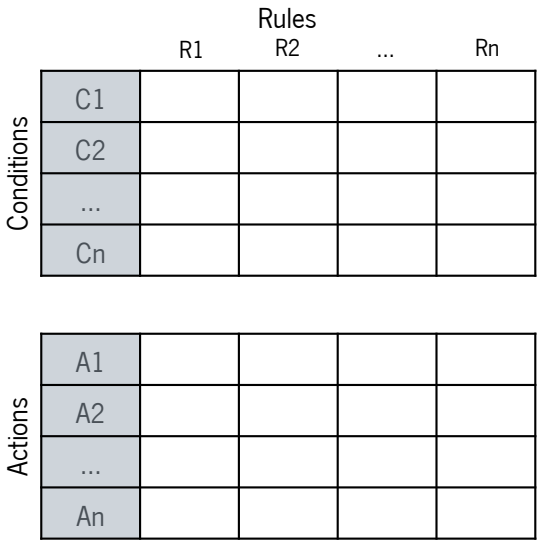


Figure 5: Structure of a decision table (adapted from (Senchenko and Ekhlakov, 2019)).

A Decision Table is divided into two parts. The first part refers to Conditions, the second part to Actions, and the junction of the two parts represents the set of rules. The two parts of the Decision Table are similar and what only changes is the context of the part (Senchenko & Ekhlakov, 2019). According to Witt (2012), Decision Tables can have two types: limited-entry and extended-entry, as shown in Figure 6.

The limited-entry type (Figure 6a), in the first part of the table, displays the conditions fully in the first column (Age >30). The subsequent columns show their Boolean values: true (Y), false (N), or not applicable (-). In the second part, actions are symbolised by an X if that action is performed according to the above conditions (Witt, 2012). For the second type, extended-entry (Figure 6b), the condition is divided in the table. The condition variable is shown in the first column, with its associated values in the subsequent columns. The same applies to the actions, where the first column presents the variable, while the following columns display the values (Witt, 2012).

In general, the purpose of a decision table is to organise conditions and actions in a simple and orderly way, enabling logical execution based on the values entered in the table. Thus, the conditions of each rule are listed and represented in a single combination. On the one hand, limited entry tables have a binary format which helps to simplify table processing. On the other hand, extended entry tables have a more comprehensive representation with greater detail of the rules and conditions. The choice of the table type depends on the purpose of the analysis and the requirements imposed on the decision-making process. The construction of the decision table must be carried out taking into account its appropriate size, type of processing and level of complexity of the application context.

	R1	R2	R3	R4
Age > 30	Y	Y	Y	N
Age <= 30	N	N	N	Y
Insulin >= 112	Y	N	N	-
Insulin < 112	N	Y	Y	
Glucose >= 128	-	Y	N	-
Glucose < 128	-	N	Y	-
Diabetes = positive			x	
Diabetes = positive	x	x		x

(a) Limited-entry decision table

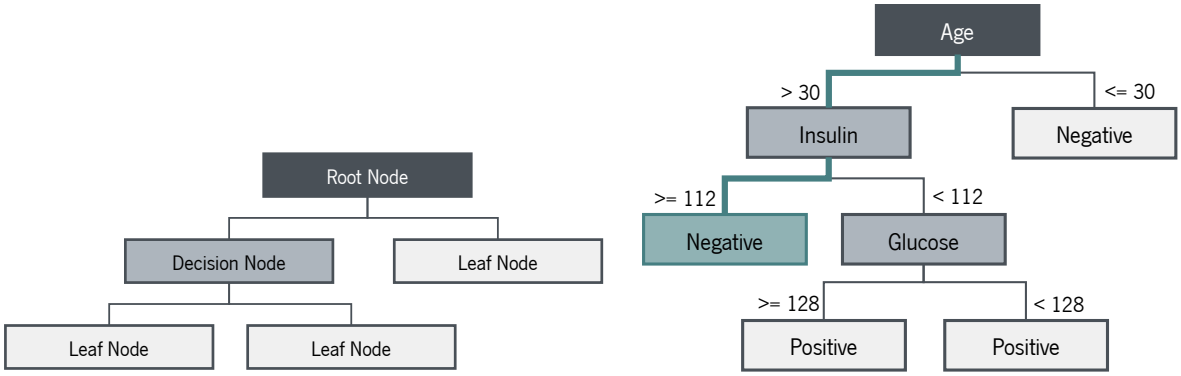
	R1	R2	R3	R4
Age	> 30	> 30	> 30	<= 30
Insulin	>= 112	< 112	< 112	-
Glucose	-	>= 128	< 128	-
Diabetes	negative	negative	positive	negative

(b) Extended-entry decision table

Figure 6: Decision table types (adapted from (Witt, 2012)).

2.4.3 Decision trees

Another way of representing knowledge is through the use of Decision Trees. Through the presentation of a graphical structure, it is possible to recognise the structure of a Decision Tree. To achieve this, it should include variables relevant to the analysis, arranged in a hierarchical tree format (Freitas, 2014). For Charbuty and Abdulazeez (2021), this form of representation is a model based on a tree structure with a hierarchy of knowledge relationships. The data representation starts at the root of the tree and is divided until it reaches an endpoint node, presenting a result. Thus, Figure 7 demonstrates a Decision Tree structure.



(a) Decision tree elements.

(b) Example of a decision tree path.

Figure 7: Decision tree structure (adapted from (Song and Lu, 2015)).

According to (Song & Lu, 2015), there are three possible types of nodes within the tree structure: the Root Node, the Decision Node and the Leaf Node (Figure 7a). The Root Node represents the first step in creating the tree and checking the condition of this node can generate one or more subdivisions. The Decision Node or Internal Node can connect to a parent node represented above the node and links to one or more child nodes below the node. Finally, the Leaf Node is considered to be the last node in the

link and forms a combination of conditions that end up giving rise to the results.

The connection of nodes in the tree is represented by branches, which can connect root nodes to decision nodes as well as decision nodes to leaf nodes. The Decision Tree path depends on the decision rules that are contained in the branches of the tree (Song & Lu, 2015), as shown in Figure 7b. Overall, this decision tree technique has several advantages in terms of the simplicity of the decision model of understanding and application, the transparency of the data and the improvement of the decision-making process.

2.4.4 Scores

Over time, there has been a need to create other ways of predicting results in organisations (Rap & Shyam, 2014). Scores are a very common model used to assign numerical values to specific indicators that determine the assessment of a particular outcome. A scoring system is a computer-based evaluation system that automatically scores or ranks the answers to a given question, taking into account the appropriate characteristics (Ramesh & Sanampudi, 2022). Scoring systems include information that is associated with a score to understand what kind of result a decision might have. Thus, these systems aim to predict outcomes so that organisations can deal with possible consequences based on what has been predicted.

These systems can be used for decision-making in different environments, such as recommendations, screening or analysing measures. The use of these systems is effective in identifying possible solutions to a given problem, based on the results obtained from the values entered. In addition, this representation technique allows for better management of resources so that they can be optimised in the development of new patterns (Rap & Shyam, 2014). Figure 8 demonstrates the structure of a score system, based on the definition of criteria and possible outcomes.

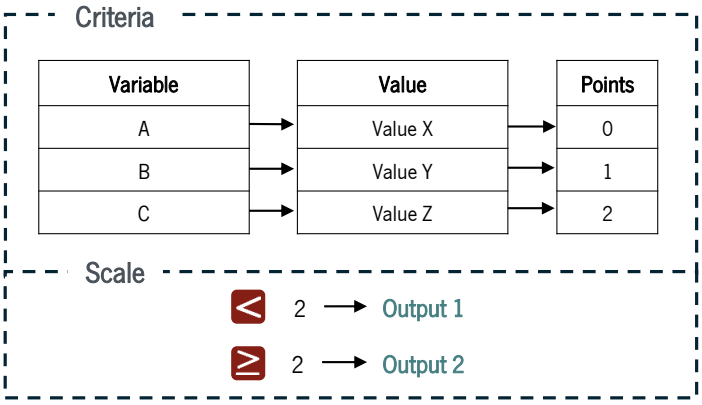


Figure 8: Score structure (adapted from (Rap and Shyam, 2014)).

Scores are generated in two components, establishing criteria to trigger a specific outcome according to the scales definition. The criteria are defined from the conjunction of variables, values and associated points. The scales are defined from the sum of the total scores obtained, where an event is triggered based on the result obtained.

The scoring mechanism operates by verifying the compatibility of entered values with predefined conditions. Upon entering a value, its corresponding score is recorded and added to the total score. This process iterates until all conditions are evaluated. Once the final score is determined, the system checks the value scale and identifies the corresponding output for the final score. Following the example in Figure 8, if the user selects variable C, the score will be 2 and the result will be output 2. In this way, the conditions that are considered valid are understood by adding up the scores acquired and analysing the result corresponding to that number.

3

Exploring Decision Support in Healthcare

After understanding the decision-making process, it is necessary to comprehend it inside healthcare organisations. In this context, this chapter explores the concept of Clinical Decision Support Systems (CDSS) and what is involved in the healthcare domain, regarding intelligence, interoperability and open standards.

3.1 Clinical decision support systems

Medical records have existed since the beginning of medical practice and have an evolutionary history (Honavar, 2020). One of the significant achievements in this history is the evolution from paper-based records to digital format. Nowadays, these records are primarily computerised, resulting in Electronic Health Records (EHR). The Centers for Medicare & Medicaid Services (2023) defines the EHR as "an electronic version of a patient medical history, that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that person's care, including demographics, progress notes, problems, medications, vital signs, past medical history, immunisations, laboratory data and radiology reports". Besides, the World Health Organization (WHO) (2015) states that EHR are "real-time, patient-centred records that provide immediate and secure information to authorised users".

The term EHR is commonly used to refer to a complete and long-term collection of a patient's healthcare data that is cross-institutional. It includes not only data specifically relevant to medical treatment but also data pertaining to the patient's overall health (Hoerbst & Ammenwerth, 2010). In essence, its objective is to facilitate the integration of patients' health history to ensure safe and appropriate treatment by combining data analysis to assist healthcare providers in delivering superior quality care to their patients (Kohli & Tan, 2016; Menachemi & Collum, 2011). EHR are expected to enhance information accuracy, mitigate medical errors, support clinical decision-making, and make information accessible for continuity of care (Honavar, 2020).

Similar to the purpose of EHR systems in storing and making available clinical data, Health Information System (HIS) deal with processing data, information and knowledge in care environments (Reichertz, 2006; Winter et al., 2010). EHR is the collection of health data relating to a subject of care stored in a HIS, which may be dispersed across various systems and clinical repositories (separate or interconnected)

(Winter et al., 2010). According to WHO (2008), a HIS generates, collects, and analyses health data to ensure its overall quality, relevance and timeliness for health-related decision-making.

Despite the benefits of HIS and EHR systems, their use has some obstacles and concerns. First, missing or lost EHR can have profound negative implications for the patient's health, as incomplete information about his health history can lead to adverse events that cause complications and increased mortality (Kohli & Tan, 2016). Other challenges encountered are due to persistent issues such as privacy, interoperability and security of clinical records. Some studies affirm that HIS lack in data exchange standards and compatible interfaces and services (Honavar, 2020; Kohli & Tan, 2016; Menachemi & Collum, 2011). Quite apart from the desire to improve quality and support healthcare, new challenges have arisen over time that HIS have to address, such as the need for interoperability not only at a technical level but also at a semantic level (Hoerbst & Ammenwerth, 2010). Furthermore, a study by the National Academies of Sciences and Medicine (2019) reveals that nurses and doctors spend approximately 50% of their working day producing EHR in front of a computer screen instead of focusing on the patient, causing an increased workload and leading to physician burnout.

Solid and reliable information is the basis for an effective HIS and is essential to support decision-making (WHO, 2008). Data relevant to health decision-making need to be collected and presented in a patient record (Winter et al., 2010). The need to assess computer-based decisions for patients and physicians has been raised, focusing on accuracy and effectiveness (Berner & Gong, 2016). Nonetheless, the complexity of evaluating HIS and the lack of a sound evidence base for its implementation have stood out (Reynolds & Wyatt, 2011). The swift implementation of these systems within a constantly evolving medical landscape adds complexity to the critical evaluation of HIS (Berner, 2007).

The representation of the decision support activity by a computerised system gave rise to the DSS D. J. Power, 2007. In the healthcare domain, many needs arise with the exponential growth of data, encouraging the adoption of IS capable of transforming EHR into knowledge. Hence, Clinical Decision Support (CDS) is pursued to assist healthcare providers in decisions through clinical KR. HIMSS (2016) defines CDS as a "process for enhancing health-related decisions and actions with pertinent, organised clinical knowledge and patient information to improve health and healthcare delivery".

Thereupon, CDSS emerge as computer-based tools that assist healthcare professionals in making accurate and timely clinical decisions. Information and knowledge are provided from various sources, such as clinical guidelines, medical literature, and patient data, to support diagnosis, treatment, and patient monitoring. CDSS can help reduce errors, improve patient outcomes, and enhance healthcare efficiency. In summary, CDSS aid healthcare practitioners in decision-making while HIS facilitate the management and exchange of patient data. The combination of these technologies has the potential to enhance healthcare delivery, improve patient outcomes, and provide better research opportunities.

With the technological advancement in healthcare, there is an evident growing demand for IS capable of storing and processing EHR (Sittig et al., 2008). Several studies portray CDSS as essential, substantial, and unique. However, it is important to identify its specific benefits to justify its adoption. According to the literature, CDSS aims to present evidence-based clinical practice to support healthcare practitioners

in the decision-making process Khalifa, 2014. Overall, improving the quality of healthcare delivery is one of the most promising expected outcomes that encourage the adoption of CDSS. It also provides better workflow management, lightening healthcare professionals' workload. This is directly related to reducing errors and malpractices in services, which increases safety and the quality of the service provided to patients (Shahsavarani et al., 2015).

The cost reduction also motivates the adoption of CDSS, using analytical tools or other mechanisms that help in the data collection process safely and effectively (Sulley, 2018). Shahsavarani et al. (2015) states that all systems should be cost-effective and have a cost-quality ratio. Moreover, computerised-based systems also allow time reduction and streamline processes due to the replacement of paper files. This saved time can be used to improve the interaction between the health professional and the patient, relieving the provider from other tasks (Shahsavarani et al., 2015). The ability to adapt to specific workflows is also seen as a benefit, meaning that a CDSS can be applied in several areas of care if it is well implemented (Shahsavarani et al., 2015; Turban et al., 2014).

On the other hand, it is important to consider the effectiveness of the CDSS developed. Shahsavarani et al. (2015) establishes three domains as being the biggest benefits of a CDSS and states that if these benefits are accomplished, the CDSS reaches its efficacy: (i) improvement of quality of healthcare and patient safety; (ii) increase of effectiveness/cost ration; (iii) improvement of medical and professional knowledge. In contrast, Jao and Hier (2010) states that reducing medical errors and improving patient safety are key points for effectiveness. At the operational level, Jao and Hier (2010) defends three key elements for a successful CDSS: (i) access to accurate clinical data; (ii) access to relevant medical knowledge; (iii) ability to use appropriate problem-solving skills. Overall, an effective CDSS can involve different levels in the decision-making process, ranging from alerting, interpreting, criticising, assisting, diagnosing and managing, being the alerts highlighted as the best strategy to achieve the effectiveness of a CDSS (HIMSS, 2017; Shahsavarani et al., 2015; Sulley, 2018).

Hereupon, Greenes (2007) affirms the importance of a DSS in the health area but highlights some non-conformities and existing failures that are not yet solved. A possible key obstacle to the slow process of CDSS adoption may regard KR for decision support, which should be in a standard form so that records can be read semantically for any system. This issue is also highlighted by Middleton et al. (2016), where the author states that the lack of clinical terminologies and standardised approaches is a limitation identified from the last decades, and, despite its evolution, it still needs to be addressed. Besides, Purcell (2005) counters that the key point for the effectiveness of a CDSS lies in its knowledge base, which must be reliable and robust.

Several concerns and requirements highlighted in the literature review merit consideration during the design phase of an effective CDSS, including: (i) creation of a configurable, intuitive and appealing interface; (ii) provide decision support in real-time and with speed; (iii) use technological interventions in a balanced and simplified way; (iv) qualified and semantically interoperable decision component; (v) representation of clinical knowledge through an agile and effective inference mechanism (HIMSS, 2017; Purcell, 2005; Sulley, 2018).

3.2 Intelligent clinical decision support

Intelligence in systems allows objectives to be pursued more efficiently with reduced user intervention using inferential or computational methods. Although it is often equated with human-like problem solving, it is essentially a mechanism programmed into the software and not a mandatory requirement for the system's behaviour (Burstein & Holsapple, 2008). Despite the various types of intelligent systems employing algorithms, knowledge bases, learning by example, or memory-based reasoning, real-time planning capabilities are increasingly being incorporated. This aligns with the phases of decision-making theory: intelligence, design, and choice (Burstein & Holsapple, 2008), as using these computational tools improves problem-solving by reducing dependence on user interaction.

When logic and linguistics are integrated into the machine part of the human-machine decision-making system, there is an improved common ground between human and mechanical information processing, making the machine appear intelligent in some artificial sense. This means that the machine's observable behavior begins to give the impression that it has some intelligence. The automation of logic and linguistics is the foundation of AI, which is a field of study aimed at investigating and developing concepts and techniques that can be applied to the development of computerised Intelligent CDSS (Bonczek et al., 1981).

In 2017, Watson established a prediction of the state of Decision Support for the next generation cycle of 2020. The author argues that every 10 years, there is a significant evolution in computer-based decision support. The evolution of computer-based DSS has followed a cyclical pattern, with significant shifts occurring approximately every decade. Starting from the implementation of DSS in the 1980s, followed by the rise of data warehousing in the 1990s, real-time data warehousing in the 2000s, and the dominance of big data analytics in the 2010s, each generational transition has brought about advancements in scope and user base, defining distinct eras within decision support technology (Watson, 2017).

From 2020 onwards, the next generation will be seen as the cognitive generation of decision support based on existing paradigms, namely integrating AI into data analysis processes. This integration is complemented by additional trends, such as cloud migration, Internet of Things utilisation, and data monetisation. AI evolution from early applications in games and theorem proving to its contemporary role in deep learning reflects its pivotal role in decision support (Watson, 2017). While the realisation of the technological singularity remains unrealised as of 2020, AI omnipresence underscores its significance in shaping the cognitive generation of decision support, characterised by a continuum of advancement inheriting and building upon preceding generations, emphasising the importance of incremental progress aligned with technological and organisational readiness (Watson, 2017).

In healthcare, intelligent systems hold immense promise for revolutionising patient care in Intensive Care Unit (ICU) settings by leveraging the vast amounts of high-frequency numeric, waveform, and EHR data to detect and forecast instability and provide intelligent CDS (Pinsky et al., 2022). The urgency to develop unbiased, reliable, and usable AI-based systems for diagnostics, forecasting, and bedside decision support in healthcare, especially in ICU environments, underscores the potential to save lives

through AI-driven real-time CDS to predict and mitigate critical instability (Pinsky et al., 2022).

However, challenges persist in integrating AI-based tools effectively into acute care environments due to past setbacks such as unacceptable performance, perceived lack of clinical usefulness, unstructured data, workflow interference, and increased clinician burden (Brahnam & Jain, 2011). The imperative lies in developing high-performing and trustworthy AI models seamlessly integrated into clinical workflows, adhering to human factor engineering principles to minimise information overload and incrementally enhance usefulness. Transitioning from conventional CDSS to Intelligent CDSS through knowledge discovery in data approach with AI tools, represents a pivotal advancement toward personalised predictions and recommendations, facilitating proactive instability mitigation and ultimately improving patient-centred outcomes on a large scale (Floares, 2010).

In the design of intelligent systems, it is recognised that the reasoning process is simpler when the representation structure reflects the structure of the part of reality under consideration (Blobel, 2017). As such, it is essential to master the representation of decision logic, structured objects and their behaviour. A universal logic based on type theory is a comprehensive framework to facilitate the comprehensive representation of multidisciplinary, complex, scalable and flexible CDSS (Phillips-Wren, 2013). Furthermore, to facilitate the sharing of computable clinical knowledge and enable intelligent collaboration in distributed environments, adopting a common language for specifying expressions and criteria becomes imperative.

3.3 Interoperability

Nowadays, the constant technological evolution in health services is notable, since the change from paper-based clinical records to electronic format (Cardoso et al., 2014). According to Peixoto et al. (2010), a healthcare unit consists of a "paraphernalia of applications" that speak different languages and are customised in different ways. Considering the growing production of EHR, there is an increasing need to maintain continuous communication between systems within healthcare domain. To this end, it is essential that such systems communicate correctly and effectively, transmitting information from one system to another, without failures or loss (Peixoto et al., 2010). Therefore, this ongoing exchange of information between systems is referred to as interoperability.

Interoperability is defined as "the ability of two or more software components to cooperate despite differences in language, interface, and execution platform" (Wegner, 1996). In general terms, interoperability and integration are sometimes confusing terms, despite they operate on different conceptual levels and serve distinct purposes. Simply put, integration aims to collect and acquire information from multiple systems for another system that requested it, whereas interoperability focuses on enabling continuous communication and exchange of information among cooperative systems (Cardoso et al., 2014).

From a healthcare perspective, interoperability plays a vital role, translating in the ability of different HIS, devices, and applications to access, exchange, integrate, and collaboratively use data in a synchronised manner. This occurs both within and across organisational, regional, and national boundaries,

aiming to deliver timely and seamless information portability and enhance the health outcomes of individuals and populations worldwide (HIMSS, 2021).

The primary objective of healthcare interoperability is to enable the distribution and exchange of patient information among healthcare professionals whenever and wherever needed (Schloeffel et al., 2006). Interoperability is not considered an optional feature in EHR systems, but rather a fundamental requirement for enhancing healthcare delivery and the well-being of diverse patient populations, without necessitating additional efforts from professionals in the field (Cardoso et al., 2014).

To define the level of interoperability of an organisation's system, a method is required capable of classifying interoperability into levels according to a set of criteria. There are currently several models and frameworks proposed by different organisations and researchers to classify interoperability (Rezaei et al., 2014). In the health sector, the levels of interoperability may vary depending on the framework or model used. However, a commonly cited model for healthcare interoperability is the Level Conceptual Interoperability Model (LCIM), defining the interoperability in seven levels (Wang et al., 2009). These levels provide a structured framework for understanding the depth and complexity of interoperability in healthcare systems. LCIM offers a conceptual structure that delineates key components necessary to achieve interoperability across hierarchical levels (Robkin et al., 2015).

- **Level 0 – No interoperability:** Systems work independently, without any interaction or exchange of information.
- **Level 1 – Technical Interoperability:** Systems must have technical connections and common communication protocols, and can exchange data between systems.
- **Level 2 – Syntatic Interoperability:** Systems need to have an agreed protocol for exchanging the right types of data in the right order. They must have a common data structure, but the meaning of the data elements is not established.
- **Level 3 – Semantic Interoperability:** Systems exchange a set of terms that they can analyse semantically. Having a common reference model gives meaning to the information and the content exchanged must be clear.
- **Level 4 – Pragmatic Interoperability:** Systems will be aware of the context (states and processes) and the meaning of the information exchanged. To do this, they must share a common workflow model, use data and contextualise the information exchanged.
- **Level 5 - Dynamic Interoperability:** Systems need to share a common execution model to redirect the production and consumption of information based on an understanding of the changes in meaning due to a change in context.

- **Level 6 – Conceptual Interoperability:** Systems are fully aware of each other's information, processes, contexts and modelling assumptions, and must have a common documented conceptual model.

Initially, level zero of the LCIM corresponds to the lowest form of interoperability, with no interactions or data exchange. Level one of interoperability is represented by technical interoperability, which consists of data exchange using defined protocols. At the second level, syntactic interoperability presupposes a traditional syntax context that defines the grammatical meaning of the data, ensuring that the structure and coding of the data is understood by both parties. Next, semantic interoperability defines the need for an IS to understand the semantics of the information. Semantic interoperability goes beyond syntax to ensure that the data exchanged has a common meaning between systems, requiring the use of common data models, ontologies and vocabularies (Wang et al., 2009).

At level four, pragmatic interoperability covers a broader context in data exchange, informing the methods and procedures that each system uses to assimilate its context. The fifth level focuses on the ability to adapt to changes in context over time, promoting dynamic technological requirements. Finally, systems that reach the last and highest level of interoperability share a common understanding of the underlying concepts and principles, pointing to compliance with rules and restrictions in different environments (Wang et al., 2009).

In healthcare, interoperability has a critical impact on the exchange of EHR to improve the quality of services (Iroju et al., 2013). Achieving a high level of interoperability in healthcare translates into easy access to patient records, better understanding of medical terms, reduced medical errors, lower healthcare costs, integration of health-related records, and better support for chronic disease management. However, this goal has not yet been fully achieved due to a number of challenges, including the heterogeneity of tools, methods and processes used in HIS. Iroju et al. (2013) emphasise the need to adopt terminologies and standards as a way of achieving full interoperability.

3.4 Open data standards

There is growing recognition of the adoption of CDSS for substantial improvements in patient safety, quality of medical care, and operational efficiency. However, concerns have been noted regarding the involvement of clinical knowledge, representing a potential obstacle to the success of the patient care process. Such deficit can impede rapid and comprehensive integration and meaningful use of effective CDSS, thus undermining their potential benefits (Reynolds & Wyatt, 2011).

TIntegrating inter- and intra-organisational information flows poses a significant challenge when coupling electronic records processes. To address this challenge, standards are typically required. In general terms, a standard describes a regulatory principle that governs a particular context (Rebstock et al., 2008). More precisely, the International Organisation of Standardization (ISO) (2004) defines a standard as "a document established by a consensus and approved by a recognised body, that provides for common and

repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimal degree of order in a given context".

In the absence of standards, integration efforts would be extremely complex due to the multitude of entities, requiring negotiation of processes, content and formats for each bilateral communication relationship. The standards mainly address information structures, transaction formats, and predefined document contents that serve to facilitate integration between systems. Consequently, the use of standards promotes interoperability by covering not only the fusion of data, but also the clarification and reconciliation of its meaning (Rebstock et al., 2008).

The definition of a standard is consensual, although disagreements arise regarding the necessary criteria for a standard to be qualified as open. Cerri and Fuggetta (2007) classify an open standard based on the following set of criteria:

- The standard must be adopted and maintained by a non-profit organisation, continuously developed through an open decision-making process and accessible to all interested parties;
- The standard must be published and its specification document must be available to the public, free of charge or for a nominal fee, allowing everyone to copy, distribute and use it without restrictions;
- The standard should ensure that any intellectual property, including potentially present patents, is irrevocably available on a royalty-free basis, allowing free implementation for all interested entities;
- There are no restrictions on reusing the standard, which allows it to be extended and used in other open standards.

Open standards approaches foster implementations and collaborations between systems and organisations that adhere to the same standard (Reynolds & Wyatt, 2011). A successful open standard achieves and sustains the goal of facilitating the presence of competing implementations by ensuring compatibility and accessibility between heterogeneous entities.

In the healthcare domain, there is a multitude of open standards designed for HIS. However, widespread adherence to these standards has not yet been achieved, thus impeding interoperability to the detriment of system integration and data exchange. Following medical information standards, there are different models capable to represent the different facets of clinical information (Rector et al., 2001). However, this presents an obstacle in the adoption of these standards due to the difficulty in representing complex care processes and purposes in health units. Rector et al. (2001) state that it can be difficult to acquire a standardised structure that meets conceptual and clinical knowledge requirements, as EHR systems must be based on an informational reference model of the standard to be adopted.

3.4.1 OpenEHR

In the daily rhythm of any organisation, the data produced grows on a large scale. In healthcare, a practitioner's performance gradually depends on these records, presenting needs at different times. Consequently, techniques capable of handling with large amounts of data originating from different locations and in different formats are needed, aiming to extract information necessary to generate knowledge for care processes (Isotani & Bittencourt, 2015). However, most of these records are not commonly available or even structured, which makes their understanding difficult and generates inefficiency (Isotani & Bittencourt, 2015).

Despite the evolution of IT, in recent decades a disparity has been noticed between its adoption and integration within healthcare. Concerns were raised about easy access for patients to their health records, the centralisation and interoperability of information, and continuity of care. In order to overcome these questions and avoid fragmentation of patient care, the motivation to create the openEHR community was born.

In 1992, an international collaboration to address the problems of poor data quality and inability of HIS was initiated, originating a medical informatics project known as the Good European Health Record (GEHR), with the aim of deepening and applying studies on the architecture of a global EHR (CORDIS, 2014). In other words, the objective was to develop an architecture that would frame the storage and access to all the clinical information of an EHR necessary to provide healthcare services to the patient, based on quality clinical and technical details (CORDIS, 2014). The project has gained importance and expansion over the years, involving more than 8 European countries. However, the research and development of the project underwent changes, sometimes influenced by uncertain or incorrect considerations (Bacelar-Silva & Correia, 2015). This was not an impediment for those involved, which led to the conservation of the project requirements, thus contributing to the creation of the first ISO standard related to EHR (Ingram, 2023).

In a phase of overcoming GEHR problems, GEHR members Sam Heard and Thomas Beale, together with University College London, innovated an archetype-based approach that encompasses two levels, one at the clinical level and the other at a technical level, thus solving the problems of GEHR implementation (Bacelar-Silva & Correia, 2015). In 2002, this approach was named 'openEHR' and the independent and non-profit openEHR Foundation was subsequently created (Ingram, 2023).

The openEHR Foundation (2003) defines the standard as "a non-profit virtual community interest organisation that aims to enable clinical healthcare to advance by better use of information and IT, ensuring universal interoperability between all forms of EHR". Hereupon, openEHR is an approach that follows the definition of an open standard, guaranteeing free access to health information specifications, being used in the management, storage and consultation of EHR. Its main objective is to promote an interoperable and organised structure for clinical records, holding clinical knowledge in a structured way to promote semantic interoperability and data integration with different healthcare establishments (César et al., 2013).

A key point to highlight regarding clinical records is how this data is modelled for transmission and

understanding by another system (Bacelar-Silva & Correia, 2015). According to Beale (2002), most information systems are based on single-level methodology, where information and knowledge are built at the same level as object and data models. Thus, a possible two-level methodology has emerged, where systems are built exclusively from information models and driven at runtime by definitions of concepts at the knowledge level. In addition, Beale (2002) highlights differences between the two models, showing that the one-level modelling has a high maintenance cost and a short duration, due to its complexity, volume and difficulty in adapting to changes, while the two-level approach has a lower cost, longer duration, speed and effectiveness.

Therefore, openEHR adopts a multilevel approach, defining an architecture based on archetypes to communicate with parts or all of a patient's EHR. This approach maintains the clinical meaning of the content while preserving the confidentiality of each piece of data as intended by the patient (Santos et al., 2010). By modelling the EHR in two levels, it is possible to separate the clinical information from knowledge, as demonstrated in Figure 9.

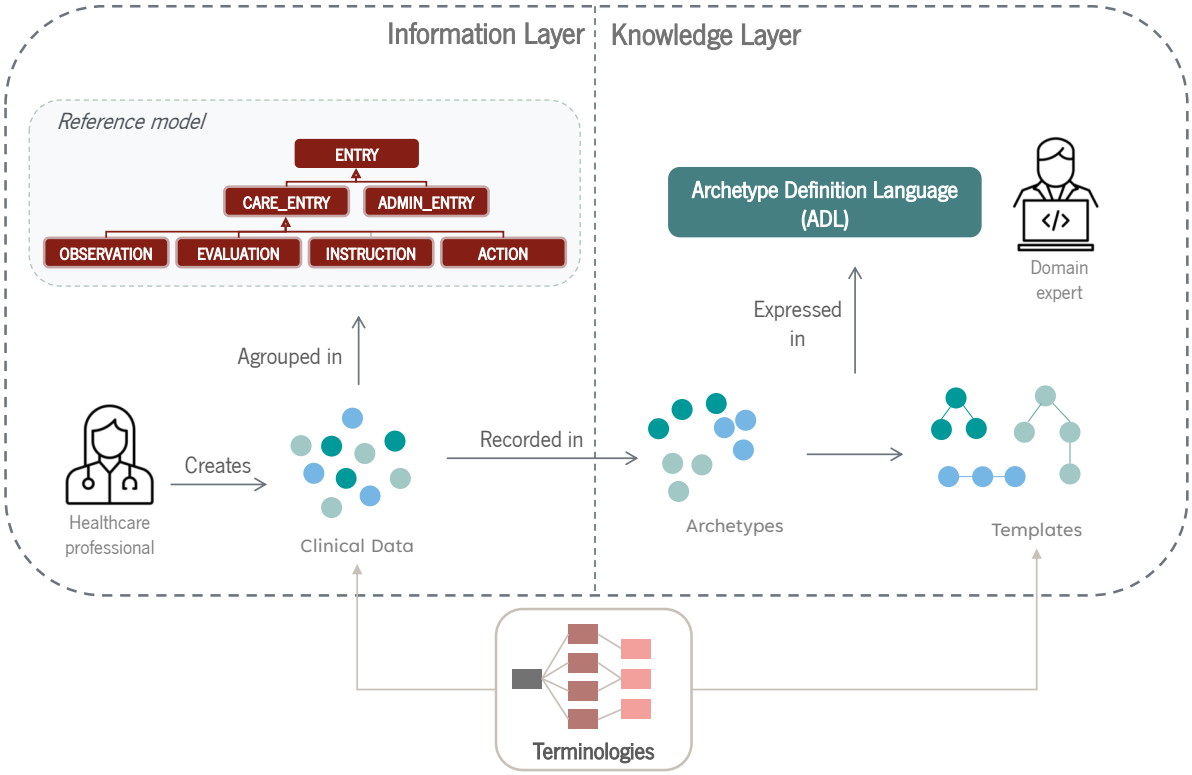


Figure 9: OpenEHR two-level architecture (adapted from (Beale, 2002)).

On the one hand, the first level of modelling is represented by the information layer that primarily consisted of the Reference Model (RM). Following a computational point of view, this layer defines the interfaces to be used in health services centered on the EHR (Beale & Heard, 2008). RM is the only level implemented in the software, which reduces dependence on systems and follows an informational point of view, that is, it is concerned with defining the information that each component stores and processes

in the system, in a non-volatile way. Thus, the RM establishes a set of entities, data or instructions of a class, which represent the information components of an EHR, such as quantity, text or date concepts.

When the provider records patient information in an electronic system, data is created and grouped into the RM. In the openEHR, all clinical information is encapsulated in 'Entries', which represent single clinical statements ranging from brief narratives to comprehensive data sets, being fundamental in defining the semantics of the EHR Information Model. The ENTRY classes, including ADMIN_ENTRY, OBSERVATION, EVALUATION, INSTRUCTION, and ACTION, categorise various types of clinical statements, aligning with the problem-solving process in clinical practice.

On the other hand, the second level of modelling is represented by the knowledge model, which focuses on building clinical content in a structured and standardised way. This knowledge is represented by archetypes and templates that give semantic meaning to RM information (Santos et al., 2010). Through modelling performed by a domain expert, archetypes are selected and combined to produce templates, capable of representing specific groups for a specific clinical purpose. Archetypes are expressed in a language equivalent to Archetype Definition Language (ADL). Furthermore, archetypes and templates also act as a well-defined semantic gateway to computerised terminologies, classifications and clinical guidelines.

According to Beale (2002), the name "archetype" denotes a "model that defines a concept from some domain, expressed according to constraints on instance structures of an underlying RM". In order to represent the semantics of the two-level modelling approach, archetypes are also understood as meta data, as they define electronic standards that characterise clinical concepts, delimiting the RM in real time and structuring the classes contained therein to define clinical knowledge (Santos & Bax, 2010). The clinical concept is understood as health notes, both in a simplified format, such as weight, height or blood pressure, and in a more complex form, such as the risk of a serious condition due to a positive family history (Leslie, 2008).

The definition of clinical content in archetypes allows the separation of data and its storage in an appropriate repository. Archetypes can be found in freely accessible online repositories. Clinical Knowledge Manager (CKM) is an open repository managed by the openEHR community that allows the management and maintenance of archetypes and templates. CKM allows the sharing and use of openEHR structures, providing universal use of the same data structure by different systems representable by archetypes, making it necessary for all systems to have access to equivalent structures.

In summary, the separation of information and knowledge generates adaptability, size reduction and greater ease of maintenance of systems with current and future clinical practice, thus solving problems of variability and change (Bacelar-Silva & Correia, 2015). Regarding the use of the openEHR standard, it provides a set of open specifications, which cover information models for clinical data, both as EHR and demographic data, and models expressed for domain content. The openEHR specifications are organised into three categories that contain specific components, as showed in Figure 10.

The category of abstract specifications includes the components: Platform services, referring to the

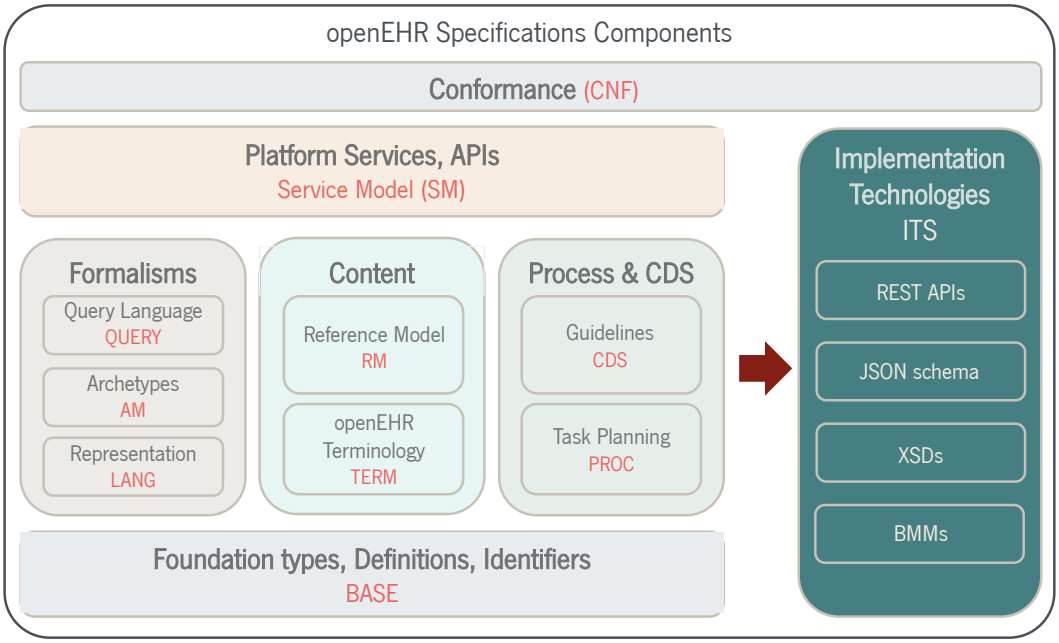


Figure 10: Components of the openEHR specifications (adapted from (Beale and Heard, 2008)).

Service Model (SM); Formalisms, referring to query languages and the archetype model; Content, responsible for the RM and terminologies; Process and Clinical Decision Support (PROC), referring to workflows and decision processes; Foundation types, regarding the base model and the resource model; and, finally, the Technology Implementation category, referring to Application Programming Interface (API) calls and data structures.

3.4.2 Standardised decision languages

Expressing and sharing computerised content to support decision processes has long been an elusive goal. The lack of commonly shared clinical information models and flexible support for multiple terminology resources were identified as key challenges for sharing decision logic across systems. In order to share computable clinical knowledge and enable intelligent cooperation in distributed environments, a common language for specifying expressions and criteria is inevitable. Over the years, some standards and norms have implemented their own languages and specifications for the representation of knowledge, both in the health area and in other areas of application. Following the need to extract and represent knowledge in a standardised way, these languages focus on representing domain knowledge and processing rules, combined with guidelines or another type of process. Therefore, this subsection aims to explore some existing standardised decision languages.

3.4.2.1 Arden Syntax

To address the challenges of sharing a knowledge base of rules in healthcare environments, particularly considering issues such as time, experience and data availability, the Arden Syntax was proposed as a solution (Hripcsak et al., 2018). The goal was to establish a common structure to represent medical knowledge that could be shared across different institutions and clinical settings.

One of the key findings was that each hospital or clinical setting could not afford to develop its own knowledge base from scratch. Instead, it was proposed that medical knowledge be made available to the public, similar to the information contained in medical books. This approach would allow individuals or stakeholders to validate and use shared knowledge according to their specific needs, rather than being tied to the IS themselves (Hripcsak et al., 2018).

Therefore, Arden Syntax emerged as a standardised language, initially developed by the American Society for Testing and Materials, later adopted by Health Level Seven International (HL7) in 1992. The language was designed as a modular and independent solution for representing, processing, and sharing clinical knowledge between different health institutions, ensuring readability, unambiguity, ease of writing, and executability. The language architecture revolves around Medical Logic Modules (MLM), which allow to organise decisions in a logical format. Using a logical coding structure, MLM represent medical knowledge independently, comprising four categories: Maintenance, Library, Knowledge, and Resource, as shown in Figure 11.

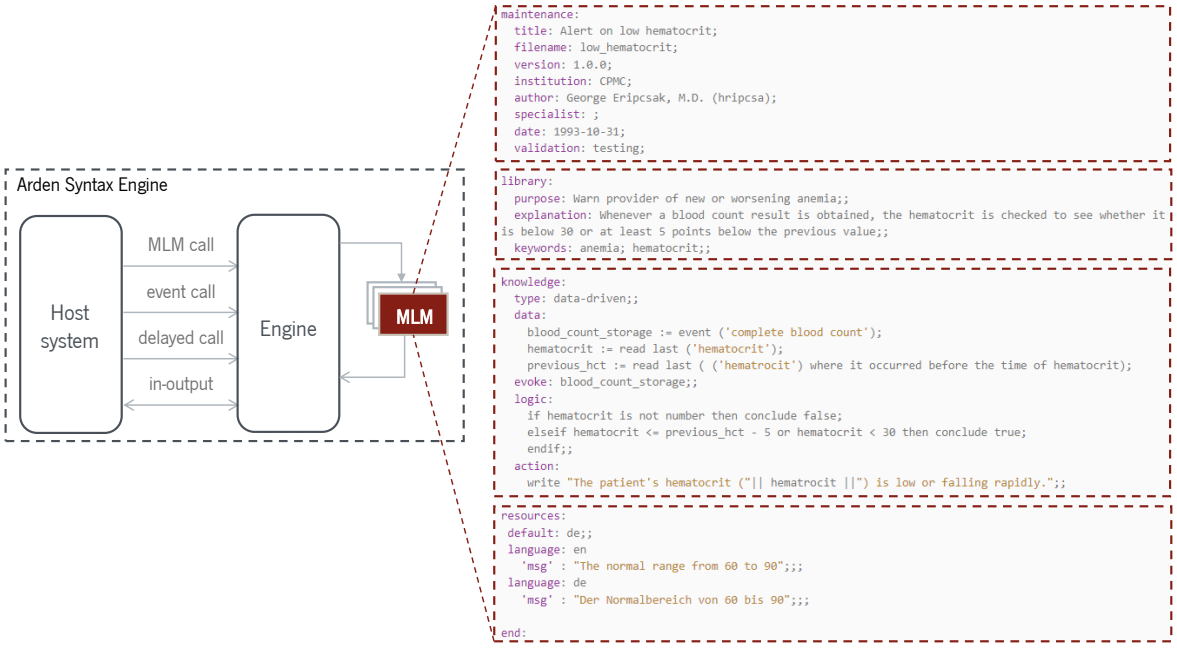


Figure 11: Arden Syntax engine and MLM structure (adapted from (Samwald et al., 2012)).

Each category begins with its name, followed directly by a colon (e.g.: maintenance:). Both the four categories and the set of slots within each category must appear in the correct order (Jenders et al., 2019). Initially, the maintenance category contains information unrelated to MLM health knowledge and

is used to describe and manage the MLM. The library category offers explanatory information, such as the purpose of creating the module, or referencing related literature. The knowledge category defines the action of the MLM, the data access and logic, where rules are represented from a combination of logical 'IF-THEN-ELSE' instructions, similar to programming languages (S. Silva et al., 2022). These rules define conditions under which certain actions or recommendations should be triggered based on patient data. Finally, the resource category specifies textual language or terminological resources that can be used within the knowledge category (Jenders et al., 2019).

Overall, MLM enable the separation of clinical knowledge from technical code, allowing the definition of variables, conditions, connections to external data sources, and mapping clauses (B. Silva et al., 2024). Furthermore, another requirement for the construction of the Arden language was the easy understanding by doctors of the logic embedded in the syntax (Hripcsak et al., 2018). Through this structure, Arden Syntax ensures that the clinical knowledge represented in MLM can interact with heterogeneous systems in order to facilitate the management and updating of the knowledge base independently.

Arden Syntax has evolved to support advanced applications such as clinical alerts, interpretations, diagnoses, and quality assurance functions globally. Its latest version integrates fuzzy logic for production rule representation, aligning with HL7's reference information model (B. Silva et al., 2024). Since then, this standardisation has facilitated the integration of CDS into EHR systems, contributing to improved patient care and outcomes.

3.4.2.2 Guideline Interchange Format

Guideline Interchange Format (GLIF) is a structured language developed by InterMed Collaboratory, aiming to facilitate the sharing, manipulation, and analysis of clinical guidelines independent of platforms and systems. In 2004, a latest version, GLIF3, was published, which enabled the modelling and representation of clinical guidelines in a structured format. GLIF3 is based on an object-oriented logical model of concepts and has an XML-based syntax (Ohno-Machado et al., 1998). To model clinical guidelines, GLIF3 follows a structure based on classes, attributes and relationships. It employs a flowchart structure, with guidelines represented as sets of sequenced nodes called guideline steps (Peleg et al., 2004). Thus, Figure 12 demonstrates the GLIF classes, attributes, and syntax.

Different classes of guideline steps are used for modelling different constructs, composing the Guideline Model Entity (Peleg et al., 2004). The *Decision_Step* class represents decision points in the guideline, providing the ability to represent different decision models. The *Action_Step* class is used for modelling actions to be performed, as tasks for example. The *Branch_Step* and *Synchronisation_Step* allow modelling of multiple simultaneous paths through the guideline. *Patient_State_Steps* serve as entry points into the guideline labeling patient states each falling into one of five classes: Decision, Patient State, Ramifications, Synchronisations, and Actions.

Overall, GLIF3 introduces improvements as enhanced flow control, object-oriented expressions, and query languages (S. Silva et al., 2022). It integrates seamlessly with HIS through a layered model, allowing

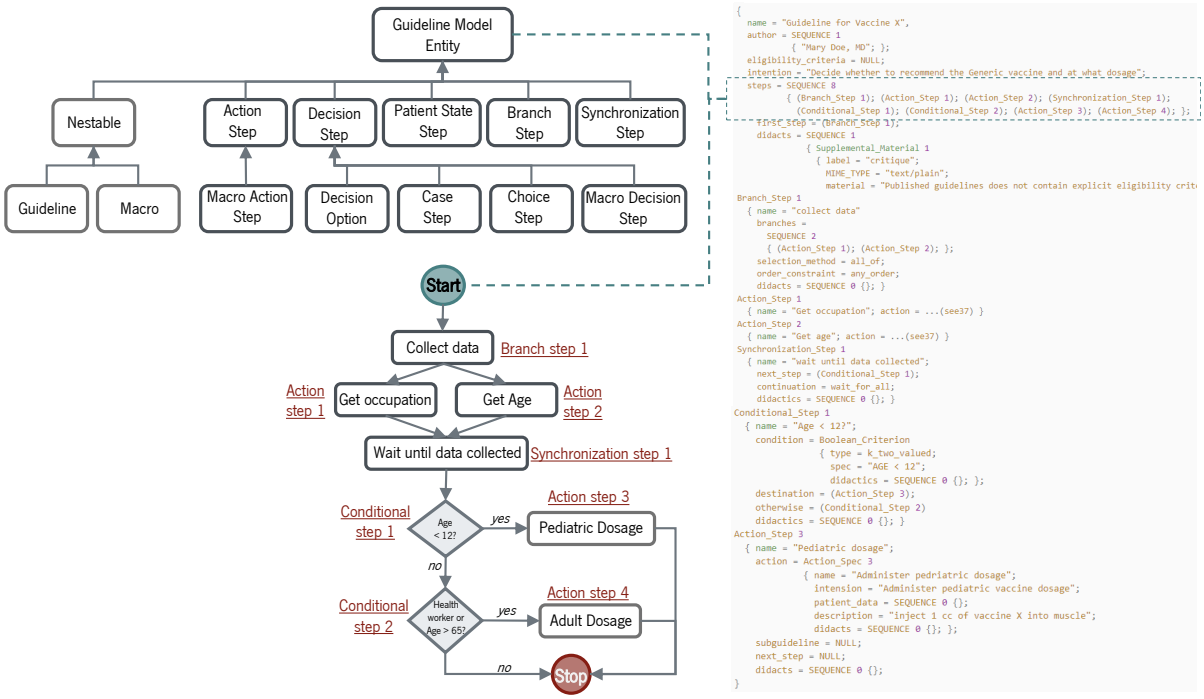


Figure 12: GLIF model and syntax (adapted from (Peleg et al., 2004))

for clearer visualisation of patient data and clinical knowledge during guideline processing. In addition, the GLIF specification incorporates a language that roots in the logical expression grammar of Arden Syntax (Ohno-Machado et al., 1998). Open standards, including HL7, are leveraged for terminology integration and syntax development.

3.4.2.3 Decision Model and Notation

The Decision Model and Notation (DMN) is a standard published by the Object Management Group (OMG) in 2015, aiming to describe and model repeatable decisions, ensuring that decision models are interchangeable between organisations. Overall, DMN provides necessary constructs for modelling decisions so that organisational decision-making can be readily represented in diagrams, accurately defined by business analysts, and possibly automated. The DMN is marked by its discerning use, being able to model human decision-making, the requirements for automated decision-making, and to implement automated decision-making (OMG, 2019).

Typically, standardised decision-making modelling requires a component that defines the specific logic of a decision to allow validation or automation. DMN was designed to be integrated with the Business Process Model (BPM) to support the coordination of decision points within business processes. Thus, Figure 13 represents the integration of the DMN standard with the BPM.

In summary, the BPM is responsible to define tasks within business processes, while the DMN defines the logic of a specific decision. Communication between BPM and DMN is carried out through the *Decide Routing* task, where the decision service is called executing the decision modelled within the DMN Routing.

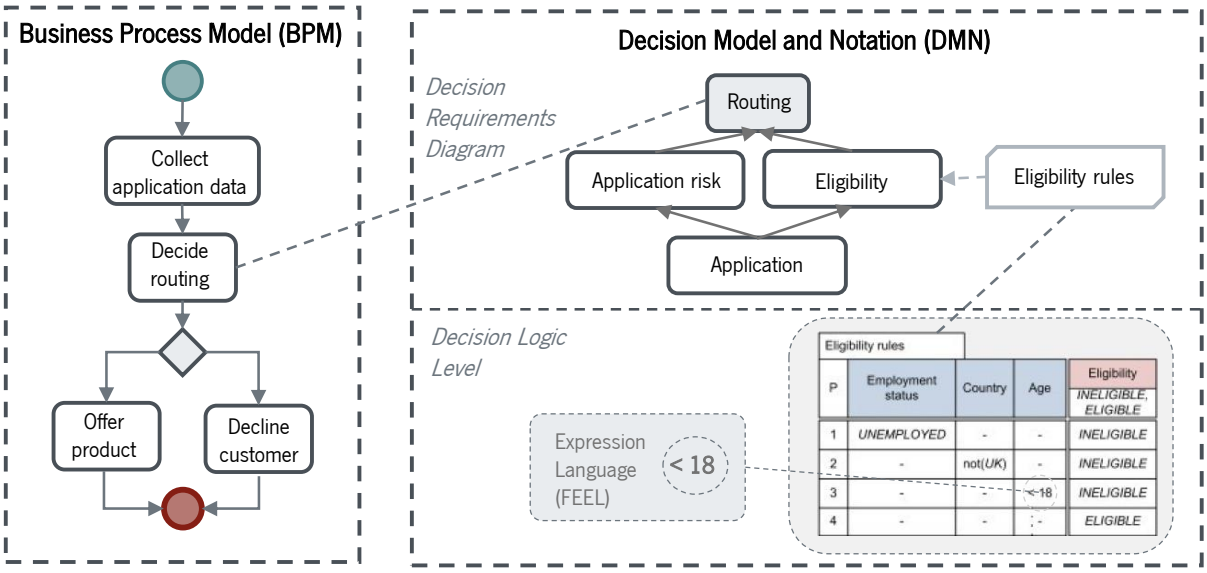


Figure 13: DMN representation (adapted from (OMG, 2019)).

Thus, DMN contemplates two components, the Decision Requirements Diagram and the Decision Logic Level. In order to form a bridge between business process models and decision logic models, the Decision Requirements Diagram is formulated to define the decisions that will be executable in the tasks. It models requirements composed of a set of elements and connection rules that constitute the respective decision (Biard et al., 2015). The Decision Logic Level provides the criteria associated with the rule conditions, identifying the input and output variables, the operators and the values, expressed in the FEEL language. In DMN, the decision logic can be represented by different models, such as business rules, decision tables, calculations, or executable analytical models (OMG, 2019).

In the DMN specification, a decision is defined as the act of determining an output value (the chosen option), from a series of input values, using logic that defines how the output is determined from the inputs (Biard et al., 2015; OMG, 2019). In this sense, the modelling of decision requirements will be based on: input data as instances of all input data required by decisions; input decisions as instances of the results of all input decisions; and output decisions as the results of evaluating all output decisions using the input decisions and the input data provided. In addition, the eligibility rules component represents the knowledge source that denotes an authority for a business knowledge model or decision.

3.4.2.4 Guideline Definition Language

Integrated into the CDS component of the openEHR specifications, the Guideline Definition Language (GDL) appears in 2015 as a language that represents clinical guidelines in a standardised way (R. Chen & Beale, 2019). The purpose of the GDL is to express decision logic as production rules. These can be combined as building blocks to support single decision-making and more complex chained decision-making processes. The GDL can be used to represent a variety of use cases, such as prompts, alerts, and reminders, detailed order sets, algorithm-based calculators, or generating and updating personalised

care plans. Therefore, GDL aims to represent a guideline in a document structure, in which it utilises reserved words that constitute its composition. GDL guidelines can be expressed in openEHR Object Data Instance Notation (ODIN) or JavaScript Object Notation (JSON) formats. Figure 14 demonstrates the GDL architecture and its structure, using the ODIN language.

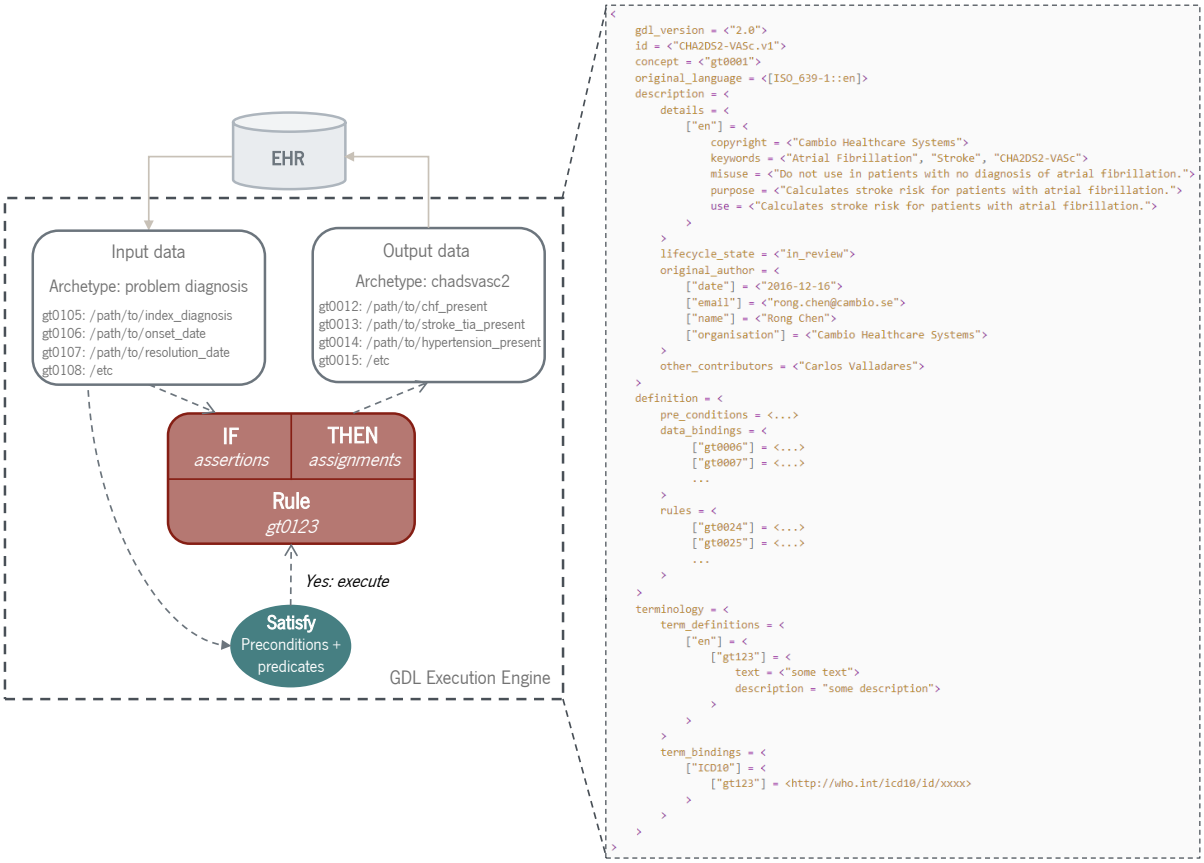


Figure 14: GDL architecture and language structure (adapted from (R. Chen and Beale, 2019))

The GDL execution engine is prepared to process rules following what is defined in the guideline syntax. The core rules engine follows a logic containing 'IF-THEN' statements, augmented by rule execution filters comprising preconditions and predicates (R. Chen & Beale, 2019). These filters determine the rules that will be executed according to a condition evaluation, where if all criteria are met, the corresponding actions will be performed. Additionally, input and output data are mapped by binding data to EHR systems or repositories.

Following the GDL structure, several key components are encompassed. Firstly, the guideline is identified considering its id, concept, language and version. Secondly, the description element includes some details about the creation of the guideline, as authorship details, keywords, state, and the guideline's purpose, use, and misuse. Subsequently, the definition section contains logical pre-conditions that must be validated before executing the guideline's rules. The predicates within pre-conditions can be defined in the data_bindings, responsible to link data elements from a source dataset to variables (possibly archetypes) via 'gt-codes' (R. Chen & Beale, 2019). Furthermore, rules are also defined in the definitions,

where utilises locally defined variables to express clinical logic. Each rule, identified by a local gt-code, is indexed with a natural language-dependent name and description. Rules may have assigned priorities to determine execution order.

Finally, the terminology element binds terms to user interface labels and descriptions in supported languages. Locally defined terms may also be bound to concepts or refsets in external reference terminologies, such as ICD10 codes. Regarding the clinical information model, GDL express decision logic using clinical standards as openEHR archetypes or HL7 FHIR resources, ensuring compatibility with common data types inherent in these standards (Bruin et al., 2020). Besides, metadata and rule expressions can be authored in any natural language, ensuring independence from specific languages.

Overall, GDL allows for chaining multiple guidelines to support complex decision-making processes, possibly being reused across various contexts, enhancing versality and efficiency (Bruin et al., 2020). The GDL currently exists in two versions, with the latest being GDL2. This new version introduces several changes compared to the original, including independent data binding for EHR data models, model definition for output objects using templates with model-level variables, and enhanced support for mathematical functions (R. Chen & Beale, 2019).

3.4.2.5 Decision Language

With the aim of providing a standardised language oriented to care processes, the Decision Language (DL) appears integrated into the Process and Clinical Decision Support (PROC) component of the openEHR specifications (Beale, 2021). DL emerged at the beginning of 2021, through a need to associate standardised decision languages with workflows, which was not contained in GDL architecture. Thus, DL remains in delineate a formal model to facilitate the encoding of decision logic present in various process-centric clinical contexts such as plans and guidelines.

Computer-interpretable guidelines serve as the primary computable artifacts for developing automated clinical plans, consisting of a plan component and a decision logic component. DL specifications contemplate this formalism, taking into account a task plan to outline structured tasks, and decision logic, comprising rules that determine decision values and declarations of subject variables (Beale, 2021). Thus, Figure 15 presents the DL conceptual architecture and its language structure.

In the DL conceptual architecture, plans are formally defined in the openEHR Task Planning (TP) specifications (Beale, 2017), where tasks are defined based on workflow modelling using the Task Plan Visual Modelling Language (TP-VML) (Beale, 2019b). When there is a decision point or a decision group in the modelled plan, the decision logic component is evoked. In DL specifications, the logic is expressed through a Decision Logic Module (DLM), consisting in several key elements as reference data, input variables, conditions, rules, and outputs. These elements are necessary for logical decision-making through the adaptable utilisation of a singular type of multi-section module, ensuring comprehensive coverage of decision logic components.

In addition to facilitating logical decision-making guided by work plans, the conceptual architecture

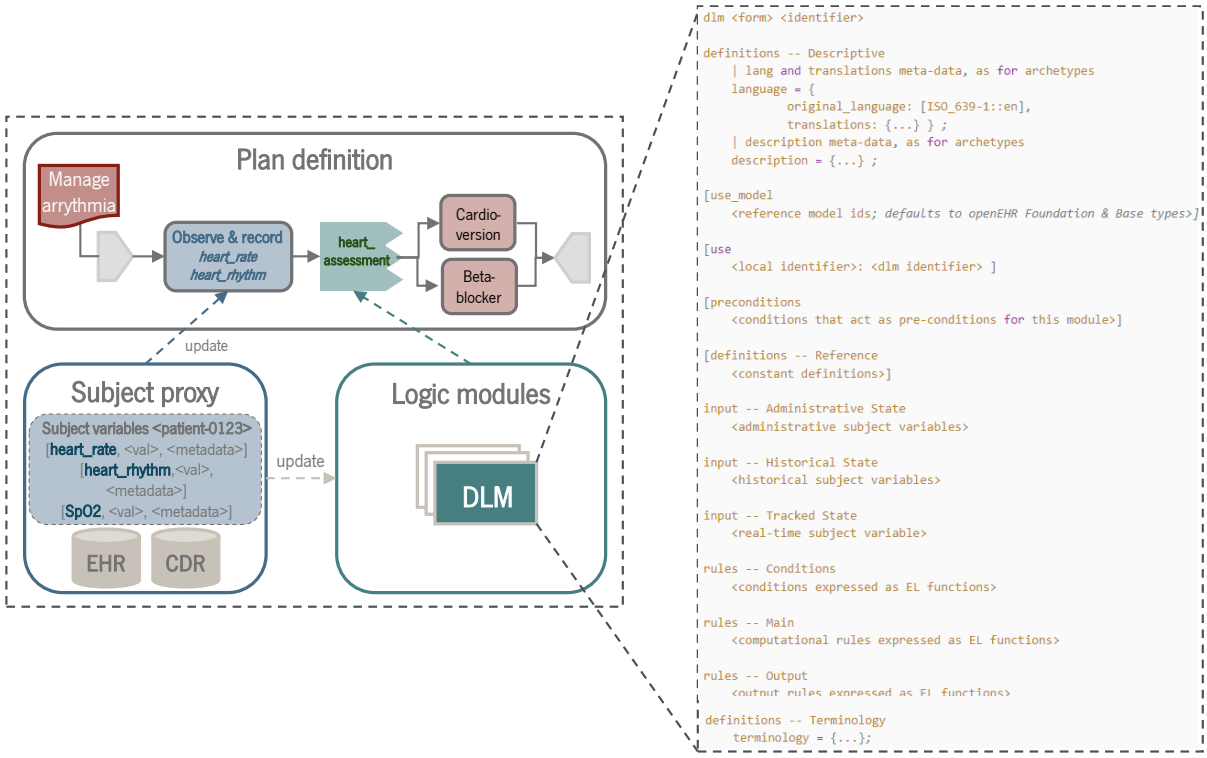


Figure 15: DL architecture and syntax structure (adapted from (Beale, 2021)).

of DL also incorporates Subject Data Proxy (SPO), which formulates variables related to states or events. Although not directly related to logical decisions, SPO enriches the decision-making process by providing essential context and information (Beale, 2017; Beale, 2021). In essence, the set of subject variables relevant to a plan or DLM is referred to as a subject proxy, representing a partial view of a real-life subject. These proxies are linked to the plan definition and DLM during application execution. A subject proxy service stores variables needed for plan execution and logic modules, and manages these proxies, retrieving data from back-end systems and other sources to keep it updated.

Therefore, a DLM incorporates a multisectional structure that offers a high-level syntax (Beale, 2021). Some sections are optional and are only used for specific contexts or formats. First, the DLM is identified by its name and version. Next, the *description* section appears as the first mandatory section, responsible for describing the DLM's referential data, such as language, purpose, authors, etc. The *use_model* and *use* sections are optional and are applied to use openEHR informational RM or to use other DLM, respectively. The *precondition* section is also optional and it defines the conditions that must be valid before the DLM rules are executed. In the optional *reference* section, constant definitions are identified, such as variables declared with fixed values.

Moving to the mandatory sections, the *input* variables represent external data entities belonging to the subject (for example, patient), which can be administrative, historical or tracked. The *rule* section incorporates conditions such as domain-specific criteria that produce Boolean results, main rules that are domain-governed structures based on condition/action paradigms capable of returning various types of

data, and outputs, which are the computed results derived from rule invocations. Furthermore, rules can function as rulesets, interrelating rules and manifesting them in different formats. Finally, the terminology section aims to provide multilingual codes to define the language and terms used in the DLM.

All symbolic constituents, encompassing constants, variables, and rules, may be treated as codes for which a translation terminology is provided, enabling a DLM to undergo translation and presentation in any natural language (Beale, 2021). In addition, knowledge can be expressed trough different representations, as rules, conditions, decision tables and scores. These functions play a crucial role in translating clinical rules into an intuitive format, making them easily understandable for healthcare professionals. The fact that DL focuses on functions enhances its usefulness in supporting clinical decisions in EHR systems. Overall, DL represents a significant advancement in supporting clinical decision-making within openEHR systems, offering a standardised and intuitive approach to encoding decision logic and facilitating effective utilisation of clinical guidelines and rules.

3.4.2.6 Overview

In knowledge-based CDSS, clinical knowledge is extracted from various sources and is converted using languages for KR. The effectiveness of CDSS is significantly influenced by the richness and versatility of this KR, dictating the breadth and depth of logic, concepts and rules it can express (Bruin et al., 2020).

To facilitate the representation of decision logic in a structured and standardised format, several standards have developed specialised languages for this purpose. In this present section, some of these languages have been described, including Arden Syntax, GLIF, DMN, GDL, and DL. Considering the good performance of a decision language, there are several aspects to consider that contribute to its characterisation. Based on the described purpose of each language through the literature review, a set of features were selected that outline the competence of these standardised languages:

- **F1 - Syntax definition language:** Allows the modelling of computerised guidelines following a standard structure. This structure must enable the expressiveness of decision logic using domain-specific concepts and their relationships (Lu et al., 2018). Decision variables and logical operators must also be considered. Priority functions can be used to define the order in which rules are executed.

- **F2 - Available interface or model:** - This functionality corresponds to the decision language already having an interface, editor or executable model available. It necessitates a tool capable of executing or creating the decision structure proposed by the standard, enabling its use for general users or context-oriented users.

- **F3 - Workflow integration:** This feature allows the integration of decision logic oriented towards work tasks. When modelling the workflow, decision points will be defined and connected to the respective decision model, enabling tasks to be automated and processes to be better coordinated.

- **F4 - Integration with other standards:** Allow integration and interoperation with other languages or standardised models.
- **F5 - Human-readable language:** In order to represent clinical knowledge in a clear and relevant way, it is important that its representation is interpretable not only by machines, but also by humans. This functionality, applied to decision languages, ensures that the modelling of decision logic is easily carried out by non-expert users. This is one of the key features of decision logic modelling, as it promotes flexibility and non-dependence on the coding of an EHR or HIS system.
- **F6 - Complex logical representation:** Decision logic is usually represented by conditional statements ('IF-THEN'). However, to promote a more comprehensive logic, different KR techniques can be adopted (e.g.: fuzzy logic, decision tables, among others).

In order to highlight the features integrated in each language described so far, Table 1 presents a mapping of this languages with the identified functionalities. The mapping was conducted by analysing the description of each language based on the literature review. In general, the inclusion of all functionalities in a decision language allows for a comprehensive, multidisciplinary, complex, scalable and flexible representation of CDSS, making it possible to process universal logic.

Table 1: Mapping of functionalities for the revised decision languages.

Standardised language	F1	F2	F3	F4	F5	F6
Arden Syntax	X		X	X	X	
GLIF	X	X		X		X
DMN	X	X	X		X	X
GDL	X	X		X	X	
DL	X		X	X	X	X

During the mapping process, a commonality was noted among all the languages, as they all provide a standardised language accompanied by its own syntax and structure (F1). On the other hand, differences were noted for the other features. In the case of F2, as far as it was possible to find, only GDL, GLIF and DMN have editing interface or executable engines available for use. Some interfaces are published by the standard itself, others have been developed by external entities. Despite this situation was not evident for Arden Syntax, this language has a freely available knowledge base. With regard the functionality F3, the Arden, GLIF and DL languages allow integration with workflows. Although Arden Syntax does not have a workflow integration provided for in the standard itself, it is possible to integrate it into other workflows services (e.g. BPM) (Jenders et al., 2019). In order to complement its purpose, all the languages allow integration with other standards (F4), with the exception of DMN, which was designed to be integrated directly with the BPM model.

Functionality F5 entails the representation of clinical concepts in variables, rules, or conditions, facilitating human interpretation. Within the specifications, both DL and GLIF languages explicitly express this objective. Even though not explicitly stated in the specifications, GDL achieves this functionality through its terminology component, enabling users to verify the meaning and description of concepts using assigned codes. Similarly, modelling rules with DMN ensures ease of interpretation of concepts. Arden Syntax also allows users to define easily interpretable concepts in the knowledge category, in spite of not mentioned in the specifications. Regarding to express decision logic in different formats, not all models encompass this functionality (F6). Arden Syntax, GLIF, and GDL predominantly incorporate conditional logic, including Boolean expressions, 'IF-THEN' statements or fuzzy logic. Conversely, both DMN and DL extend beyond these representations by integrating decision tables and scores.

Concerning to the performance of Arden Syntax, a current problem is known as the "curly braces problem" (Samwald et al., 2012). This issue corresponds to the ability to make the decision support layer to communicate with the EHR system. Due to the heterogeneity of EHR, a reference to the keys used in Arden Syntax is required to refer to external data entities. This problem goes beyond semantic interoperability, but rather a question of transforming epistemic data into ontic entities that reflect reality in real time (Beale, 2020). DL aims to solve this problem by integrating with the SPO, and is thus a conceptual solution to the curly braces problem (Beale, 2020).

Furthermore, some studies have pointed out some differences between certain languages. In particular, Bruin et al. (2020) has carried out a study to compare Arden Syntax and GDL, highlighting their differences in terms of expressiveness and syntax. The authors stated that Arden syntax was designed focusing on readability, resembling that of functional and object-orientated programming languages, and based on natural languages, which makes it readable for both technical and non-technical users (Bruin et al., 2020). In addition, the Arden Syntax offers a wider and more diverse range of operators, including boolean and fuzzy logic, totalling 176 operators. On the other hand, GDL is designed to be agnostic towards natural languages and its syntax resembles that of markup languages such as XML. It is more rigid compared to the Arden Syntax and defines a total of 28 operators in its specification.

Notwithstanding, Peleg et al. (2001) conducted a study to point out differences between Arden Syntax and GLIF. The authors affirmed that Arden Syntax and GLIF may play complementary roles in representing clinical knowledge for decision support. Arden Syntax is suitable for representing individual decision rules in self-contained MLM, which are typically implemented as alerts or reminders triggered by clinical events. On the contrary, GLIF is designed to encode complex guidelines that unfold over time. GLIF has mechanisms to manage complexity and additional constructs that may be unnecessary for expressing simple alerts and reminders. While Arden Syntax is more suitable for representing individual decision rules, GLIF is more appropriate for encoding complex clinical guidelines (Peleg et al., 2001).

Compared to the languages developed from the same standard, the openEHR, the DL and GDL languages serve different purposes. Although GDL was created first and is in a stable state with many features included, there are still gaps that need to be covered. DL has therefore been developed to replace GDL2 expressions and rules so that they can be serialised in a way that is readable by humans and not

just machines. Part of the idea of DL is to provide a clear, human-readable rule language, and to provide some more powerful representations than those of GDL, such as condition chaining, decision tables, and defining ranges and occurrences for variables. Also, GDL has no integration with workflows, it is focused on rules, data access and result generation, so it is a smaller and more integrated formalism, less flexible but easier to implement.

Overall, from the mapping shown in Table 1, it was possible to verify the completeness of each language, with DMN, GDL and DL being the most complete, failing to achieve one of the six functionalities identified. The limitations found for DMN are that it can not be integrated with other standards, since it was created to support business processes. In addition, this language was designed to support business rules, which makes it difficult to replicate in the complexity of the healthcare context. For GDL, the limitation is that it is not integrated with workflow modules, which prevents the automation of tasks in healthcare processes. DL lacks on having an engine or editing interface available, which is normal due to be recently created and its specifications are still under development, which could be an opportunity for research.

Part III

Contributions

4

Towards an Effective Clinical Decision Support System

Once the theoretical concepts involved in this work have been described, the contributions relevant to its practical application will be presented. This chapter reveals the results obtained from a systematic review of the literature, which served as the basis for formalising a maturity model for effective CDSS.

4.1 Contextualisation

When evaluating an IS, effectiveness denotes the capability of a system to fulfil its designated purpose within a predefined interval and specified environmental conditions. Diverse terms are used to characterise system performance, necessitating precision to align measures with the system's objectives (Green, 2001). The assessment of system effectiveness is intricately linked to considerations of structure, measurement challenges, and the allocation of resources and values that form the basis for the system's evaluative criteria (Mitter, 2002).

In an organisation, the most common measures of performance are effectiveness and efficiency, where effectiveness is most often used to assess the achievement of defined objectives. Efficiency relates to the optimisation of resources to achieve the desired outcomes (Bartuseviciene & Sakalyte, 2013). Discrepancies arise in the valuation of organisations, with emphasis on indicators such as efficiency and effectiveness. While efficiency involves the cost-effectiveness of treatment to individuals or society, the most efficacious treatment may not align with the most cost-effective option. Despite managerial, supplier, and investor perspectives that might equate these terms, it is underscored that each term retains distinct meanings (Bartuseviciene & Sakalyte, 2013).

In a business context, effectiveness assesses the extent to which an organisation achieves its goals or aligns its outputs with the economic and social environment. This measurement determines the alignment of organisational activities with policy objectives or the realisation of the organisation's goals (Bartuseviciene & Sakalyte, 2013). Efficiency, on the other hand, quantifies the relationship between inputs and outputs, emphasising the successful transformation of inputs into outputs. Resource allocation across

alternative uses is pivotal in efficiency considerations, clarifying that operational excellence in the utilisation process does not inherently guarantee outstanding performance in the market (Bartuseviciene & Sakalyte, 2013).

IS effectiveness is a multifaceted construct that lacks a singular, comprehensive measure of success. Evaluating the effectiveness of an IS is considered partly contingent on its capacity to deliver high-quality service to its user base (Pitt et al., 1995). Numerous studies have attempted to identify factors contributing to IS effectiveness, exploring various metrics and scales for evaluating these factors. DeLone and McLean (1992) recognised the challenge in defining the dependent variable, the IS success, and proposed a model wherein systems quality and information quality independently and collectively influence use and user satisfaction. These, in turn, directly impact individual outcomes, subsequently contributing to organisational effectiveness. Notably, existing metrics appear predominantly product-oriented, with the service quality of the IS department, as perceived by users, emerging as an indicator of IS effectiveness. While models for IS and business exist, a comparable framework for CDSS is notably absent (Thong & Yap, 1996).

In IT management, maturity models have emerged as crucial instruments facilitating organisational positioning and informed decisions for change (Becker et al., 2009). Despite the proliferation of over a hundred maturity models to support IT management in recent years, the underlying procedures and methodologies leading to their development remain inadequately documented. The responsibility for designing and utilising IT effectively rests with the organisation's IT management. This requires a thorough understanding of which aspects to measure, how to measure them, and which benchmarks to use for evaluating the organisation's current state and determining a specific level of quality or maturity. Thus, maturity models aim to provide useful tools for addressing these complexities (Becker et al., 2009).

A maturity model, in essence, comprises a succession of levels delineating the evolution path of a specific class of objects (Becker et al., 2009). It embodies an envisaged, desired, or typical progression, represented as discrete stages, with each stage necessitating the fulfilment of defined criteria and characteristics. The analysis of the current state serves as the basis for deriving recommendations for improvement measures, prioritising them, and aiming for higher maturity levels. However, the proliferation of maturity models for similar applications raises questions about their usefulness in assessing organisational capabilities and formulating improvement strategies (Poeppelbuss et al., 2011).

Maturity, defined as an assessment of organisational capabilities within the framework of a specific discipline, is conceptualised through maturity models as normative reference frameworks that define logical and desired paths of evolution (Becker et al., 2009). In short, maturity models serve as tools for assessing the current state of the organisation, guiding the derivation, prioritisation and monitoring of improvement measures (Poeppelbuss et al., 2011).

4.2 Related work

According to Marley (2000), in healthcare, the efficacy of a procedure refers to the performance of a procedure under non-ideal and real-world circumstances. This is in contrast to controlled trials that can sometimes distort typical practices. Meanwhile, effectiveness is defined as the extent to which a procedure achieves its intended effect in routine clinical settings, as best assessed through observational studies (Marley, 2000). Some studies have looked at the effectiveness of CDSS, contextualising the relevant parameters in their implementation.

Although CDSS enhances processes establishing clinical effectiveness, further research is needed to guarantee proper application of guidelines and the realisation of improved clinical outcomes. Current studies on clinical outcomes and cost-effectiveness lag behind those focused on process outcomes, highlighting the necessity for long-term prospective cohort studies (Murphy, 2014). Such studies are crucial for gaining a comprehensive understanding of how CDSS impacts morbidity and mortality over time. Murphy (2014) states that optimising the integration of CDSS recommendations into healthcare providers' practices requires more trial. CDSS recommendations, often derived from evidence-based practice guidelines, face challenges in provider buy-in. Improving ease of use, integration into workflow and continuous knowledge updates are proposed strategies for advancing evidence-based medicine through CDSS. The review analysis conducted by Murphy (2014) indicates greater adherence to CDSS recommendations when counselling is provided to both providers and patients. Patient-orientated CDSS is suggested as a potential frontier for improving the quality of healthcare, underlining the need for further exploration in this direction.

The recent developed study from Sutton et al. (2020) showed an overview of the state of the art in the use of CDSS. In a broad view, a set of functions and benefits regarding CDSS usage were identified, as well as potential problems. It was showed that CDSS assist healthcare professionals for different tasks and patient care decisions. However, CDSS support has proved to be limited, and there is still an incessant search for advances in interoperability, implementation efficiency, and user accessibility. Negative impact on the usability of the system can lead to over-dependence on it, so the system's impact should be continually evaluated. Besides, the authors also highlighted the difficulty of maintaining the knowledge rules that feed the CDSS up to date. To this end, a possible solution is to implement a knowledge management service and a performance measurement and analysis system for CDSS (Sutton et al., 2020).

Sarkar and Samal (2020) state that EHR incorporated into CDSS have proven to improve care processes. However, CDSS still present challenges that hinder their effectiveness. Data heterogeneity, usability issues, and widespread dissatisfaction with EHR mark daily problems in the use of CDSS. The adoption of these systems also show limitations in the software architecture for representing EHR, as well as the need for specific assessments of contextual implementation. The lack of interoperability between different EHR systems is a major challenge, as is the need for a multidisciplinary and collaborative approach to the design and implementation of CDSS. To overcome these challenges, Sarkar and Samal

(2020) recommend sharing CDS approaches that can be integrated and interoperable with any EHR or HIS system, to provide a viable and usable system. The design of the CDSS should be articulated with workflow processes, occurring alongside with the cognitive behaviour of healthcare professionals.

In order to evaluate the effectiveness of CDSS, many studies assess the systems applied to a specific context, among them, Sunjaya et al. (2022) reveal a systematic review developed to assess the impact of CDSS in managing breathlessness disease. The review presents contradictory results on the effectiveness of CDSS for breathlessness in primary care and outpatient services. Disease-centred CDSS, have demonstrated better compliance with guidelines and clinical benefits. However, although CDSS for breathlessness in the emergency department showed positive results, overall healthcare utilisation did not differ significantly. In terms of healthcare providers' response, satisfaction and improved knowledge were observed after intervention with CDSS, but low adherence (<50%) suggested that some CDSS may not be well received or easy to use. Factors that influence these results may include trust in the evidence, presentation of recommendations and adherence to guidelines. Health system-wide factors, including time constraints, had an impact on the success of CDSS, as some analysed studies indicated potential time savings, while others reported longer visits, possibly influenced by a lack of familiarity with the CDSS. Despite this, the benefits of CDSS in improving clinical outcomes and health service utilisation are emphasised in the study conducted by Sunjaya et al. (2022). In summary, the authors recommend that future studies focus on rigorous clinical parameters, integration with evolving modes of healthcare delivery and addressing barriers to CDSS implementation, while ensuring that algorithms align with the needs of clinical practice (Sunjaya et al., 2022).

Constructing, implementing and maintaining CDSS requires careful attention and thoughtful design to mitigate these risks, using evidence-based strategies to ensure their effectiveness and safety (Sutton et al., 2020). To conclude, CDSS continues to evolve and require ongoing research to understand both their limitations and opportunities to improve patient care. Achieving effectiveness in CDSS implementation hinges on a comprehensive, patient-centered approach, underlining the vital role of patient involvement in improving the quality of care through CDSS usage.

4.3 Systematic literature review

Previous Systematic Literature Review (SLR) have addressed the performance of CDSS to evaluate their use and effectiveness. However, most of these studies are developed based on a specific context or purpose. To fulfil the objectives outlined for this doctoral work, a SLR was developed to formulate the problem faced and outline the research gap.

4.3.1 Background

According to Handler et al. (2016), a HIS should provide a comprehensive view of clinical records during patient encounters, encompassing evidence-based decision support, quality management, results

reporting, and support for various care-related activities. Consequently, a decision support component is required to guide clinical processes, whether standalone or integrated into a HIS (Handler et al., 2016).

Decision support activities help users achieve specific objectives. In the clinical information area, this support is formalised by a CDSS that employs models and techniques through a KR infrastructure. As a result, a DSS serves as a system dedicated to helping professionals acquire knowledge and make decisions in a specific domain, thus mitigating uncertainties in the decision-making process. Overall, CDSS provide the information and knowledge needed to simplify the daily tasks of healthcare providers and improve the quality of services.

Improving the quality of care is one of the most promising anticipated outcomes that encourages the adoption of CDSS. Despite the evident benefits of adopting a CDSS, the literature review has shown limitations in its implementation. Purcell (2005) states that implementing an effective CDSS is an arduous and slow task involving different purposes, technologies, and organisations. The effectiveness of CDSS is multifaceted, depending on delivering high-quality service, with factors such as information and system quality that influence patient satisfaction (Sunjaya et al., 2022). Previous studies on CDSS demonstrate improvement in preventive services, appropriate care, and clinical and cost outcomes. However, increasing provider adherence to CDSS recommendations is crucial for optimising its effectiveness, with ongoing research into the factors that influence adherence. Although evidence exists supporting the effectiveness of CDSS, certain studies have shown limited improvements in process outcomes, indicating variability in effectiveness across different contexts (Murphy, 2014).

To further investigate the state of the CDSS developed in literature, a SLR was conducted. The proposed objective was to analyse a set of articles that address a CDSS, to identify trends in the characteristics of its design. In addition, the level of maturity of the systems reviewed was also observed, to provide an analysis of their effectiveness. In this sense, for this SLR two Research Question (RQ) were formulated:

- **RQ1:** What are the most common trend characteristics in a CDSS?
- **RQ2:** What is the maturity level of the CDSS based on the decision-making theory proposed by Simon?

In summary, RQ1 aims to analyse the characteristics of the CDSS developed, covering aspects such as the purpose of care, the recipient of the intervention, technological functions, among others. RQ2 aims to characterise the CDSS reviewed in terms of their effectiveness, verifying their level of maturity using a proposed model.

4.3.2 Methods

This SLR was conducted based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statements (Moher et al., 2009), followed by a checklist and a flow diagram (Hak et al., 2022).

4.3.2.1 Information sources

Five online data sources were selected based on their relevance to this work. Firstly, a search was carried out on Scimago comprising two areas of study: IS and multidisciplinary. From there, journals with a Q1 quartile in the last 5 years and an impact factor of over 150 were analysed. Journals were selected that had the potential to have articles more closely related to the aim of this study and that were already known to the authors, such as: Decision Support Systems, Nature Research Journal and Plos One. To complement the study, two public repositories were chosen: the PubMed library (medline) and the electronic library of the Association of Information Systems (AIS). Table 2 provides information on the types of data sources selected.

Table 2: Information about the selected data sources (source: Scimago Journal and Country Rank via www.scimagojr.com, accessed on May 13, 2022).

Data Source	Publication Type	Subject Area	Quartile	H-Index
AIS e-library	Repository	IS	-	-
DSS	Journal	IS	Q1	161
Nature	Journal	Multidisciplinary	Q1	1276
Plos One	Journal	Multidisciplinary	Q1	367
PubMed	Repository	Biomedical	-	-

4.3.2.2 Eligibility criteria and search strategy

When it comes to developing a SLR, selecting the right studies is crucial. Thus, it was necessary to define specific eligibility criteria to ensure that only the most relevant and informative studies were selected. The eligibility criteria defined were: (i) published studies in article format; (ii) open access or free full text; (iii) written in English; (iv) articles addressing a DSS in healthcare; (v) computerised or electronic CDSS.

To meet these criteria, search filters were applied. The articles to be selected needed to address practical cases of a specific CDSS, hence excluding literature review articles or those not focusing on a particular CDSS. The search strategy involved sorting publications from the most recent to the oldest, within the time frame of January 1, 2000, to December 31, 2020.

To identify studies falling within the desired scope, query terms were utilised encompassing variations of "Clinical Decision Support System" or "Decision Support System in Healthcare" terms. The primary analysis strategy involved scrutinising the title, abstract, and keywords of each scientific publication. In cases where these aspects fell short, a complete reading of the entire article was made to ensure they met the inclusion criteria.

4.3.2.3 Data extraction and management

During the screening process, each publication in the search results underwent independent evaluation, involving a thorough examination of titles, abstracts, and keywords. If the initial criteria were met, the full text was then carefully reviewed. In instances where there was disagreement or uncertainty, the supervising reviewer intervened to provide guidance and contribute to the discussion. Once eligible articles were identified, data extraction focused on four key aspects of CDSS, grouping it in:

- **Knowledge management:** This group focuses on how information and expert knowledge are organised, stored and used in a CDSS. It covers techniques for representing and managing clinical knowledge, such as algorithms, rules or ontologies, and how this knowledge is represented to aid decision-making processes.
- **Technological features:** This category explores the diverse range of technologies features incorporated within a CDSS to support its functionality. These features can have different purposes and can work together to deliver decision support capabilities.
- **Type of system:** The type of system refers to the architecture or overall design of the CDSS, which can vary depending on the intended purpose and functionality. The CDSS can have a user interface or be a specific decision model or component.
- **System integration:** This group refers to the integration approach of the CDSS, possibly being a standalone or autonomous system, or integrated into an existing HIS.

These category groups were deemed most pertinent for this SLR objectives. Additionally, relevant information such as clinical setting, study design, recipient of intervention, and care purpose was extracted. Textual analysis of the articles and keyword searches facilitated this data extraction process. To ensure organised management and facilitate analysis, the extracted data were systematically recorded on an appropriate spreadsheet.

4.3.2.4 Quality assessment and data synthesis

In conducting this SLR, the primary focus was on identifying the evolving trends within CDSS, particularly in terms of their KR, technological attributes, system type, and system integration. Thus, all the reviewed studies contemplate a CDSS designed for a specific purpose. Adherence to robust reporting standards was ensured by following the PRISMA checklist. Eligible publications underwent meticulous assessment for methodological quality, compliance with inclusion criteria, risk of bias, assumptions, and the clarity of evidence-based findings. However, no specific methodological assessment tool was applied.

Following the five primary data sources, it was curated a set of publications within the scope of CDSS, guided by predefined search strategies and inclusion criteria. The findings, presented through tables and narrative summaries, provide insights into the varied CDSS showcased in the reviewed literature, aiming to

delineate overarching trends. Through a comprehensive evaluation of pooled data from matching results, accounting for the total number of studies and their likelihood of occurrence, instances were observed of both clinical and statistical heterogeneity among the studies.

4.3.3 Results

By adhering to the defined methodology, the results obtained have been analysed in detail and will be presented in this section.

4.3.3.1 Study selection

Following the guidelines outlined in the PRISMA statements (Moher et al., 2009), the study selection process was carefully executed, guided by a flow diagram illustrated in Figure 16.

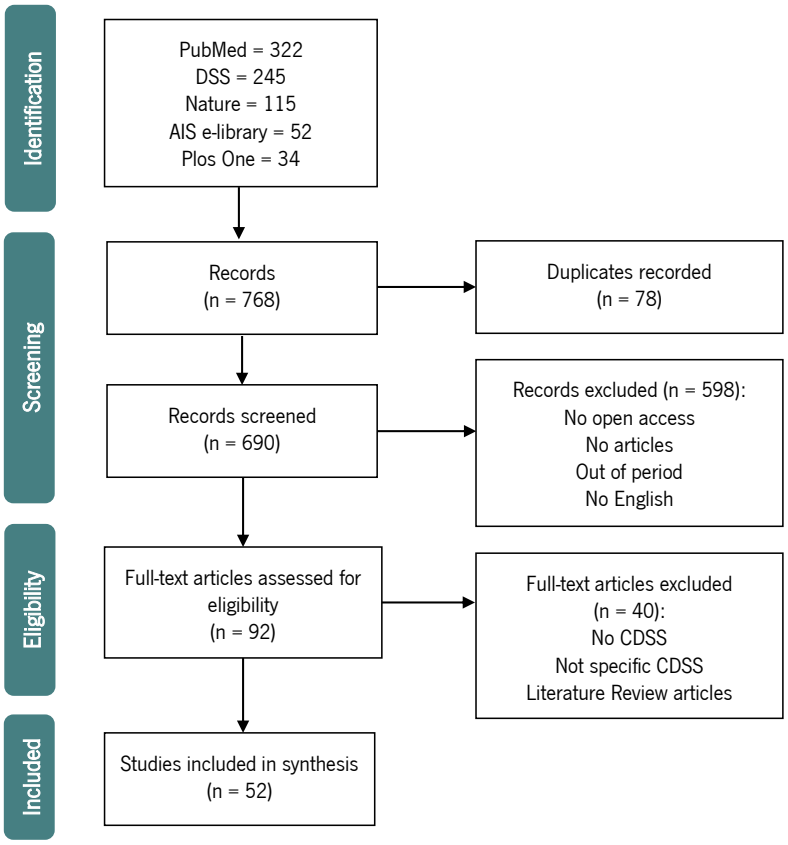


Figure 16: Flow diagram developed in the SLR study (adapted from (Hak et al., 2022)).

The search was based on five data sources, identifying a total of 768 records pertinent to this study focus. After removing duplicate entries, 690 unique records were screened, where titles, abstracts and keywords were reviewed. Lastly, articles failing to meet predefined selection and search criteria were excluded, comprising: non-article format; unpublished articles; not in English; out of period; not open access. The selected studies that passed the initial selection stage were subjected to full-text reading

to determine their final eligibility. Ultimately, 52 articles were deemed suitable for inclusion in this SLR, aligning with the research objectives by addressing specific CDSS.

4.3.3.2 Study characteristics

Studies meeting the inclusion criteria were characterised according to a set of attributes. The period under consideration covers from 2000 to 2020, with 50% from 2020, giving priority to the most recent ones. The studies were searched in the five chosen data sources, with eighteen studies from PubMed (34.62%), eleven studies from Decision Support Systems journal (21.15%), ten studies from PlosOne (19,23%), and five studies from Nature (9.62%). Remarkably, diversity was noted in the studies' countries of origin, covering four different continents. However, the majority stand out to the United States of America, representing nineteen studies (34.62%).

Examining healthcare settings, the majority of studies (28.85%) occurred in any healthcare setting, followed closely by those within hospital settings and hospital academic centres, each constituting 21.15%. General practitioners emerged as the primary recipients of intervention (32.69%), with CDSS interventions notably affecting patients, albeit largely indirectly.

In general, the design of the reviewed studies focuses on evaluating CDSS effectiveness concerning cost, implementation, and usability. Furthermore, findings underscored a significant association between CDSS and clinical intervention, with the primary purpose of care often revolving around specific workflows (32.69%), followed by addressing particular patient diseases (15.09%).

4.3.3.3 Outcomes

The information extracted from the studies that were considered relevant for the desired purpose generated a set of outcomes, based on the characterisation of a CDSS.

Knowledge management: The representation and formulation of the acquired knowledge is one of the most important steps in the development of a CDSS. To identify the most used techniques for knowledge management, the approaches used in the reviewed studies were identified (demonstrated in Table 17). Clinical Practice Guidelines (38.46%), rule-based modules (40.39%) and algorithmic logic (38.46%), were the most used approaches to knowledge management in the designing of a CDSS. These techniques were used individually or in combination with others. The formulation of a knowledge base was also identified in thirteen studies (25%), in combination with other techniques. Inference engines were identified in seven studies (13.46%), which were also considered in some studies, as reasoning engines. Three studies (5.77%) provided IF-THEN statements, and eight studies (15.39%) applied methods based on variables. Terminology standards and clinical classification systems were present in five studies (9.62%), applying, in particular, ICD10 codification and HL7 communication protocol. Bayesian and neural networks were used in two different articles (3.85%). Finally, three studies (5.77%) used data mining techniques to reproduce the desired knowledge. Two studies (Falciglia et al., 2020; Lee & Lee, 2020) were excluded from pooling, as the method used in the KR process was not identified.

Technological features: Technological interventions are the characteristics that help a system fulfil its purpose. The most common technological feature approached in the CDSS is the recommendation and suggestion feature identified in twenty-four studies (46,15%) (demonstrated in Table 18) Information management and monitoring are the second most common feature in the systems, covering eighteen studies (46,15%). The third most desired feature is alerts, notifications and reminders, covering fourteen studies (26,92%). Following it is the purpose of reducing errors mentioned in eleven studies (21,15%). Eight articles (15,38%) design the CDSS for assessment reasons. The prediction feature is also used for eight studies for different purposes (15,38%). The automation and prioritisation of processes is considered to be of great importance and is addressed by seven articles (13,46%). The triggering of events is addressed by four studies (7,69%). The standardisation of the clinical process is desired by four studies (7,69%). Three articles (5,77%) highlighted the calculation and scoring methods as features of a CDSS. Finally, the cost and time reduction is seen as a main feature in two studies (3,84%).

System integration: The results related to the integration of the CDSS, showed that 51,92% of the articles (twenty-seven) use a standalone system (demonstrated in Table 19). The remaining studies show that their CDSS is integrated with another system, as well as using the information from these systems. Thus, eleven studies (21,15%) reveal that they integrate their CDSS with an EHR system; five studies (9,62%) integrate their system with a specific HIS; four studies (7,69%) integrate with a Computerized Provider Order Entry (CPOE) system; in this sequence, three studies (5,77%) integrate their CDSS with both EHR and CPOE; two studies differentiate their integration with an Electronic Medical Records (EMR) system.

Type of system: Most studies (19.23%) use a web-based application to present the system interface to the user. Nine studies (17,31%) describe their CDSS as a computerised tool, not specifying the type of software or interface used. Eight studies (15,38%) develop their CDSS in a software application. Regarding the logic used, five studies (9,62%) are based on ML techniques, and four studies (7,69%) are AI-based. Three studies (5,77%) develop their CDSS in a mobile application and, still, four studies (7,69%) cover a mobile and web application. Two studies (3,85%) describe their CDSS as knowledge-based, and other two studies (3,85%) present the CDSS as data analytics. Other types of systems were considered in unique studies, such as cloud computing (1,92%), data-layer infrastructure (1,92%), image retrieval expert system (1,92%), user interface (1,92%), and web application integrated with data analytics (1,92%). The detailed results are demonstrated in Table 20.

Different groups displayed varied outcomes regarding CDSS type, knowledge management, system integration, and technological features. Despite this diversity, a predominant trend was identified among the studies analysed. Figure 17 illustrates the three most commonly utilised approaches within each group as per the results obtained in the reviewed studies.

Regarding knowledge management and representation, the most common techniques are rule-based modules, clinical practice guidelines, and algorithmic logic. Regarding technological interventions or features, prominent trends encompassed recommendation and suggestion, information management and

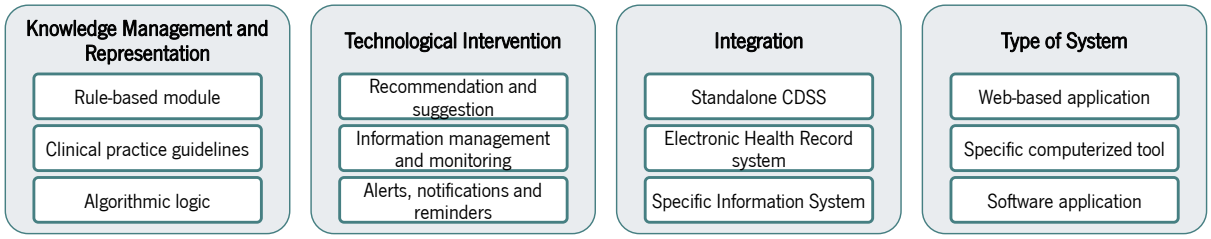


Figure 17: Trends in the characterisation of a CDSS for each SLR group.

monitoring, as well as alerts, notifications, and reminders. Standalone CDSS emerged as the most prevalent, followed by integration with EHR systems and specific HIS. Among system types, web-based applications, specific computerised tools, and software applications ranked highest in frequency.

Although individual results varied, a trend towards combined approaches was evident. In particular, the most common sequence in knowledge management involved a fusion of algorithmic logic with clinical practice guidelines. Similarly, in technological functionalities, a prevalent combination included recommendations and suggestions along with alerts, notifications and reminders.

4.3.3.4 Temporal evolution

Figure 18 demonstrates the temporal evolution of knowledge management and representation techniques used in studies. It is possible to verify that the rule-based module and the algorithmic logic have been present since 2000 until today, mostly. Clinical practice guidelines, on the other hand, proved to be a current issue due to their presence from 2013 to 2020. In general, the characteristics remain in existence over time, with a greater occurrence in 2020 due to the number of articles analysed that year. In contrast, the characteristics of the Bayesian network, IF-THEN statements and neural networks were considered more recent, emerging in 2014.

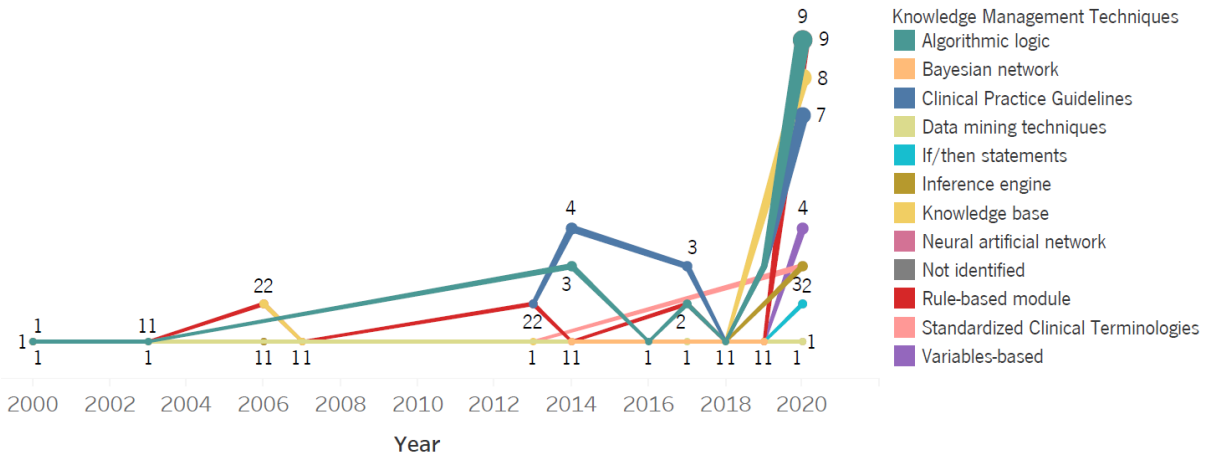


Figure 18: Temporal evolution of knowledge management group.

According to Figure 19, the integration of standalone CDSS has been increasing in recent years. The integration with EHR systems, oscillated between 2014 to 2020, standing out also in the last year.

Specific HIS have been integrated into the CDSS from 2000 to 2020, regularly.

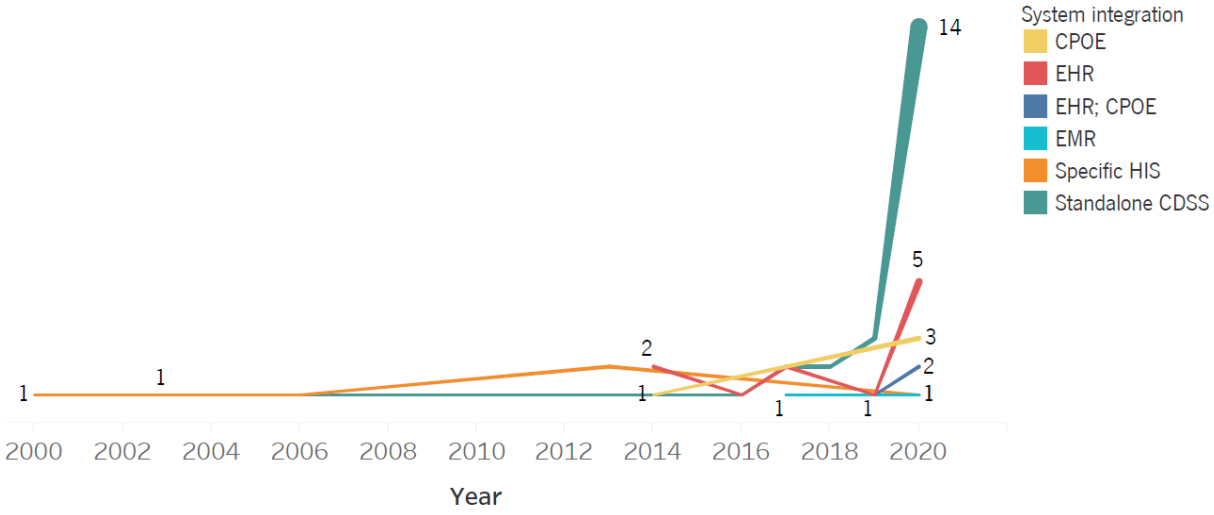


Figure 19: Temporal evolution of system integration group.

Regarding the type of system, Figure 20 demonstrates that specific computerised tools have been present since the beginning of the time interval and were more present in the year 2020. Software application, image retrieval expert system, and ML-based, are the most popular in recent years. Mobile applications remained constant and web-based applications were more prevalent in 2013.

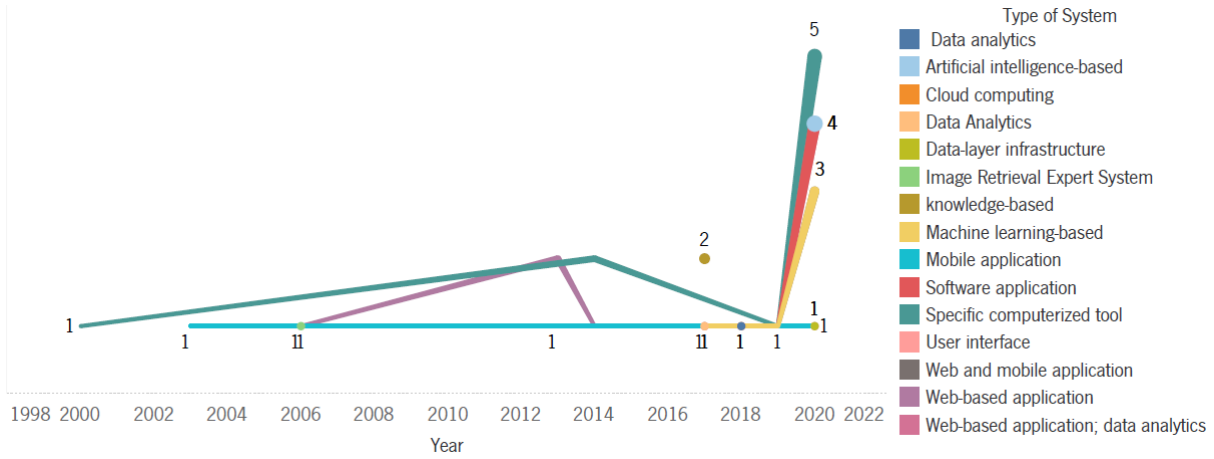


Figure 20: Temporal evolution of type of system group.

For CDSS features, alerts, notifications and reminders, and information management and monitoring features were more present in 2020, as shown in Figure 21. The recommendations and suggestions item was present from 2003 to 2020, with a notably increase in the last year. Standardisation was present in 2000 and only returned in 2020. The calculation and scoring, cost and time reduction, and prediction features were considered the most recent ones.

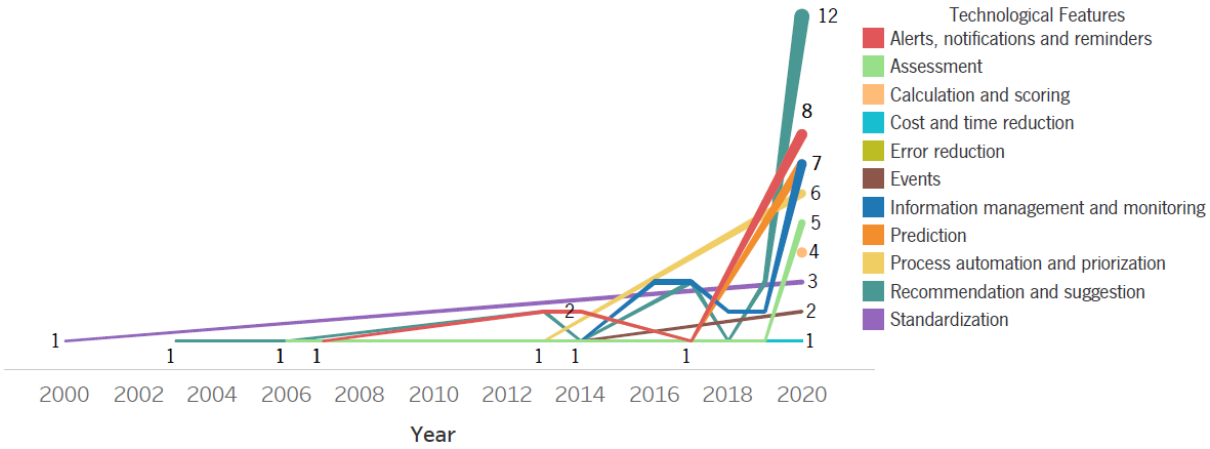


Figure 21: Temporal evolution of technological features group.

4.4 Maturity staging model

When a CDSS does not produce the desired results, several causes are likely, such as an incorrect definition of the problem, a poor evaluation of the alternatives, or inadequate implementation. The proposed alternative may not be successful, leading to a new analysis of the problem, the evaluation of alternatives, and the selection of a new alternative. Thus, evaluation is a crucial factor as decision-making is a continuous and never-ending process.

In addressing the second RQ within the SLR, a method or model was necessary to evaluate the maturity of the reviewed CDSS. As existing approaches did not align with the defined objectives of this work, a specific model was developed. Drawing upon the decision-making theory proposed by Simon (1960), a Maturity Staging Model (MSM) was formulated. The MSM is a four-step model designed to gauge the maturity level of a CDSS. Consequently, the model delineates four progressive stages based on the phases of the decision-making theory, as exemplified:

- **S_4 - Stage 4:** Implementation + Choice + Design + Intelligence
- **S_3 - Stage 3:** Choice + Design + Intelligence
- **S_2 - Stage 2:** Design + Intelligence
- **S_1 - Stage 1:** Intelligence

Stage 1 (S_1) is the initial stage, corresponding to the Intelligence phase, where the CDSS demonstrates basic capabilities and does not yet have a clear definition for its purpose. It focuses on acquiring information and recognising problems or trends that can influence healthcare decision-making. Stage 2 (S_2) corresponds to the Intelligence and Design phases, incorporating the design aspect into the CDSS. Here, the system structures the information in a meaningful way, which may involve developing algorithms

or rules to organise the data and generate potential recommendations or knowledge for healthcare professionals. At stage 3 (S_3), the system has already gone through the Intelligence and Design phases and is now in the Choice phase. At this stage, the CDSS moves towards facilitating decision-making processes by presenting viable options or alternatives based on the analysed data, and providing recommendations or suggestions for healthcare professionals to make informed choices regarding patient care. The culmination of the Intelligence, Design, Choice and Implementation phases results in stage 4 (S_4), which is the highest level of maturity for a CDSS. This stage extends to implementation capabilities, where the CDSS can carry out the recommended actions or interventions in the context of healthcare, actively contributing to clinical workflows, and increasing efficiency and effectiveness in the provision of patient care.

The transition between each phase of the MSM is governed by a distinct set of criteria. These criteria are made up of three to four conditions outlined for each phase, as shown in Table 3. For a system to be classified in a specific stage, it must fulfil at least one of the conditions indicated.

Table 3: Criteria for classifying MSM stages.

Phase	Condition 1	Condition 2	Condition 3	Condition 4
Intelligence	Have access to the history of past decisions	Ability to predict what may happen to the clinical situation (e.g. with ML and data mining models)	Having structured and available information capable of accessing specific clinical information to characterise the situation	Allow access to data to assess the clinical situation of patients
Design	Definition of clinical context variables	Ability to develop and present alternative solutions to a clinical situation	Use of modelling techniques/ procedures	Use of models or set of models to learn to decide
Choice	Be able to simulate and evaluate each of the available alternatives	Choice of best alternative as recommended solution based on applied criteria or models	Application of computational models to ensure the operation of the chosen solution	-
Implementation	Application of the chosen option in a real environment	Monitoring and evaluation	Data collection from monitoring and evaluation	Be able to record past decisions

In the Intelligence phase, for example, the criteria include access to historical decision data and the ability to predict clinical scenarios using ML models. The Design phase requires the definition of clinical context variables and the presentation of alternative solutions. The Choice phase requires simulating and evaluating the available options, culminating in the selection of the best solution based on pre-defined criteria. Finally, in the Implementation phase, the chosen solution is applied in a real context, with ongoing monitoring, evaluation and data collection to inform future decisions.

Drawing upon this concept, each stage within the MSM reflects a phase of the decision-making theory. These stages are defined by specific criteria that the system must satisfy to advance. If the system meets at least one criterion within a phase, it qualifies as having traversed that particular stage. Notably, the stages are cumulative, meaning the system proceeds to the subsequent stage only after fulfilling all requirements of the preceding phases. For example, for a CDSS to be in Stage 3, it must have at least one condition from the Intelligence and Design phase. This principle is encapsulated in the MSM formula, which is articulated as follows:

$$MSM = \sum_{i=1}^{4} S_i$$

$$S_0 = 1$$

$$S_i = \begin{cases} 1 & \text{if } S_{i-1} = 1 \text{ AND } \exists k\ Ci, k = \text{true} \\ 0 & \text{otherwise} \end{cases}$$

The formula for calculating the MSM level is the sum of the phases passed, capable of calculating the maturity level of the system. S_i signifies the system's progression through each phase i. This iterative process accumulates the stages passed, ultimately reflecting the system's maturity level. In essence, S_i serves as a binary indicator: it's set to 1 if the system satisfies at least one condition ($\exists$k Ci,k is true) and the previous stage is equal to 1 ($S_{i-1} = 1$). Otherwise, S_i remains at 0. It's noteworthy that the system starts at phase 1 ($i = 1$), where only the criteria for that specific stage are assessed. This approach ensures a comprehensive evaluation, considering the progressive nature of maturity attainment within the system.

4.5 Concluding remarks

A SLR was undertaken to formalise the current state of the art of CDSS. The first research question (RQ1) was to identify the tendency of adopted approaches in CDSS development across the studies analysed. To categorise the revised CDSS, information about four predefined groups were extracted, as knowledge management, technological intervention, system integration and type of system. While recognising the multifaceted nature of CDSS characteristics, the focus remained on information directly relevant to the primary objective of the CDSS developed, beyond aiding decision makers in the decision-making process.

The results showed that the most commonly used techniques for knowledge representation in CDS systems are modular rule-based approaches, clinical practice guidelines, and logical algorithms. Technologically, CDSS exhibited recurring features such as recommendation and suggestion mechanisms, monitoring and information management functionalities, and alerts and reminders. Typically, CDSS operated either as standalone components or integrated seamlessly with EHR systems or specialised HIS.

The prevalent types of systems identified encompassed web applications, specific computer tools, and software applications.

Addressing the second question (RQ2), a preliminary classification was conducted during the review process to ascertain the phase of the decision-making process model encapsulated by each CDSS. Inspired by Simon's decision-making theory, the CDSS were evaluated across four pivotal phases: Intelligence, involving analysis, exploration, and problem description; Design, encompassing the development and analysis of potential solutions; Choice, where the most suitable solution is selected; and Implementation, dedicated to applying the chosen solution to resolve the identified problem. This structured approach facilitated a deeper understanding of how CDSS align with the decision-making process, offering insights into their functional dynamics and developmental trajectories.

In order to identify the current level of maturity of the systems reviewed, the proposed formula was applied based on the criteria of each phase. Thus, Table 4 illustrates the intersection of MSM stages with the three most common characteristics of each group. This cross-referencing took into account the top three techniques most frequently adopted by studies for each defined group.

Table 4: Evaluation of the level of maturity of the CDSS analysed in the SLR.

Approach	Stage 1	Stage 2	Stage 3	Stage 4	WAVG
Knowledge management					
Rule-based module	21	16	4	1	1.64
Clinical practice guidelines	20	12	5	2	1.71
Algorithmic logic	20	13	7	2	1.79
Technological features					
Recommendation and suggestion	24	13	5	0	1.55
Information management and monitoring	18	9	7	1	1.74
Alerts, notifications and reminders	14	9	3	0	1.58
System integration					
Standalone CDSS	27	16	6	1	1.62
EHR	11	6	3	1	1.71
Specific HIS	5	4	1	0	1.6
Type of system					
Web-based application	10	8	2	0	1.6
Specific computerised tool	9	4	2	1	1.67
Software application	8	6	1	0	1.53

During the data extraction and selection process within the SLR, each study was assessed to determine its current phase within the decision-making theory, leveraging the criteria outlined in the MSM (Table

3). Consequently, the stages of maturity were determined by counting the number of articles showcasing each approach, upon its manifestation in each phase. It was recognised that these values are cumulative, implying that to advance to a particular stage, the preceding stage must have been fulfilled. Notably, all studies pertaining to each characteristic initially reside in the Intelligence phase. Furthermore, it is important to underscore that within the knowledge management and technological features groups, multiple approaches may be employed within the same CDSS, either individually or in combination with other approaches.

Following the identification of the MSM stage for the revised CDSS, the maturity was calculated using a Weighted Average (WAVG), a dynamic metric ranging from 1 to 4. This calculation factored in both the number of studies in each phase and the corresponding phase number, with 4 representing the highest level of maturity. The WAVG showed very similar values, meaning that the CDSS of the reviewed studies predominates in Simon's Intelligence and Design phases, equivalent to stage 2 of maturity. The recommendation and suggestion (1.55) and software application (1.53) characteristics have the lowest values nearly reaching the previous phase of Intelligence. The algorithmic logic characteristic stands out the most and shows that it is closer to achieving the upper stage of maturity (stage 3), meeting the Choice phase.

The findings revealed a significant shortfall in the maturity levels of the reviewed CDSS, with none of them progressing beyond phase 2. This circumstance suggests a crucial gap in healthcare systems, wherein CDSS are unable to effectively guide actions in clinical settings or participate in their implementation. Such findings sound an alarm regarding the current trajectory of CDSS development, signalling a pressing need for heightened awareness and strategic interventions. It unveils a disconcerting reality wherein CDSS, instead of advancing towards optimisation, remain entrenched in developmental stages that fall short of their intended efficacy. This prevailing immaturity reflects broader challenges within the health sector, highlighting discrepancies between envisioned outcomes and actual implementation. The main causes can include an inadequate understanding of the problem, difficulties in selecting optimal solutions and deficiencies in usability testing protocols. Also, the chosen alternative may not be successful, which will lead to a new analysis of the problem, the evaluation of alternatives and the selection of a new alternative. Thus, addressing these underlying issues is crucial to bridging the gap between CDSS potential and real-world impact, thereby enhancing decision-making processes within healthcare contexts.

Overall, the SLR undertaken enabled the completeness analysis of CDSS, covering different approaches, techniques and purposes of use. The main contribution of this review was the proposed MSM, which allowed to identify a gap between the state of the art and the desirable stage of maturity to provide an effective CDSS. The conducted SLR selected a set of studies that address the development of a CDSS, tracing a global trend of their characteristics, and to assess their level of maturity. As far as is known, other SLR studies have been developed (Anchala et al., 2012; Curtis et al., 2017; Jia et al., 2016), but the primary focus is on assessing the CDSS effectiveness within specific clinical contexts rather than providing a comprehensive evaluation of their effectiveness as a whole.

However, some limitations related to the SLR developed should be emphasised. Firstly, it was not

possible to carry out a meta-analysis due to the variation in the type of studies analysed in the SLR, as well as to use a methodology to assess the quality of the studies. The number of eligible studies in the sample was also limited. Another limitation relates to the characterisation of CDSS, as some studies did not directly explain the approach used. Thus, a larger sample of studies should be considered in future work.

Nevertheless, it is well known that, in the clinical area, regulation and ethical issues limit the application of more advanced stages of the decision-making process (e.g. choice and implementation), preventing the maturity of stage 4 from being reached. Thus, some of the difficulties in the adoption of CDSS may be related, such as the development of methods to support the choice phase of the decision-making process; interoperability between medical devices and HIS; technology acceptance; ethical and regulatory restrictions; weak involvement of professionals and organisations. An in-depth analysis should be carried out to uncover the main constraints that prevent the inclusion of CDSS in the highest phase of decision-making. A lot of work should be done in the future to mitigate those limitations, starting with: i) consider a larger sample of studies; ii) determine the accepted range of values for the maturity stage in particular clinical context of application; and iii) depict what needs to be reached to fill the current maturity gap for developing an effective CDSS.

5

Designing a Decision Logic System

This chapter introduces a logical decision system designed to overcome the gaps identified in the previously described SLR. Starting with contextualisation, the importance of decision logic systems in real-world applications is explored. Related work is then described, surveying existing approaches in the field. The primary goal of this chapter is to demonstrate the development of a decision logic engine, which forms the foundation of the proposed artefact. The related architecture is explained in detail, including its components and functionalities. It also embraces the processing of decision models and how the system interprets them. Through a system overview, information about the internal functioning of the engine and its use is provided. Finally, the main findings and insights obtained from this exploration are presented, clearing the way for further advancements in the CDSS domain.

5.1 Contextualisation

A data-driven decision is structured in a decision component that includes individual and composite decision nodes, which outline alternatives dependent on external information (Batoulis et al., 2015). In the day-to-day life of organisations, adaptable systems are required to monitor and respond to constant change autonomously in line with predefined application logic. Decision services facilitate this process by enabling the selection of one of multiple alternative process logic at decision times, thereby encapsulating the rules that govern decision-making and runtime conditions under which decisions are processed (Zarghami et al., 2012).

As stated in the reviewed literature, CDSS are not achieving the intended objectives outlined during their design phase. Some limitations of design practices in CDSS are highlighted in the literature, resulting in an important barrier to the adoption and effectiveness of these systems (Kawamoto & McDonald, 2020). Being a process that requires resources, such as costs and time, organisations generally prefer to adopt commercially available solutions, which were created for a specific context or in a very general way, not fulfilling all the necessary functionalities (Trinkley et al., 2021). Therefore, it is encouraged that best practices are applied in the design of the CDSS to accomplish its intended objectives (Trinkley et al., 2021).

In the design process of a CDSS, it is imperative to include the dynamic interactions of healthcare professionals with clinical information throughout each decision-making phase, ensuring the optimisation of a CDSS, its relevance to health decision-making, and to achieve efficacy within real contexts (Zikos, 2017). To fulfil their intended objectives, the knowledge disseminated by CDSS ideally mirrors clinicians' authentic decision-making processes and cognitive exertions. Accordingly, it is important to align CDSS with the inherent cognitive processes of clinical decision-makers, recognising the value derived from merging health data with human knowledge and experience (Zikos, 2017).

Design considerations for an effective CDSS, entail the integration of ES with interactive models capable of storing and processing new information from practitioners (Zikos, 2017), as well as the adequate KR through data availability. In general, a mismatch between the information needed for decision rules and the availability of that information in the EHR is the main cause of failure of CDS intervention studies. When complete and accurate information is available, supplier compliance can be exceptional. External data will be difficult to use for decision rules unless the data sources follow the guidelines of standard coding systems (Kawamoto & McDonald, 2020).

There is a need for the CDSS to be aware of the temporal context in which decisions are made, recognising the variability in data availability at different decision points. System considerations imply that CDSS explicitly informs users about the data availability required to make accurate recommendations. System conditions involve annotating sets of critical variables known to interact as drivers in CDSS models (Zikos, 2017). Furthermore, it is important to model known interactions between clinical variables, recognising the greater usefulness of health data when analysed together.

5.2 Related work

The current body of knowledge lacks comprehensive theories concerning decision systems capable of predicting system success and guiding designers to develop effective CDSS (Mastrianni, 2023). Certain studies address the exploration of CDSS design intended to support clinical teams operating within critical care environments. These studies advocate the need for a CDSS that not only improves decision-making but also facilitates and coordinates the work performed (Mastrianni, 2023).

When outlining the operational requirements of a CDSS, two main facets emerge as fundamental considerations. Firstly, interoperability, emphasising the ability of CDSS to promote the uninterrupted exchange of data from EHR or HIS. However, interoperability goes beyond the mere exchange of data, requiring the accessibility, syntactic and semantic interpretation of elements such as historical data and real-time records, through integration with any system (Gatsios et al., 2021). Secondly, the imperative to improve workflow emphasises the need for iterative usability evaluations and rigorous pilot testing before implementation. This meticulous approach is essential to ensure the smooth integration of CDSS into the existing clinical workflow, thereby improving its adoption (Gatsios et al., 2021).

To successfully implement and manage a CDSS at a large scale, it is important to have a thorough understanding of its architecture and infrastructure. This understanding will enable the utilisation of various technologies, clinical information standards, and clinical terminologies, to facilitate the development and management of CDS components. Hereupon, Marco-Ruiz et al. (2020) identified important factors for designing a CDSS, embracing: software architecture, information standards, clinical terminologies and codifying systems, governance and shared development, and knowledge base. Particularly in the domain of rule-based systems, having a knowledge base is essential to compile rules in the CDSS algorithm for generating recommendations. The specification of medical decision algorithms and logic-based methods, such as rule-based and ontology-based approaches, are considered the most efficient due to their intuitive nature and simplicity in knowledge management. Furthermore, Marco-Ruiz et al. (2020) also state that EHR systems have been harnessed to enable data reuse, particularly through highly structured data formats such as the openEHR standard. The standardisation approach of EHR allows direct reference to the same standardised information schema used by different systems.

The predominantly rule-based nature of most existing CDS systems has led to a shortage of fully functional prototypes or commercially viable systems suitable for real-world use. This deficit is largely attributable to efforts that failed to analyse the systemic complexities inherent in the clinical process, resulting in limited operational success and acceptance. Initially, the design paradigm essentially revolved around formal clinical reasoning based on the empirical knowledge of medical specialists. In addition, design efforts seem to have been predominantly technology-orientated, with the predominant adoption of rule-based structures, in which clinical reasoning rules, such as those governing diagnosis and treatment, are directly transcribed into the system. However, these one-to-one mapping approaches do not offer the flexibility needed to promote a socio-technical clinical reasoning system capable of dealing with the multifaceted dynamics of clinical decision-making (Raghupathi, 2007).

Despite the complexities of the domain, many clinical reasoning ES persist in employing this representation approach, which lacks the adaptability needed to cultivate a comprehensive socio-technical system capable of accommodating the aspects inherent in clinical reasoning processes. While rule-based representation and problem-solving approaches may be sufficient for strictly structured domains, their application remains limited in scenarios that require openness, smoothness, complexity and generality in cognitive processes (Raghupathi, 2007). In particular, the considerations on softness emphasise the importance of subjectivity and value in the design of cognitive CDS systems. Adopting openness in the design of CDSS facilitates flexibility, allowing for the incorporation of diverse interacting domains, accommodating contributions from multiple external sources of information and specialised knowledge, considering the varied reasoning mechanisms that are an integral part of clinical decision-making processes (Raghupathi, 2007).

5.3 Design and development

The journey towards designing an effective CDSS is complex and full of challenges and opportunities. Once the obstacles have been recognised, a search starts to find solutions that promise to overcome the challenges associated with adopting CDSS. The promotion of open standards and knowledge sharing has been increasingly associated with CDSS, enabling the creation of a vast evidence-based knowledge base to produce reliable decision-support artefacts (Sutton et al., 2020).

Some standardised open data approaches have already been created to solve the problems identified, but they still lack semantic representation of clinical knowledge, workflow synchronisation and data access linkage (Beale & Chen, 2021). In 2021, DL was created by the openEHR standard to overcome these obstacles, responding to the need for a standardised decision component to support healthcare workflows. Through DLM, the DL specifications support clinical decision-making by developing computer-interpretable guidelines through workflow-orientated production rules. This approach is open and interoperable and can be integrated into any HIS system.

The SLR developed (chapter 4) identified the most widely used approaches to designing CDSS. In the review, it was observed that the use of standards and interoperability techniques were among the least used, which may prevent the system from achieving the desired effectiveness. In addition, the SLR identified the most common approaches and characteristics in the adoption of CDSS based on four groups: knowledge management and representation technique; technological features; system integration; and type of system.

As a proposal, an artefact was developed to process standardised and structured decision rules based on the openEHR DL specifications. The design of the proposed artefact considered the results obtained and selected different knowledge representation approaches, technological interventions and rule processing models. A rule-based system capable of processing clinical practice guidelines through an algorithmic logical inference engine is thus considered. Furthermore, as a knowledge-based system, the proposed architecture provides a knowledge base to store the decision modules created. In terms of technological features, the system will focus on information management and monitoring, process automation and prioritisation, recommendation and suggestion, events and standardisation. Calculation and scoring will also be considered. The decision support module designed can be used as a standalone system with the possibility of being integrated into other HIS or EHR systems. As far as the type of system is concerned, the proposed logical module is a back-end service integrated into a web-based application.

5.3.1 System overview and processing

To elucidate the openEHR specifications, it is essential to incorporate the various components that provide modelling templates and archetypes for representing EHR in a standardised manner. These specifications enable the development of flexible, vendor-neutral EHR systems that can adapt to changing clinical

requirements and technological advances. Alongside the specifications, the ecosystem promotes the creation of openEHR-compatible software applications, tools and libraries, as well as the sharing of clinical knowledge through openEHR-based clinical content repositories. Through active collaboration and adherence to open standards, the openEHR ecosystem strives to empower healthcare stakeholders across different institutions to innovate and improve patient care (Beale & Heard, 2008).

Archetypes, templates and forms are integral components of openEHR, working cohesively to ensure the consistent collection, structured storage and retrieval of clinical data in a meaningful format (Beale, 2002). Together, they establish a standardised, flexible and scalable manner for managing clinical data, thus facilitating the sharing and exchange of data between different HIS and organisations, promoting interoperability (Oliveira et al., 2022). Archetypes serve as reusable, modular building blocks that outline the structure and content of clinical data elements. It specifies the data types, units, constraints and other properties of specific clinical concepts, such as patient demographics, test results and medication information (Beale, 2002; Oliveira et al., 2022). Templates, on the other hand, comprise collections of archetypes that specify the structure of specific clinical records, such as progress notes, drug prescriptions or diagnostic test results. Templates guarantee a standardised structure and content for clinical records, enabling consistent and meaningful data collection (Oliveira et al., 2022).

In this sense, the proposed artefact is integrated into an openEHR ecosystem, as represented in Figure 22. The system overview falls into a three-tier architecture, with the following computing layers: (i) data layer, where data is managed and stored; (ii) logical layer, equated to an application layer; (iii) presentation layer, represented by a user interface(s). It is worth mentioning that the main focus of this doctoral work is the Decision Logic Engine (DLE) within the logical layer, the other services are referenced solely to illustrate their interaction with the proposed artefact.

The application layer is the logical layer of the artefact represented by the DLE, which integrates a knowledge base and an inference engine. In general terms, the DLE aims to represent and process a protocol or a guideline through a rule or a set of rules in which, if the condition is considered true, it triggers one or more events. Synchronously, the inference engine works together with the knowledge base, processing the rules related to the defined decision module. Whenever a request is received, the inference engine retrieves the structure of the respective decision module from the knowledge base and executes the requested rule.

Moreover, the data layer consists of external services and data binding, which retrieve data from data sources (such as HIS or EHR) through queries or API calls. In addition, there is a service called SPO, which binds data from the subject. The SPO is used when a subject variable needs a value that the user does not provide. In this case, the DLE sends a request with the variable expression, and the SPO responds with the value.

Finally, the presentation layer is responsible for representing the user interface, where it contains two different applications. On the one hand, forms are presented in an independent interface that consumes openEHR structures, based on the modelling of archetypes and templates. On the other hand, a web interface was developed for the DLE to allow the creation of rules associated with the proper services.

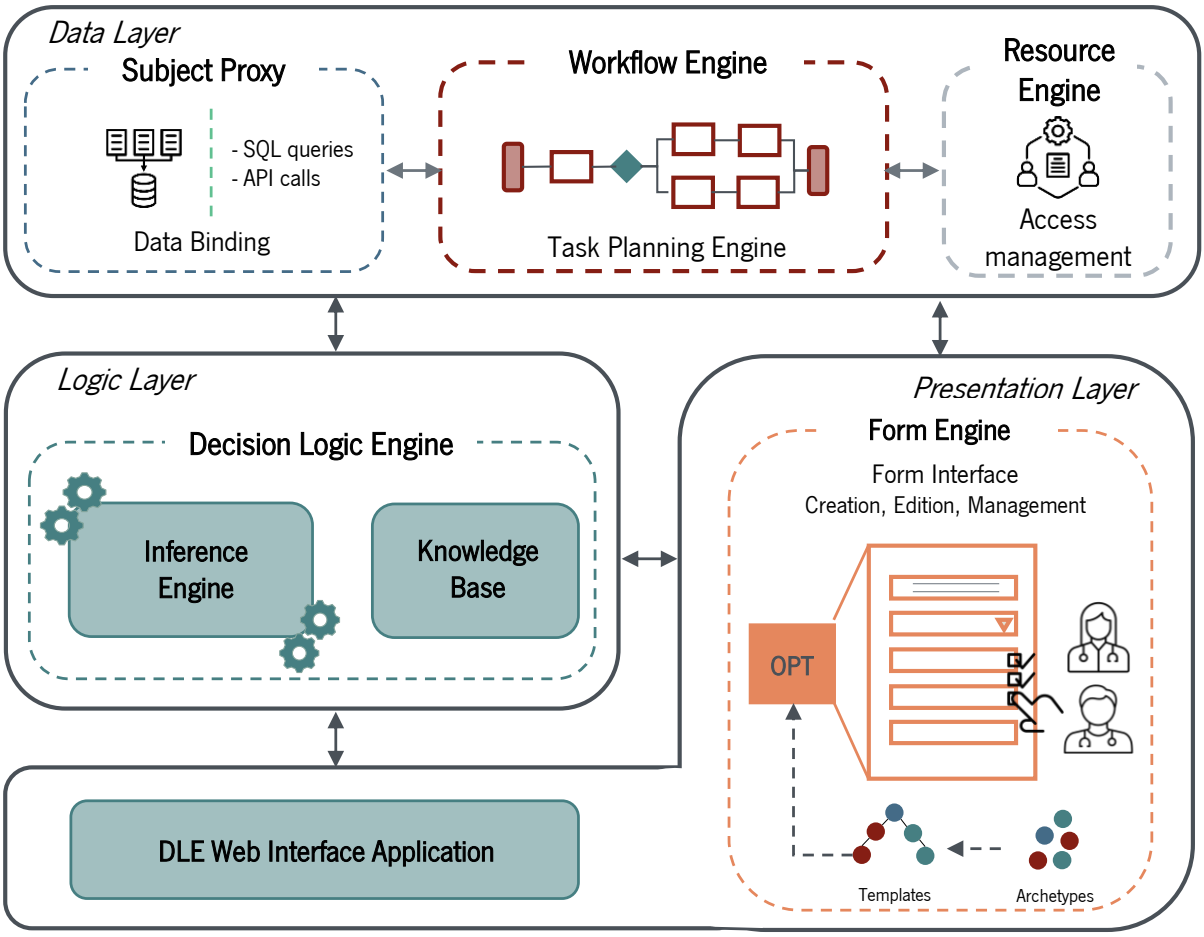


Figure 22: System architecture overview.

Thus, the decision modules created are better managed, facilitating their editing and allowing them to be quickly accessed in a graphical view.

In the system overview, the Form Engine (FE), the Workflow Engine (WE), and the Resource Engine (RE) are the services and applications that are constantly making requests to the DLE. FE is an application that represents openEHR structures, such as archetypes and templates, in a form visualisation (according to the Archetype Model of openEHR specifications Beale & Heard, 2008). These forms can contain associated clinical and operational rules, that is, rules that act on the structure of the form (e.g. making a field mandatory, visible, editable, etc.). WE is responsible for processing workflows and task plans (according to the TP specifications Beale, 2017). As they are oriented to workflows, tasks are associated with decision points that follow a determined branch according to the predefined conditions. When a decision point is found in the flow, the WE sends a request to the DLE to process the predefined rules associated with the decision point in question. RE is responsible for managing administrative processes such as access permission, team management, and resource management, requiring the processing of administrative rules. These described services were developed separately but are integrated with the DLE and are in constant communication.

The interaction between the three services begins with the import of previously modelled openEHR templates, resulting in Operational Template (OPT) files. FE converts the modelled templates into a user-friendly form interface for inserting and manipulating data. In parallel, the workflow of the associated context is modelled, where the work tasks and decision points of the flow are defined. Published forms can be referenced as tasks to support the execution of the workflow. Next, the rules associated with both the workflow tasks and the form fields are defined in the DLE, automating the application of decision rules in both processes. Finally, the entire structure is implemented in the hospital context, creating and storing consistent, accurate and standardised health data.

After receiving the input variables, the DLE checks whether the conditions for executing a given rule are met. If the values assigned to the form fields do not fulfil the criteria of a rule, an empty object is returned. Conversely, if the values received comply with the conditions defined in the rule, DLE returns the event that must be executed, containing the variable and the corresponding action. FE then initiates the necessary actions for each field based on the response received. Figure 23 illustrates the HTTP requests exchanged between services and the DLE, in two different scenarios. In the first scenario, a healthcare professional enters a value that triggers the execution of a rule, while in the second scenario, no rule is activated. This provides a clear representation of the data flow and communication between the two servers during the operation of the rule-based system.

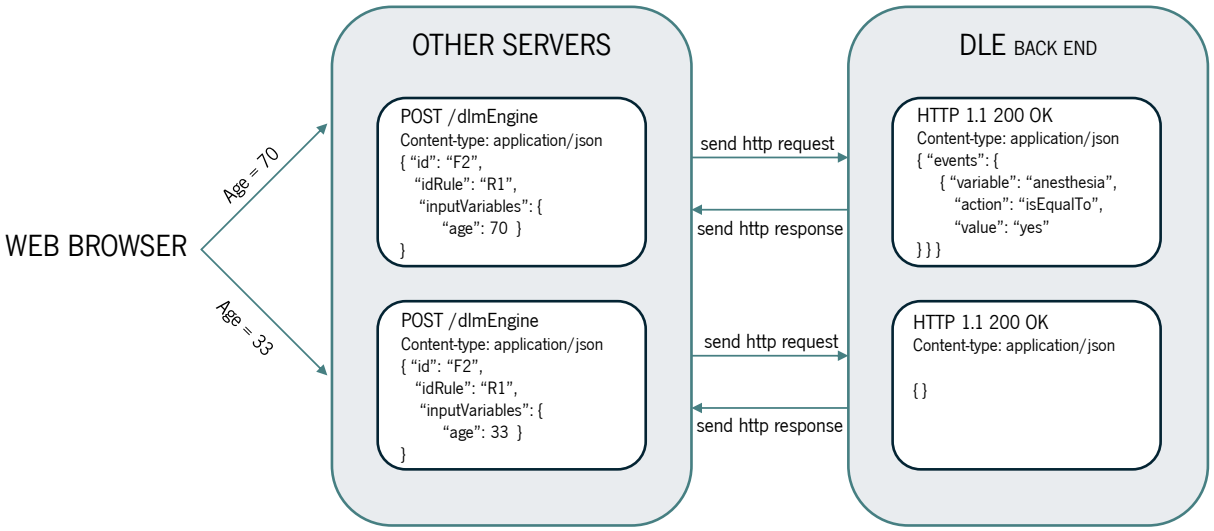


Figure 23: HTTP request and response interactions between the DLE and other servers.

The practical development of the integration of DLE with WE marks a significant advance in the openEHR ecosystem. This interaction enables the handling of all conditional structures within a Work Plan (WP), covering condition groups, decision groups and event groups, with the support of rule processing. Essentially, when the materialisation path of a WP reaches a decision point, a request is sent to an API provided by the DLE service, along with the associated variable. Subsequently, the DLE processes the rules and conditions associated with the request and returns a response. On receiving this response, the WE associates it with the respective branch (decision branch, condition branch or event branch) and

proceeds with its execution.

Within the openEHR ecosystem, WE plays a key role in orchestrating hospital tasks by referencing openEHR forms. Meanwhile, FE empowers healthcare professionals with user-friendly interfaces for entering and retrieving data, guaranteeing data accuracy and standardisation. Importantly, the data provided by healthcare professionals in the form fields can dictate subsequent paths after the form has been submitted. Through the integration of WE and FE, healthcare providers can ensure that pertinent information is captured and utilised in patient care plans, ultimately improving patient outcomes and operational efficiency. This integration promotes better decision-making based on timely and accurate data.

5.3.2 Proposed architecture

A data-based decision is represented by a decision structure consisting of simple and compound decision nodes, which represent alternatives based on external information. A decision is the act of determining an output value from several input values, using decision logic that defines how the output is determined from the inputs. In turn, the value expressions and knowledge of the decisions define the logic used to make actions. The combination of decision requirements and decision logic forms a decision model.

A logical model uses predicate logic to represent knowledge, employing a directly programmed inference mechanism with specific properties. In essence, the construction of logical models consists of treating all the information needed to solve problems as a set of facts and statements, represented in a logical component. Knowledge is thus encapsulated in a set of formulae and acquired in a simplified way by applying inference procedures through a logic programming language.

Turning the attention to the work at hand, the DLE has been developed with its architecture tailored to meet the specified objectives. The architecture of the proposed artefact was designed based on the DL specifications of the openEHR standard. In summary, DL delineates a formal model to encode decision logic for various clinical contexts. It includes logical processing for plans and guidelines, which are essential to express computerised rules. Hence, Figure 24 demonstrates the architecture designed for the proposed system, comprised of an inference engine and a knowledge base.

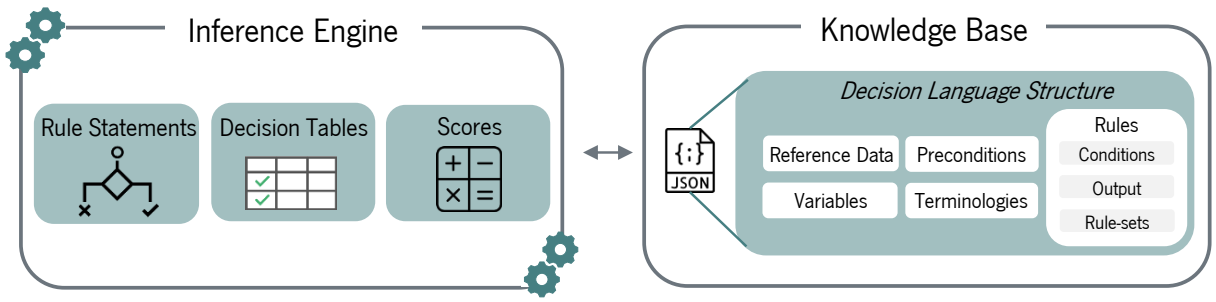


Figure 24: Architecture of the proposed artefact.

As a knowledge-based system, maintaining a knowledge base to oversee the decision modules is essential. The DL conceptual architecture outlines its structure by incorporating DLM, a multi-sectional

module with sections for description, input variables, rules, and terminologies (Beale, 2021). In this architecture, the decision structures are stored in the knowledge base as modules written in JSON files based on the DLM structure. A DLM contains mandatory and optional sections, the mandatory ones being: reference data that identifies the purpose of the module created, author data, type of integration, among others; context variables associated with the decision module, which may be of the input or output type; and expression of rules through conditions and related events. As optional sections, the decision module can have associated preconditions, use other decision modules, and use terminologies capable of coding and classifying clinical concepts.

As a rule-based decision logic system, the inference engine is responsible for processing decision logic as rules in an algorithmic way. It is part of a system that takes in variables and values, applies logical reasoning, and produces new insights or actions. Currently, rules can be expressed in the DLE using one of three models: rule statements, decision tables and scores. Rule statements are similar to IF-THEN statements, where a condition must be valid for executing the rule. Decision tables are a tabular way of expressing a rule, where a set of conditions and possible actions that vary according to a value is determined. Scores are rules based on mathematical calculations.

Furthermore, a web interface was developed to allow the creation of decision modules simple and user-friendly, ensuring ease of interaction. The solution includes predefined sections according to the DLM structure specified in the openEHR DL specification and also by needs identified in the context of use. When the decision module is created, the inference engine processes it in response to decisions requested by other services.

5.3.2.1 Knowledge-based structures

The modelling of decision logic separately from the processing allows keeping the logic in a dedicated decision model and the processing in a dedicated process model (Batoulis et al., 2015). Thus, decision rules can be explicitly specified by separating decisions from the process control flow. The proposed artefact enables the derivation of new knowledge by executing different decision logic models on pre-existing information.

Initially, openEHR created a decision language to support clinical guidelines called GDL (as explained in detail in section 3.4.2). To add more functionalities, a second version of GDL was< developed, aiming to improve the previous version. GDL2 is already implemented in some HIS to support clinical decisions (Beale & Chen, 2021). Of late, a need was identified to support workflows and simplify the syntax of the language, and, in consequence, the DL specification was presented. DL proposes a sectioned structure capable of building decision modules for the representation of clinical guidelines and rules. In this sense, DLM is used in EHR systems, as a way of assisting plans, guidelines and data entered through rules. Figure 25 outlines the DLM structure incorporated in the proposed artefact.

The DLE class model is based on the DLM structure of the openEHR DL. Of all the sections contained in the specifications, three mandatory sections and one optional section were considered for the DLE

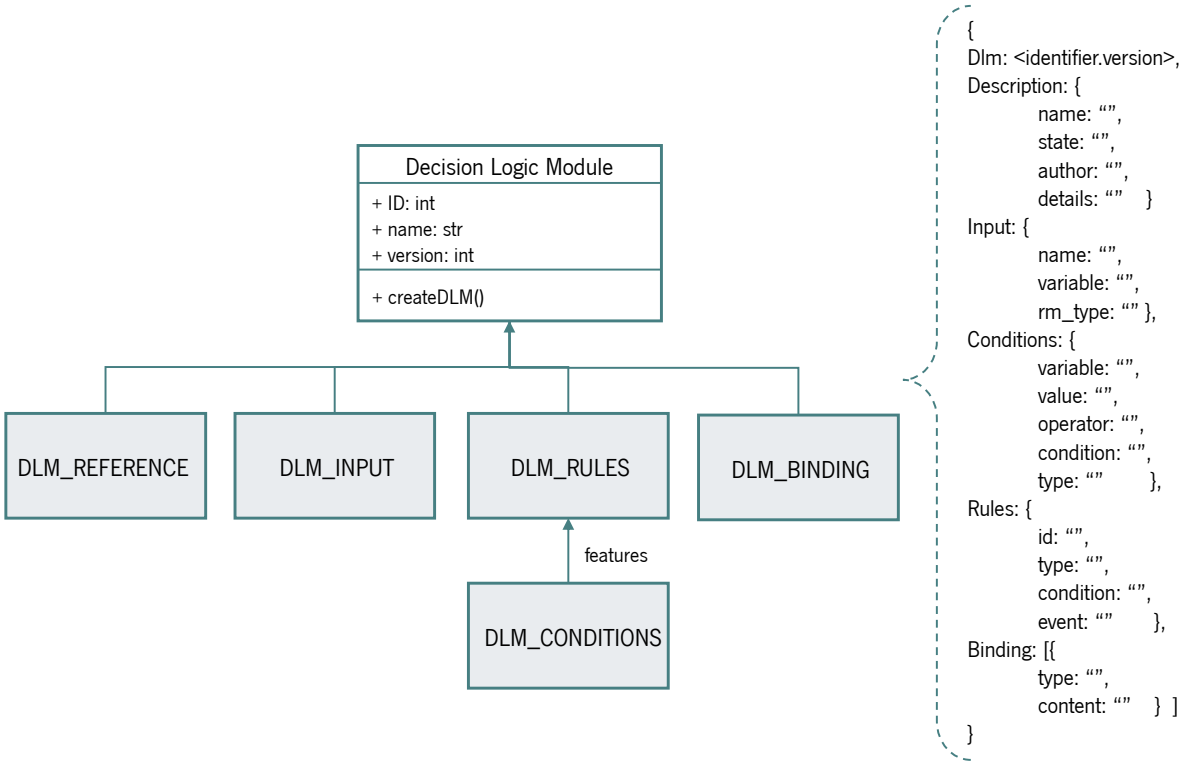


Figure 25: Class diagram of the DLE proposed.

knowledge structure: *DLM_REFERENCE*, *DLM_INPUT*, *DLM_RULES*, *DLM_BINDING*, respectively. The main class is the *Decision Logic Module*, responsible for representing the decision knowledge through the creation of modules. In the proposed artefact, this structure adhere a document-oriented format, specifically JSON structures. The creation of a module begins with its identification number, name and version. The referential data within the *DLM_REFERENCE* class provides a more comprehensive description, encompassing authorship details, organisational information, creation and modification dates, terminologies and languages, among others. Additionally, this section records the integration type of the respective module, such as whether the DLM is integrated in a form, resource, or workflow.

Versioning is an extremely important point in characterising a DLM. DL specification approaches versioning as a numerical representation combining a form of *MAJOR.MINOR.PATCH*. *MAJOR* indicates changes that are incompatible with the original version, *MINOR* refers to simpler changes as adding functionalities that are compatible with the original version, and *PATCH* corresponds to correcting minor errors. In DLE, the version of the DLM is represented in the same way, but the versioning process is combined with the lifecycle state of the DLM. In other words, the life state of a DLM in DLE can have four values: in development, in production, discontinued, and deleted. When a DLM is created, its status automatically changes to 'in development' with version 0.1.0. Other versions can be created and worked on in parallel in the development state. However, when a DLM is published, i.e. goes into production, its version becomes 1.0.0. Only one version of a DLM can be in production. When a new version of the same DLM goes into production, the status of the previous version automatically changes to 'discontinued'. The

'deleted' status can only be applied to a DLM in development, and it is not possible to delete DLM that have already been in production but to discontinue them. The fact that a DLM has the status of 'deleted' and is not in fact deleted, allows for the extensive construction of a history of DLM records and avoids accidental data loss.

The *DLM_INPUT* class refers to the declaration of context-orientated variables. In DLE, a variable is an element that represents something, which can be a subject variable, a clinical concept, or even a field on a form. A variable is composed of a name, an identifier and a type, and can be a subject variable, a rule variable for unavailable values, or a calculation variable. In essence, subject variables are data linked to a specific subject and are directly interlinked with the SPO service. These types of variables have values recorded in EHR repositories and are returned by the SPO service, due to the need to obtain values from past records or even real-time data that is being stored in other services. On the other hand, rule variables are elements that don't have a fixed value, where the variable value depends on another value (e.g. Fever=38°C THEN Fever='has fever'). In DLE, rule variables follow the structure of a decision table. Calculation variables, on the other hand, are calculation variables that have a value when a previous calculation is carried out (e.g. Body Mass Index (BMI) calculation). This calculation can include numerical values, operators and even depend on the values of other variables.

As DL currently only presents specifications for linking with subject variables, specifically orientated towards workflows, integration with forms was one of the challenges addressed in this work. For the most part, form variables are associated with form fields, which are the data elements defined in archetype modelling. It is crucial that the DLE can interpret the data types in the openEHR template structure. Table 5 shows the data types covered by the DLE and how it behaves, restricting the type of operators and values for each data type.

The *DLM_RULES* features the *DLM_CONDITION* class, as rules are created from a set of conditions that trigger specific actions. These conditions are characterised by variables, operators and values, which trigger a set of potential outcomes. As the set of rules unfolds, various conditions interact, paving the way for a series of actions to be carried out. Integrated into a set of rules or in an individual way, rule execution produces results that act directly on decision-making. In DLE, conditions are formed by combining the variables defined in the INPUT class with an operator and a value, thus forming a rule expression. Table 6 presents the operators covered by DLE, where A simulates a variable and B simulates a value.

As well as operators to express rules, operators are needed to form sets of rules. Thus, DLE includes conjunction and disjunction operators to string together conditions in a rule. 'ALL' is defined as a conjunction operator equivalent to 'AND', where all the conditions defined within this operator must be true. On the other hand, the 'ANY' operator works as a disjunction operator equivalent to 'OR', where at least one condition of the set defined must be true.

When a variable has a dynamic value, i.e. the value is not received directly from the DLE, it is fetched via the data binding service. The *DLM_BINDING* class is responsible for this behaviour, where the data binding can be defined in the DLE itself or via the SPO service. Firstly, the name of the variable and the type of call (either by QUERY or by API call) are registered. Then the type of call is specified, either by

Table 5: Archetype data types covered by DLE.

Datatype	Description	DLE operator	DLE values
DV_TEXT	Data with text values	Text type	String values
DV_CODED_TEXT	A combination of a code and a text value. Corresponding codes are provided by coding systems and terminology services	Text type	Predefined values from archetype modelling
DV_BOOLEAN	Boolean data, i.e. true/false or yes/no values	Text type	Predefined values from archetype modelling
DV_QUANTITY	Values that represent quantities, expressed by a quantity (numerical value) and a unit (measures)	Numerical type	Numerical values for the quantity and predefined values for the units
DV_ORDINAL	Represents integral score values, having a code, a text, and a numeric punctuation value	Text and numeric types	Predefined values from archetype modelling
DV_COUNT	Countable quantities that can have a range	Numerical type	Numeric and between values
DV_DATE	Representation of a point in time measured in the Gregorian calendar, specifying the year, month and day	Text and numerical type	Date picker value
DV_DATE_TIME	Represents a point in time specifying the year, month, day, hour, minute and second	Text and numerical type	Date picker value
DV_INTERVAL	Defines an interval (range) of a comparable type, used to define intervals of dates, times, or quantities (whose units coincide)	Text and numerical type	Range of two values

defining the matched query or by defining the service and parameters to call in the case of the API. This class is defined in the openEHR DL specifications, but it is still under development, which has made its implementation in the DLE a challenge.

In general, defining a structure that logically represents knowledge makes it easier to define rules in daily processes. Additionally, this standardisation makes it easier to transform clinical guidelines into a computerised format that can be understood by different EHR or HIS systems. Besides, it is worth noting that healthcare professionals will be able to easily transpose their cognitive knowledge through these structures without relying on internal changes to the system. This is achieved by modelling the decision modules using the structure presented, which in turn will be executed and interpreted by the DLE.

Table 6: DLE condition operators.

Operator	Type	Description	Example
equal	Text	Variable must be equal to the value	A === B
notEqual	Text	Variable is different from the value	A !== B
lessThan	Numeric	Variable must be minor than the value	A < B
lessThanInclusive	Numeric	Variable must be minor or equal to the value	A <= B
greaterThan	Numeric	Variable must be major than the value	A > B
greaterThanInclusive	Numeric	Variable must be major or equal to the value	A >= B
between	Numeric	Variable must be within the defined range of values	A <= min(B) & A <= max(B)
in	List	Variable must be included in the value. Value is an array	A.indexOf([B])
notIn	List	Variable cannot be included in the value. Value is an array	[B].indexOf(A)
contains	List	Variable is an array and must include the value	[A].indexOf(B)
notContains	List	Variable is an array and cannot include the value	B.indexOf([A])
dynamicValue	Dynamic	Variable has a dynamic value, the Binding service must be called	callBinding()
-	-	Variable may have any value for the condition to be valid	N/A

5.3.2.2 Decision models

The logical inference engine operates by continuously checking and executing rules in cycles. During each cycle, several rules can be activated and added to the list of working rules. This rule-based system makes it easy to track how specific conclusions were reached since it stores the history of rule activation and the contents of the working memory. This tool allows the monitoring of the activated rules, making it possible to reconstruct the reasoning process that led to a particular conclusion.

Production rules Production rules are a simplified way of expressing rules, based on IF-THEN statements. The 'IF' component is represented by conditions, where it can be one or a set of conditions. These conditions have a variable, an operator and a value associated. It functions as a comparable system, where the input variable will be comparable with the stipulated value according to the pre-defined operator. Figure 26 represents the processing of rule statements in the DLE, indicating the defined logical

structure, the representation of this structure in a JSON document, and a graphical visualisation.

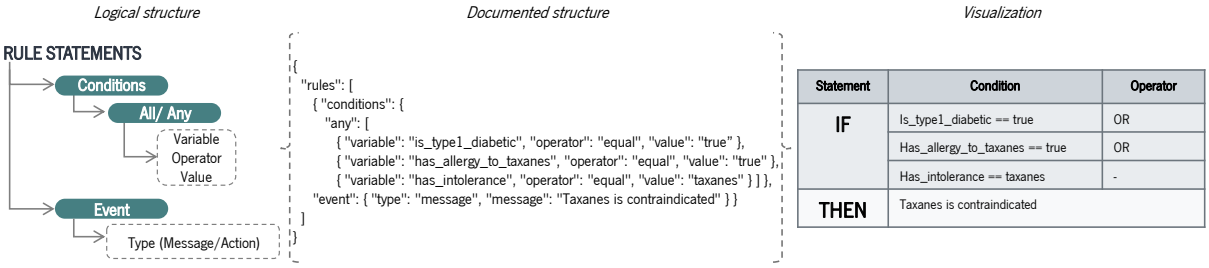


Figure 26: Production rules model processing.

The basis of the logical structure is conditions and events. Conditions have a related conjunction operator (ALL/ANY), which indicates whether the conditions are dependent (if both are true) or whether at least one must be true. After the validation of the condition(s), an event is triggered, which can be a message or an action. The JSON structure has the same logical structure, where rules are created from a condition or a list of conditions connected by 'ALL' and 'ANY' operators. In the visualisation of the example shown in Figure 26, the represented rule is composed of three conditions that at least one of them must be true. If the input parameters satisfy the conditions, a 'message' event is triggered with the text informing that the drug taxanes is contraindicated for the patient.

Decision tables Decision tables are a way to express rules in a tabular representation, composed of a collection of associated input and output expressions specifying which output entry applies to a certain collection of input entries (OMG, 2019). By placing the entries in table cells, the decision table represents the rules in an abbreviated format. In DLE, the structure designed to process decision tables is presented in a logical, documented, and graphical view in Figure 27.

The logical structure is based on columns and rows. The columns identify the input and output variables integrated into the rule. Rows are formed by a set of cells associated with each column, where all possible combinations of conditions are determined. As shown in the visualisation part of the Figure 27, a decision table is formed by a list of N input variables and M output variables, and a set of input entries and output entries. That is, the input and output sections can have one or multiple variables and entries. However, a decision table can have three types of orientation: horizontal with rules as rows, vertical with rules as columns, and crosstab with rules composed from two input dimensions (OMG, 2019). In this work, the focus is on the horizontal format, where the rules are expressed as rows, the input columns are on the left side, and the output columns are on the right side of the table. The standard positioning is based on inputs and outputs and allowable values on a grid of cells.

The JSON structure describes an example of a decision table based on a breast cancer guideline adapted from an example proposed by the openEHR community (Beale et al., 2022). The respective decision table aims to identify the molecular subtype of cancer in the patient, with five possible outcomes. This is formed by four input variables and one output variable, where conditions are determined for each variable. In a nutshell, the decision table produces output value 'o1' if the value of variable 'i1' fulfils

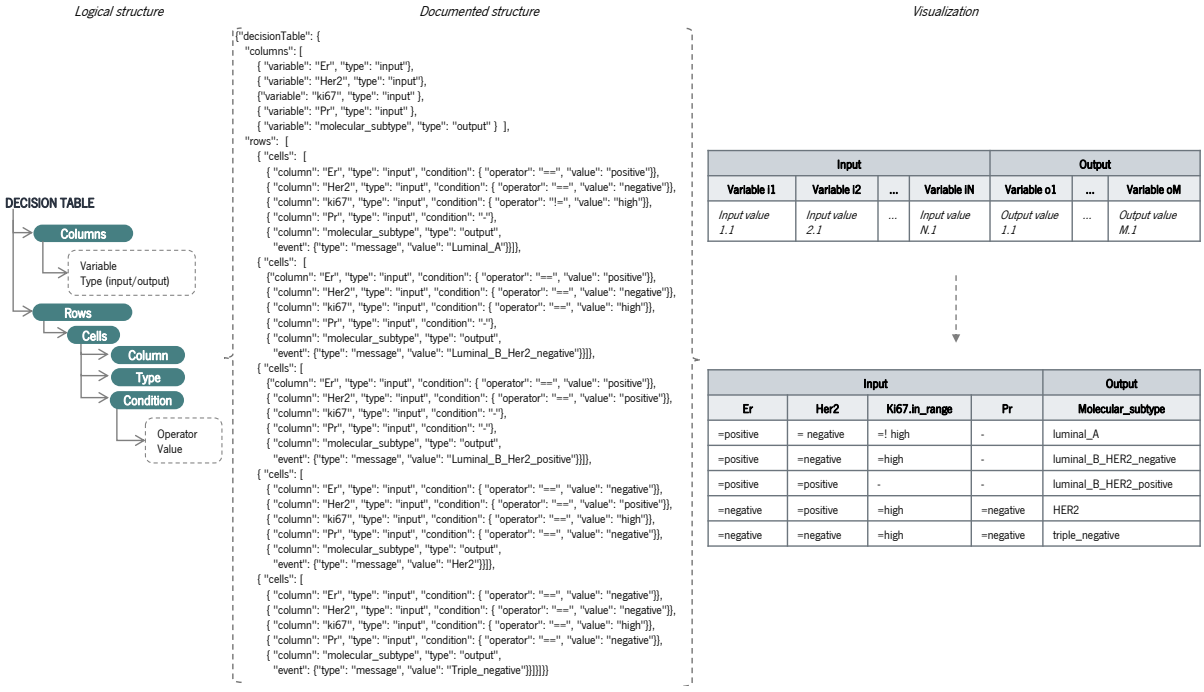


Figure 27: Decision table model processing.

input value '1.1' and the value of input variable 'i2' satisfies input value '2.1', indicating that the rule is satisfied. Taking the example of the first row, the molecular subtype is considered 'luminal A' if the input value of the ER variable is 'positive', the input value of the variable Her2 is 'negative', and the input value of the variable KI67 is other than 'high'. Each value of the variable satisfies the input value if it is set to '-', meaning that the value of that variable is irrelevant to the processing of the rule.

Decision tree As the name implies, decision trees use a tree-based approach to expressing rules. A decision tree is composed of a hierarchical structure based on father and child data nodes (Podgorelec et al., 2002). The decision tree starts at the root node, that encompasses variables as data nodes, branches as conditions and leaves as rule output. The data nodes describe the condition and, if true, proceed to the next associated node. The nodes are connected as data objects, which can have two possible paths to follow. Although a decision tree can have its own decision logic structure, when developing the logic engine it was realised that the result was very similar to the logic of production rules. This is because decision trees have a similar structure to IF-THEN statements. The trees proved useful in graphically visualising the rule structure, as shown in Figure 28.

To better explain how decision tree processing works, the example of the molecular subtype rule to the breast cancer guideline (Beale et al., 2022) was applied. The decision tree starts with the 'ER' variable which can have two values: positive or negative. If the value is equal to negative, the path to follow will be through datanode 1 for PR variable, otherwise it will be followed by datanode 2 for Her2 variable. The connection of the variables demonstrates their dependencies, that is, for the rule output to be 'Luminal B Her2 positive', both the condition Er=positive and Her2=positive must be valid. In this case, the 'OR'

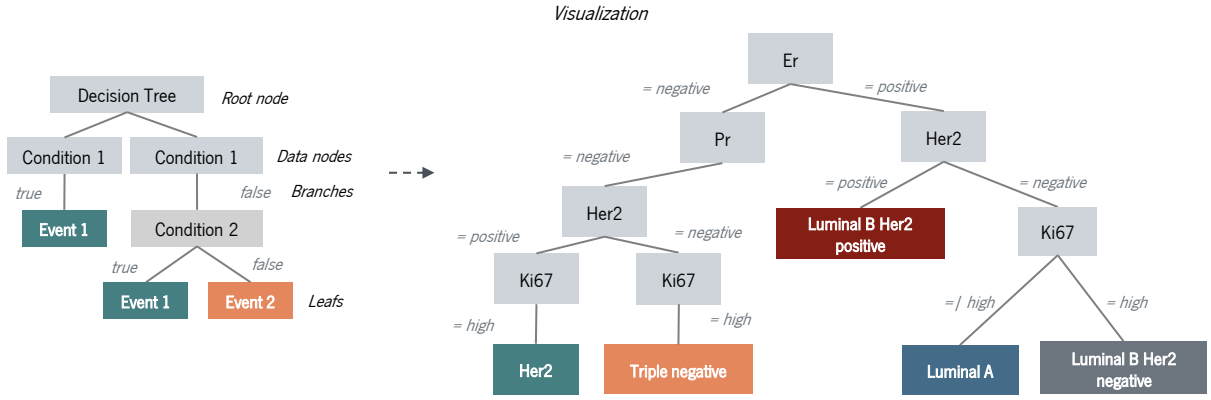


Figure 28: Decision tree model visualisation.

conjuction means another datanode path for at least one condition be valid.

Prediction The decision models of a CDSS can have different functionalities. The models presented so far focus on processing and executing predefined rules. In order to add intelligence to the proposed artefact, a prediction module was designed. This module is composed of three main stages as shown in Figure 29, with the aim of generating decisions and rules for clinical contexts.

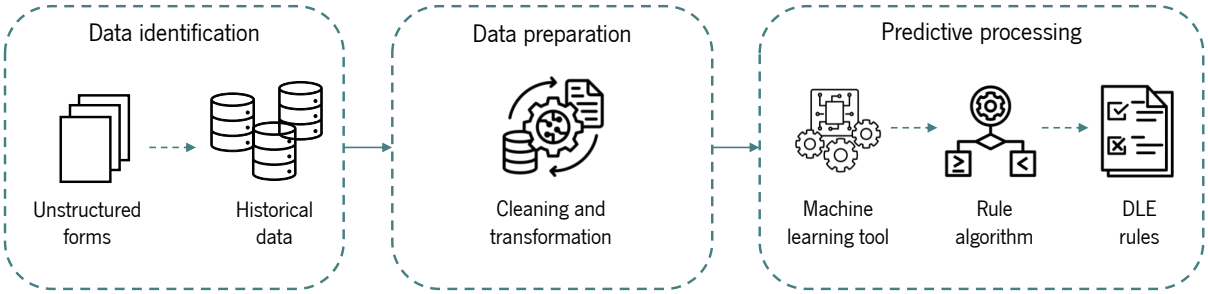


Figure 29: Prediction model processing.

The first step, data identification, involves identifying data from legacy systems, which in turn is in unstructured form. Many healthcare organisations still rely on older systems that store historical patient data. This data can come from various sources, such as handwritten notes, free-text fields in EHR and other unstructured documents. Data management techniques are used to extract the necessary information, ensuring that all data points are captured. Next, the data preparation stage begins, where the extracted data is cleaned and processed to avoid errors and facilitate accurate analysis. After the preparation phase, the data is imported into a ML tool. In this environment, the prepared data is analysed to predict possible clinical decisions and production rules. ML algorithms process the data, identifying patterns and correlations that may not be immediately obvious to human clinicians.

Finally, the predictive process initiates where decisions rules are generated. Through the processing algorithm, the rules obtained are transformed into rules with the structure of the DLM, designed to be

consumed by the proposed DLE. The DLE uses these rules to provide real-time decision support, offering clinicians actionable insights based on the most up-to-date and comprehensive data available. To summarise, the prediction module of a CDSS follows a rigorous and systematic process to transform unstructured and old data into valuable clinical information. Through identification, extraction, preparation, and ML analysis, this module plays a vital role in improving the quality and efficiency of healthcare provision.

5.3.3 Decision system flow

To represent and visualise the entire process of creating a decision module in DLE, Figure 30 shows a detailed flow diagram with a sequence of actions. The purpose of this diagram is to distil and generalise the diverse features of the artefact, fostering a more profound and nuanced understanding and enhancing overall comprehension of its capabilities.

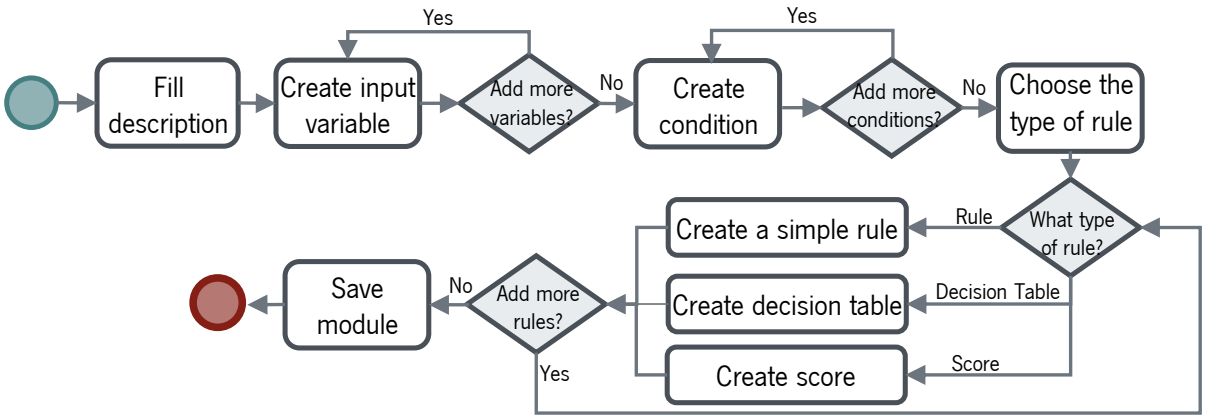


Figure 30: Flow diagram of creating a decision module in DLE.

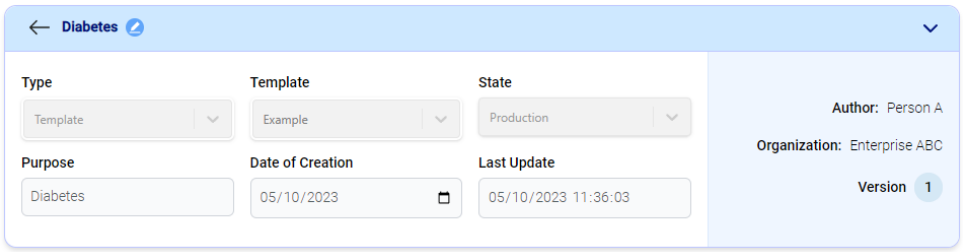
The process initialises by filling in the fields in the *Description* section, which include details about the model (type, status, purpose, creation date, etc), as well as information about its author. The second step is to create the input variables, which can comprise different types, such as input, form field, subject proxy, rule variable, and calculation. The diverse types of variables enable the system to create both complex variables, like rule variables with specific conditions, and simpler ones that only require the input of a name. After that, there are two options: create more input variables or proceed to the next stage of the flow. Once the input variables have been defined, the conditions can be created, as these require an input variable to be joined with an operator and a value. The definition of the conditions in the model are important for the next functionalities.

Once that step has been completed, the process allows for the creation of more conditions or the selection of the type of rule to be created. To create rules, decision models must be selected, which can be production rules, decision tables and score. As stated before, each model has a different way of knowledge representation, leading to a clear distinction in their respective workflows. Simple rule statements operates on IF-THEN logic, decision table involves a set of rules with varied outputs, and

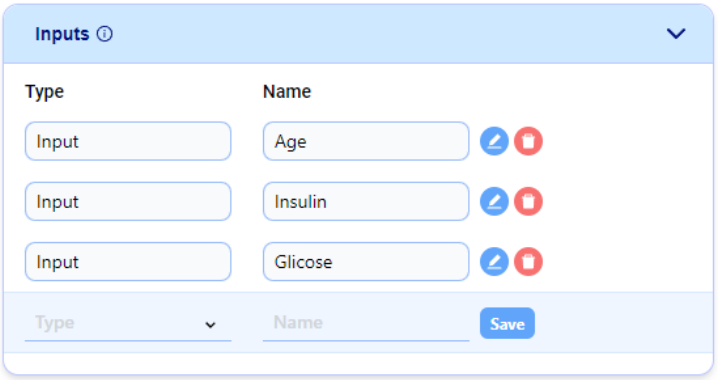
score combines criteria with assigned points, and totals them to produce an output. The process can be expanded by incorporating additional rules or proceed with model validation. After having all the fields created, the tool system is responsible for validating the model, checking whether there are errors in the data entered or missing. Once validated, the model is stored in a standardised form and can be readily integrated and interoperable with the inference engine and other services.

In order to improve the user experience, a web-based application was developed to facilitate the creation of a decision module. The tool developed has a multisectional structure, based on DLM classes. At first glance, a management area of the decision modules created to date is displayed, with some related information such as the name, context, version, status, author responsible and creation date. To start a new process, the option to create a new module must be selected. The sections contained in the creation of a new module will be demonstrated next and will contain a clinical example of the diabetes care flow. It is worth noting that these examples are fictitious and have not been applied in a real context.

When starting to create a new decision module, the first section to be displayed is the module description section. All the relevant data about the module is related to its class and is easily identified and understood in the interface, respecting its theme and creation details. Figure 31 visually represents the initial components of the tool, namely the 'Description' and 'Input' sections.



(a) Description section.



(b) Input section.

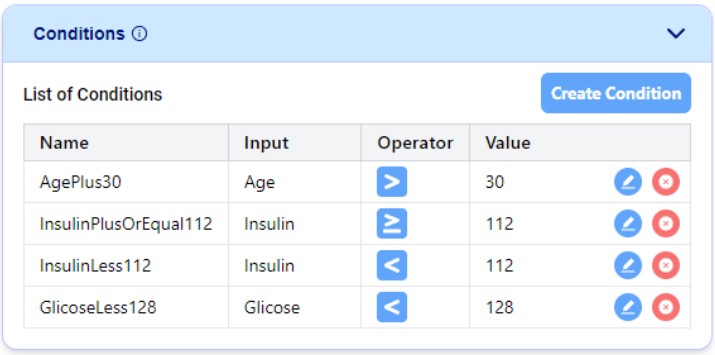
Figure 31: Description and input sections.

In the Description section, Figure 31a, it is necessary to indicate the type of module to be created, which can be a template, a workflow, or a resource, and, in turn, associate the previously created template or task plan. The clinical purpose of the decision module must also be indicated. The creation date, update

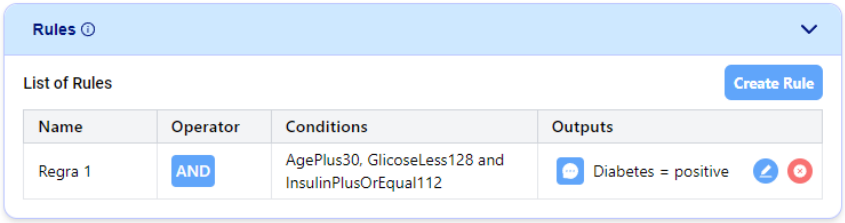
date, status, version, and author information will be automatically recorded by the system. Figure 31b presents the input section that allows the creation of variables to be used in accordance with the rules. Variables have a name, a type, and a possible value that may or may not be associated.

The input variables will provide a starting point for creating the conditions. Therefore, a condition is structured by combining a variable, an operator, and a specified value, identified by an intuitive name. The conditions created are represented in a list, as shown in Figure 32a, which can be edited or deleted. The main effort was to associate the operators defined in the DLE with symbols for better understanding, i.e., '=' (equal) or '>' (greaterThan), contributing to the logical connectives that define the relationships between these variables and values.

After defining conditions, the next section is responsible for creating decision rules related to the inference model, which may be production rules, decision tables or scores. Figure 32b represents the list of rules that are composed of one or more conditions, with a logical operator (AND or ANY) to relate them. If the conditions are truthful, an output is triggered, which can be of the event or message type.



(a) Conditions section.



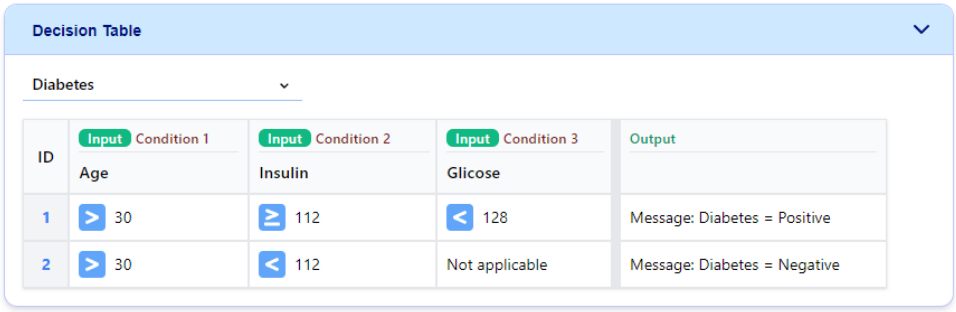
(b) Rules section.

Figure 32: Conditions and rules sections.

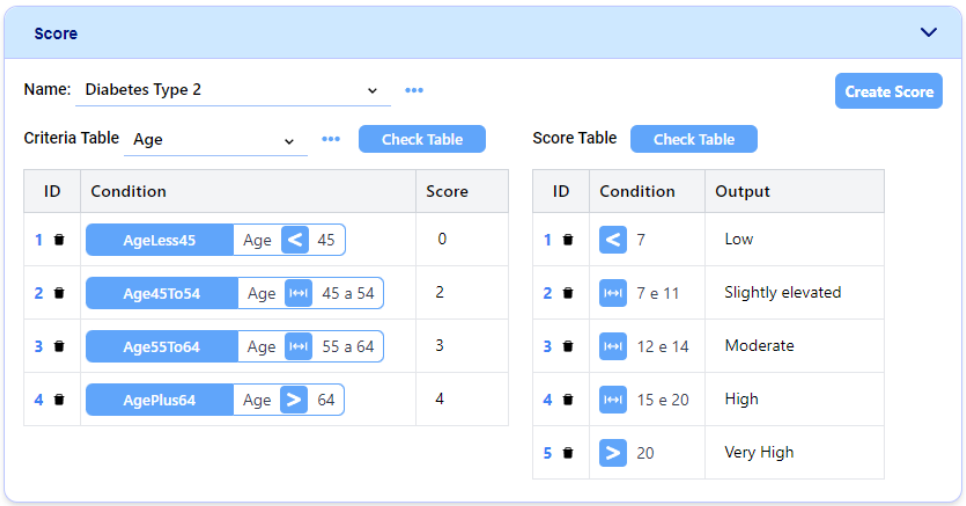
In the case of decision table (Figure 33a), the goal was to create a decision table that was 100% personalised, i.e. the entire process of creating the set of rules, as well as the associated outputs, are all selected in the table itself. There is a division in the table where it is clear that there are conditions on the left and the outputs on the right. Columns can be related with a variable or a rule type.

Scores are a point-oriented decision model, containing two types of tables for criteria and scales (Figure 33b). Each criteria table is linked to a variable and its conditions are associated with a value

point. In the end, all the points are added up and the result can be seen in the scales table, which contains various conditions in relation to the final score. In the tool is possible to create various criteria tables and then access them via a dropdown. Figure 33b presents a table of criteria for the type 2 diabetes risk assessment score for the variable 'age', however, there are other variables associated with the criteria tables for this case, such as BMI, waist circumference, among others.



(a) Decision table section.



(b) Score section.

Figure 33: Decision table and score sections.

Once all the components have been filled in, the rules created can be tested in an appropriate area within the tool. The rule execution area, as illustrated in Figure 34, has direct communication with the DLE inference engine. By indicating the desired module, it is possible to simulate the execution of a rule by entering the values of the variables, enabling to test its functionality.

Overall, the proposed system comprises several sections based on the DL structure. Through a step-by-step process, decision rules can be formulated by specifying variables, conditions and rules. The developed web platform serves as an interface for the DLE, ensuring user-friendliness for healthcare providers. As a result, the establishment of this logical system fosters the emergence of a CDSS that is both semantically interoperable and adaptable.

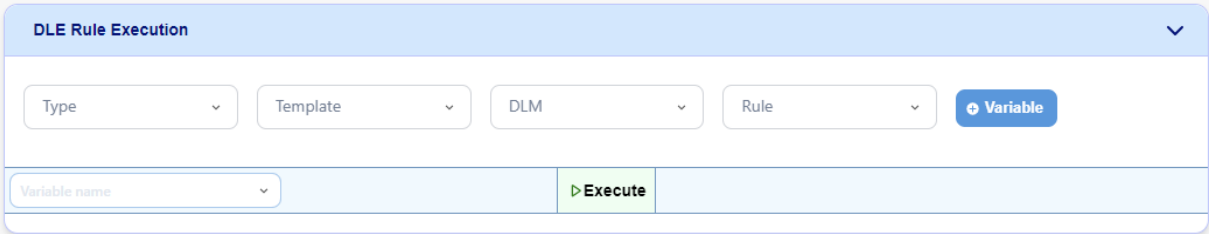


Figure 34: DLE rule execution area.

5.4 Concluding remarks

Designing a CDSS is a time-consuming process and involves big efforts. For this work, the proposed artefact comprises a CDSS originating from the design of a rule-based logical decision system. Its pillar consists of a solid knowledge base and an adaptable inference engine. By using the DLE, rules can be expressed by three different decision models - production rules, decision tables and scores - offering a robust structure to guide clinical decision-making processes. The incorporation of multiple decision models allows the system to accommodate diverse clinical scenarios and preferences, providing doctors with flexible, personalised decision support that aligns with their specific needs and workflows. Whether through the precise application of production rules, the structured approach of decision tables or the differentiated assessment of scores, the system allows healthcare providers to make informed, evidence-based decisions that optimise patient care outcomes.

One of the main strengths of this system lies in its adherence to the openEHR standard, specifically in the DL, which improves interoperability and facilitates seamless integration with existing HIS. This adherence ensures that the system can effectively communicate and exchange data with various EHR platforms and other HIS, thus maximising its usefulness and impact in different healthcare contexts. However, it is important to note that the DL specifications are still under development and contain incomplete information. Consequently, some obstacles were encountered in understanding the DL specifications, which could compromise the development of the DLE. However, this challenge has been overcome, bringing a new contribution to the scientific community. Besides, given its application within a real hospital setting, any uncertainties were addressed collaboratively with specialists from both IT and medical domains. Thus, the incomplete aspects of the DL were appropriately finalised, ensuring alignment with specifications.

This chapter showcases the integration of the artefact with different openEHR-based systems and services, affirming its interoperability and versatility across diverse care contexts. Furthermore, the adopted flow for the proposed decision system allows the easy creation of rules regardless of the coding of the system. The multi-sectional approach of the DLM facilitates the interpretation and association of each component involved in the rule. Thus, healthcare professionals, as the end users in this case, will have the ability to define the necessary rules for any clinical workflow without relying on IT specialists. This demonstrates a major step forward in the design of CDSS, enabling the formation of a collaborative environment involving healthcare professionals in the rule creation flow, allowing them to be independent from HIS developers.

To summarise, the proposed CDSS represents a fundamental advance in healthcare technology, offering a versatile and interoperable solution to guide clinical decision-making. With its basis in openEHR and the use of logical models, the system has the potential to revolutionise the way healthcare providers handle patient care, ultimately leading to better outcomes and higher quality of services in all care settings.

6

Clinical Decision Logic: A Practical Point of View

After outlining the design of the proposed artefact, this chapter aims to demonstrate its real-world application within a hospital setting. Three demonstration cases will be addressed, encompassing different care scenarios, including medical imaging exams, corneal transplant, nutritional risk screening, and obstetrics.

6.1 Contextualisation

CDSS aims to support the provision of integrated, effective, safe and high-quality healthcare. However, the amount of data produced every day in different formats and data structures from different systems is a major obstacle to the quality of healthcare, by producing different clinical artefacts with semantic interpretation (Kopanitsa, 2017). The EHR produced daily need to be extracted and used to generate clinical knowledge. Nonetheless, most of these records are not commonly available or even structured, which leads to dispersion, inability to understand and sometimes loss of data. Consequently, data standardisation promises to overcome these challenges, leading to efficient data analysis and better CDS techniques for care processess (Hak et al., 2020).

One of the most significant points of the adoption of CDSS in healthcare organizations is its ability to deal with complex and uncertain situations in which certain traditional approaches may be insufficient (Shahsavarani et al., 2015). By drawing on recorded knowledge of past cases, a CDSS can provide personalised and contextually appropriate recommendations, tailored to the unique characteristics of each patient. After adaptation, the recommended solution is proposed to address the current problem. This recommendation is often based on the outcomes of similar cases in the past, providing a valuable reference for decision-making.

Nevertheless, healthcare professionals maintain the ultimate responsibility for verifying the suitability of the recommendation and making any necessary adjustments based on their clinical judgment and the specific needs of the patient. In addition, CDSS should facilitate the continuous improvement of health systems. As new situations are encountered and the results recorded, the knowledge base must increase, enriching the repository of records available for future decision-making. This iterative process promotes a cycle of continuous improvement, in which the system becomes increasingly able to provide accurate

and effective recommendations over time.

6.2 Related work

Despite the widespread computerisation of processes in care institutions, the way care processes are handled differs from service to service, even if they are part of the same organisation. Numerous studies have explored various solutions within this domain. Marcos et al. (2013) developed a study with the aim of developing a CDSS based on archetypes to make it compatible with EHR from different institutions. By modelling openEHR archetypes, it was possible to map the necessary clinical concepts, associating them with structural and terminological semantics. For shared CDS integration, Marcos et al. (2013) sought a mechanism based on guidelines capable of separating data references from logical decision rules. To this end, an inference engine was developed based on the standardised guideline representation language, PROForma. The proposed approach was applied to a demonstration case for colorectal cancer screening designed to compare the efficacy of two screening procedures. The authors concluded that the use of archetypes proved satisfactory for achieving interoperability between CDSS and EHR and offers several advantages, particularly from a data model point of view (Marcos et al., 2013).

More recently, Li et al. (2020) proposes a shared approach based on openEHR modelling for diagnoses and treatments in the case of Covid-19. The approach followed an analysis of the Covid-19 diagnosis and treatment China guidelines, identifying the data items used. This was followed by the construction of the template, based on the modelling of archetypes to represent the concepts of the domain. The template developed was inserted into the openEHR-based clinical data repository and retrieved by API services. In addition, this study used a CDSS tool capable of consuming these structures, consisting of a knowledge base and an inference engine. There is no evidence of rule creation for this study, however, the authors point out that the representation of the guideline in a modelled form for this care flow proved to be satisfactory (Li et al., 2020). The openEHR modelling covered all the requirements and facilitated the application of the process, particularly due to the separation of information from knowledge. When there are updates to diagnostic and treatment knowledge, only the template needs to be updated, while the applications remain unchanged, thus facilitating the rapid integration of the latest knowledge into clinical practice.

Based on the motivation to overcome interoperability problems found in CDSS, Li et al. (2021) carried out a study to develop a patient screening tool based on openEHR to resolve concept incompatibility and improve query performance. OpenEHR archetypes and templates were chosen to define concepts directly from EHR. In defining the proposed approach, a need was identified to generate instances of rules in the modelling. To this end, the authors used openEHR's Expression Language (EL) to define the syntax of expressions for specifying archetype rules, particularly for defining screening conditions. Arithmetic operators, relational operators and logical operators were used to form the EL-based rule operations. Although some concepts can be defined according to rules directly from openEHR models,

some complex concepts and constraints cannot be derived from these models in practical cases. The approach adopted by Li et al. (2021) facilitates interoperation between systems, however, it does not provide a flexible approach to defining CDS rules. This limitation is also emphasised by the authors, who state that transforming conditions into a computer-interoperable format facilitates the representation of rules and the extraction of knowledge (Li et al., 2021).

Newer research indicates a broader perspective on openEHR, comprising various specifications components. The need for a conceptual formalism for clinical pathways motivated Iglesias et al. (2022) to adopt the TP specifications. Their study aimed to represent typical process patterns for treating infections. Using a four-phase methodology, the authors identified the main concepts for the infection pathway, modelling the workflow and its relevant concepts, and analysing the results. By applying this approach, the authors conclude that it was possible to easily represent the same applied logic as previous processes but in a simpler way. Despite mentioning DL specification as a complementary component to TP, this study only addresses DL decision modules as a possibility of integration, with no real practical applications and leaving the development of DL rules for future work (Iglesias et al., 2022).

6.3 Demonstration

A CDSS plays a crucial role in increasing efficiency, accuracy and patient outcomes in various departments of a hospital. The application of the proposed decision logic system will be explored with regard to its application in four different use cases: the imaging examination pathway, the corneal surgery circuit; nutritional risk screening; and obstetric care. All the demonstration cases have been tested and applied in the same Portuguese hospital centre. The application in a real environment demonstrates its versatility and effectiveness in improving clinical workflows, enhancing decision-making processes and ultimately optimising the results of patient care in a hospital environment.

6.3.1 Imaging exams use case

The automation of hospital workflows is of fundamental importance in modern CDSS, improving operational processes and better patient care (Johnson et al., 2014). The adoption of automated workflows, particularly those aligned with open standards such as openEHR, facilitates the capture of accurate data, promotes better communication channels and ensures the timely execution of tasks among healthcare professionals. These efforts culminate in reduced errors, improved patient outcomes and optimised use of resources (Iglesias et al., 2022). In order to demonstrate the operation of the proposed system, this demonstration case focuses on automating the process for the imaging exams pathway conducted in a Portuguese hospital centre.

After implementing the proposed system, data was collected on the triage process, revealing a positive acceptance of the proposed artefact by healthcare professionals. This is underlined by an analysis showing a notable reduction in waiting times for outsourcing management. In summary, this use case

demonstrates the application of a new approach to the imaging workflow using the openEHR specifications, culminating in an automated process with structured data generation. The comparison of this new approach with the previous approach is remarkably positive, marking a fundamental step towards efficient knowledge discovery through the recording of high-quality structured data.

6.3.1.1 Introduction

Improving clinical workflows within hospitals is a critical concern for healthcare management at all levels (Y. Chen et al., 2015). Inefficient workflow performance not only leads to wasted resources but also compromises the quality of healthcare delivery (Ozkaynak et al., 2016). A significant barrier to the adoption of automated processes is the inadequate representation of unstructured records into actionable knowledge (Wulff et al., 2020). The dispersed and heterogeneous storage of records hinders efficient communication among systems, thereby impeding interoperability and risking data loss (Cardoso et al., 2014).

Open standards, such as openEHR, aim to address this challenge by advocating for standardised structures and interoperable models (Demski et al., 2016; Haug et al., 2018). The openEHR standard specifications, through its archetype-based data model, offer the application of standardised and automated workflows through rules and task definitions (Christensen & Ellingsen, 2016; Kalra et al., 2005). Therefore, the objective of this use case is to develop a novel approach to hospital workflows focusing on the imaging exams pathway. Key variables within this workflow include exam types, available resources, and contextual factors influencing requests. External requests or outsourcing also play a significant role in imaging exam workflows. The overarching objective is to establish efficient hospital workflows capable of reducing errors, implementing safety protocols, eliminating unnecessary redundancies, and guiding patients toward the most effective treatment paths.

6.3.1.2 Methods

The methodology employed in this use case is outlined in Figure 35 and consists of distinct phases and steps. The initial phase involved establishing direct communication with the team responsible for the workflow to gather requirements. Following this, the components of the proposed system were modelled and integrated, including archetypes and templates, DLE rules, WE tasks, and FE forms.

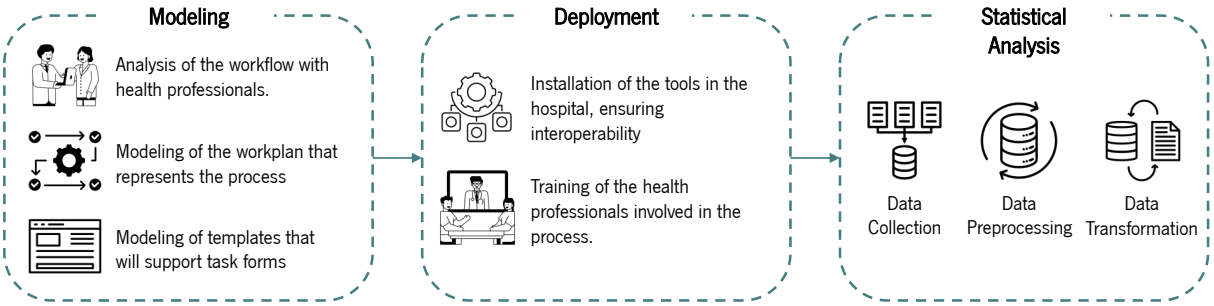


Figure 35: Adopted methodology for the imaging exams use case.

Requirements gathering The requirements-gathering phase involved conducting focus groups, consisting of interviews and meetings with healthcare professionals, including doctors and administrative technicians, who play key roles in the imaging workflow. The existing process was not fully computerised and used scattered resources such as paper records, spreadsheets and legacy systems. This made it difficult for professionals to work, wasting time recording and searching for information they needed, as well as correcting errors. Thus, the need arose to automate the process of clinical triage of imaging requests, which often require external processing due to capacity constraints. The workflow encompasses distinct teams, each responsible for different aspects of the process: the Magnetic Resonance Imaging (MRI) team, Computed Tomography (CT) team, and the management office handling external requests. Consequently, it was imperative to assign tasks to team members based on their capabilities, roles, and functions.

The development of openEHR templates, which form the foundation for data entry forms used in various imaging exam workflow tasks, began with gathering data requirements. The main stakeholders involved in this process included healthcare experts familiar with openEHR, archetype development, clinical terminologies, and rule definition. Throughout this process, three primary scenarios emerged: clinical screening/triage (SC1); manage external request (SC2); confirm external result (SC3).

Modelling The modelling phase focused on ensuring that all the functional and technical requirements were met. Given the lack of modelling experience in the hospital community, collaboration between openEHR experts and healthcare professionals was essential. To carry out this process, various tools were used, such as Draw.io for creating TP-VML diagrams (Beale, 2019b) complemented with specific libraries, and Archetype Designer (AD) for modelling archetypes and models (Oliveira et al., 2021).

After modelling in the respective tools, the work plan was exported as an OPT file and then converted to JSON, having been improved to include some points that could not be integrated with the modelling tool used. The finished JSON was stored in the database as a document, ready to be materialised and computed by WE. With regard to the openEHR structures, the stakeholders determined the content of the archetypes, their structural organisation and the applicable data restrictions, such as data types, cardinality, occurrences and specific data values, including terminologies for coded values. The search for relevant archetypes was carried out in the CKM repository. When there were no corresponding archetypes, new ones were created.

With the selection and modelling of archetypes, templates were developed based on a combination of purpose-oriented archetypes. Unlike archetypes, templates are adapted to specific contexts, prioritising the usability of information over general reuse. The archetypes were collated and constrained into templates representing the requirements of each initial scenario, using the AD tool. Although three scenarios were identified, only two models were created: *Clinical Order Triage* and *External Order Management*, since different template configurations could produce different data sets from the same archetypes. The first template served SC1, while the second served SC2 and SC3. These templates were exported in OPT

format and then converted into a JSON Data Template (JDT) structure to facilitate interpretation and manipulation (Beale, 2019a). Finally, each JDT template was injected into the FE tool, where professionals with modelling knowledge formatted the user interface forms.

Deployment Ultimately, the system had to be implemented, tested, and deployed within the hospital institution. This implementation involved integrating a suite of components from the proposed system. The WE was integrated to manage all workflows modelled by the health professionals, including materialization, task status, decision management, allocation of performers, events, and actions management. FE was responsible for converting openEHR templates into forms, allowing professionals with modelling knowledge to format the user interface forms, such as setting colours and letters, showing/hiding fields, associating functions, refsets, etc. The DLE was crucial to define and process clinical and operational rules, supporting the logic of the process for both the FE and the WE. Rules were created following a set of conditions, in order to verify its veracity. In this use case, a HIS was used, which presents a detailed list of the tasks assigned to health professionals and allows the submission of forms to complete these tasks. Several user demonstrations were realised, accompanied by comprehensive documentation to ensure the proper and straightforward use of the modules provided.

Data analysis After successfully implementing the solution within the hospital, health professionals commenced executing tasks, forms and rules using the openEHR ecosystem. These activities were logged in a structured database, facilitating data extraction for further analysis. The dataset comprised 18795 recorded events, encompassing six types of activities (sending for triage, request triage, outsourcing request, outsourcing management, outsourced result confirmation, and triage recovery), and 6815 exam requests. These events were documented between mid-October 2021 and December 2022. To assess workload variation over time, key attributes were included, such as *request_id*, *event_type*, *user* and *date*. Additionally, a second dataset was compiled, focusing specifically on the hospital's MRI outsourcing activity. This dataset comprised 15064 records from 2018 to 2022, sharing the same attributes as the first dataset. However, it also incorporated order dates and waiting days between order and outsourcing management dates. This data collection was possible due to the existence of older EHR containing outsourcing details, contrary to the non-digital clinical triage process.

Furthermore, a performance analysis of the DLE was conducted to guide the focus of this work. The data analysis provides information involving the evaluation of response time, which has a direct impact on the user experience and the care provided to patients. A CDSS with fast response times guarantees timely access to vital information, facilitating decision-making and automation of the workflow implemented. In addition, the system's capacity for processing requests was assessed. A reliable CDSS must effectively manage incoming requests, whether for diagnostic assistance, treatment recommendations, or medication alerts. The evaluation of request management analyses the scalability of the system and its performance regarding the different workloads of the flow handled.

6.3.1.3 Results

This use case application reached the implementation of the imaging exam pathway in a Portuguese hospital, alongside the existing infrastructure. The system was gradually deployed to facilitate a smooth transition, initially involving a limited number of users. Functional demonstrations and explanations of tool usage were provided to ensure team members' understanding. Figure 36 presents the outcomes obtained with the application of the proposed system. Based on the archetypes and templates modelled, three forms were processed by FE. In parallel, three task plans were defined within the WE, and two DLM with three rules each were developed according to the DLE processing. As a result of the implemented flow, 17908 tasks were submitted.



Figure 36: Overview of the outcomes obtained from the proposed system.

Imaging exam workflow As stated before, the workflow was modelled according to the openEHR TP specifications, resulting in three task plans, as shown in Figure 37. To meet the necessary prerequisites, three interconnected task plans were modelled: *Manage Imaging Exam Requests*, *Clinical Triage*, and *Outsourcing Management*.

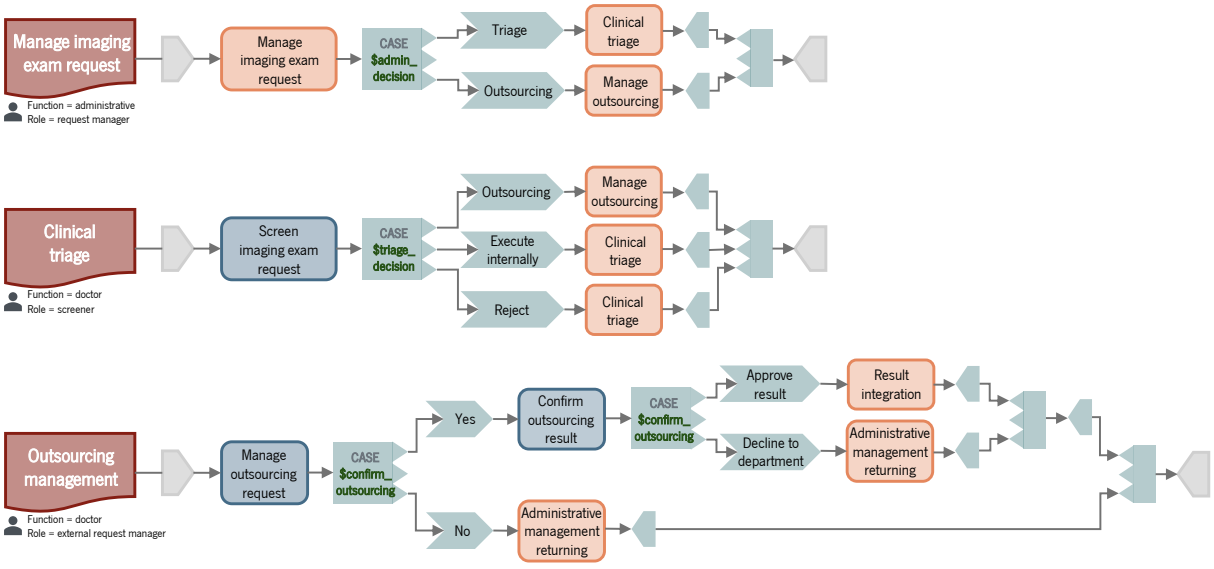


Figure 37: Manage Imaging Exam Request WP modelling.

The *Manage Imaging Exam Requests* plan allows for the triage of imaging exams and/or referral to external entities (outsourcing). The first task of the top-level task plan involves a system request to ensure interoperability with the IS responsible for managing all exam requests. This task includes sending a

request, awaiting a system response, and subsequent management via customized actions, specified by distinct key values tailored for remote events.

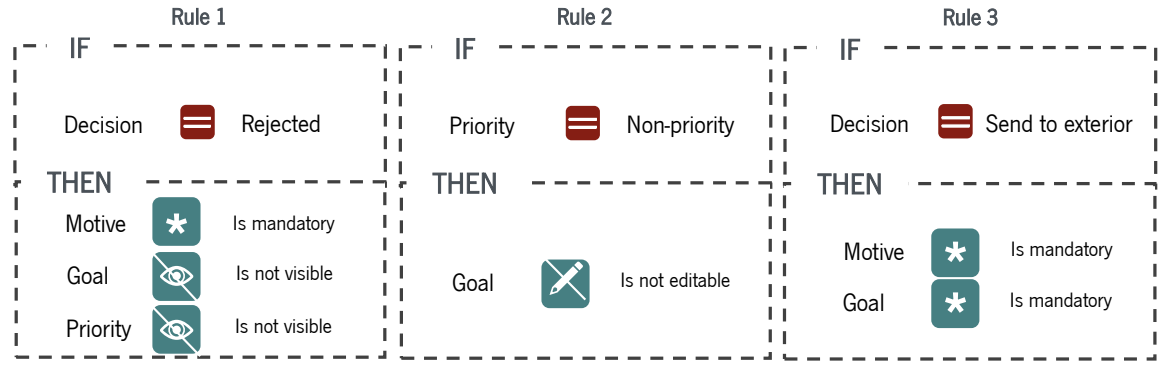
Upon successful completion of the initial task, the *$admin_decision* rule is called. The *$admin_decision* is a decision group that represents the decision structures of the TP specification. A Decision Group defines a decision point or a 'case' in which there is more than one possibility to proceed with the flow. These possibilities or conditions are the decision branches defined by the decision group. When a decision group is encountered, the WE sends a request to the DLE, prompting the execution of rules associated with a previously created DLM. This DLM is linked with the TP in the DLE's knowledge base, facilitating the processing of rules contained in the logical module of the workflow. Upon evaluating the rule conditions and deriving a conclusive outcome, the DLE sends the result back to the WE service, determining which decision branch to follow.

In this case, the first decision group (*$admin_decision*) refers to the decision to make the imaging exam at the hospital itself or an external institution (outsourcing). If the physician's evaluation indicates an outsourcing approach, the *Manage outsourcing* TP is activated. Allocated to the external exams management team within the demographic, this TP comprises two performable tasks with distinct forms. The management form in the first task allows professionals to determine whether the request should proceed externally or be declined. If outsourcing is settled, a confirmation task arises to verify the outsourcing results. The form for this task evaluates the request's outcome, confirming outsourcing result receipt, department refusal, or simple request refusal. In the case of result refusal, the process repeats, as the main task group includes a repeat task property, with the stopping condition being the 'Declined' state of the variable *outsourcing_result*. On the other hand, if the physician's evaluation indicates that the exam should be realized in the hospital, *Manage outsourcing* TP is activated.

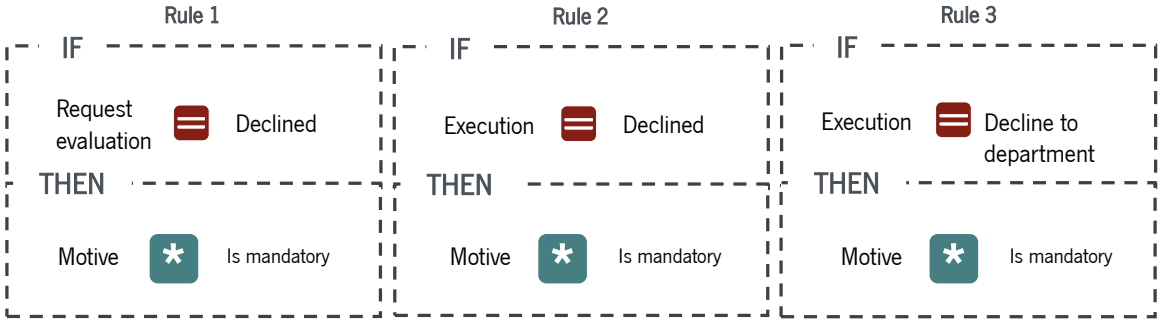
OpenEHR forms and decision rules As outlined in the modelling phase of the methodology, the selection of archetypes and the construction of templates originated forms processed from FE. These forms were linked to distinct performable tasks within the imaging exam workflow, serving as storage schemes for various patient tasks. They are integrated into the HIS that is a web application for healthcare teams to fulfil their assigned tasks.

Each form features decision rules established and executed by the DLE. Two logical decision modules have been created in the DLE, corresponding to DLM1 for clinical triage (Figure 38a), and DLM2 managing exam requests abroad (Figure 38b). The rules created for the two DLM were all of the production rule type, as illustrated in Figure 38.

For the first rule of DLM1, the condition is to have the variable *Decision* equal to rejected. If this is the case, the *motive* field becomes mandatory, and the *goal* and *priority* fields are not visible. On the other hand, if the *Decision* is equal to send to exterior (rule 3), the *motive* and *goal* fields are set to mandatory. The second rule defines the type of priority, where if the request is not defined as a priority, the *goal* field is left not editable.



(a) DLM1: Decision triage.



(b) DLM2: Exterior request.

Figure 38: Rules created for the imaging exam use case.

For the exterior request DLM, rule 1 defines the *request evaluation* as declined, transforming the *motive* field as mandatory. In rule 2, if the variable *Execution* is equal to *declined*, then the *motive* is mandatory. For rule 3, the *Execution* must be equal to *decline to department* for the *motive* be mandatory.

Performance analysis After completing a successful testing phase, the initial version was rolled out in the end of 2021, although not all aspects were initially addressed due to subsequent requirements. In this context, conducting a performance analysis becomes imperative to objectively evaluate the impact of the solution implementation. Emphasising the DLE, an analysis of its performance was carried out for this use case, presented in Figure 39.

The Average Response Time (AVGRT) for both decision modules was calculated using the response time of the requests and the total number of requests. The Average Number of Requests (AVGREQ) per day was also calculated, using the total number of requests divided by the total number of days covered. Figure 39a presents the results obtained from applying the metrics. For decision triage (DLM1), the AVGRT was 661.6ms, whereas for the external request (DLM2) it was 493.8ms. This indicates that the external request module is 167.8ms faster than the decision triage module. Although there is no concrete evidence explaining this difference, since both modules have the same number of rules created, the fact that DLM2 only has one event to trigger in each rule may contribute to the shorter response time.

Furthermore, the number of rules executed by the DLE for each decision module was counted, as



(a) AVGRT and AVGREQ for both DLM.



(b) Count of rules executed for the forms.

Figure 39: Results obtained for the imaging exams use case.

shown in Figure 39b. It was found that, for the decision triage DLM, rule 1 (corresponding to the decision being rejected) was the most called, with a difference of almost half to rule 3. This indicates that most requests for imaging exams were rejected instead of being forwarded for an external request. In contrast, for the external request DLM, there was no significant difference in the number of executions among the three rules.

To conclude, Figure 40 shows outsourcing orders from 2018 to 2022 (depicted by bars) alongside the average yearly wait days for processing (represented by lines), offering insights into the impact of the proposed system. Although more outsourcing tasks were completed in 2022, there was a significant reduction in the average days between exam requests and outsourcing team management, indicating a notable improvement compared to the overall average (dashed line). Given that the MRI outsourcing management circuit integrated the solution in 2021, these reduced wait times in 2022 suggest a positive impact attributable to the system's implementation.

The mean difference in waiting days between 2019 and 2022 is 30.857, indicating the magnitude of the change. In other words, patients experienced approximately 30.857 fewer waiting days on average in 2022 compared to 2019. Besides, it is noted that clinical triage tasks were predominant at the beginning, with a notable shift towards outsourced examinations in the following months. This transition can be attributed to the initial workflow restrictions, where requests had to undergo clinical triage before being managed externally. Particularly significant is the increase in outsourced management from February

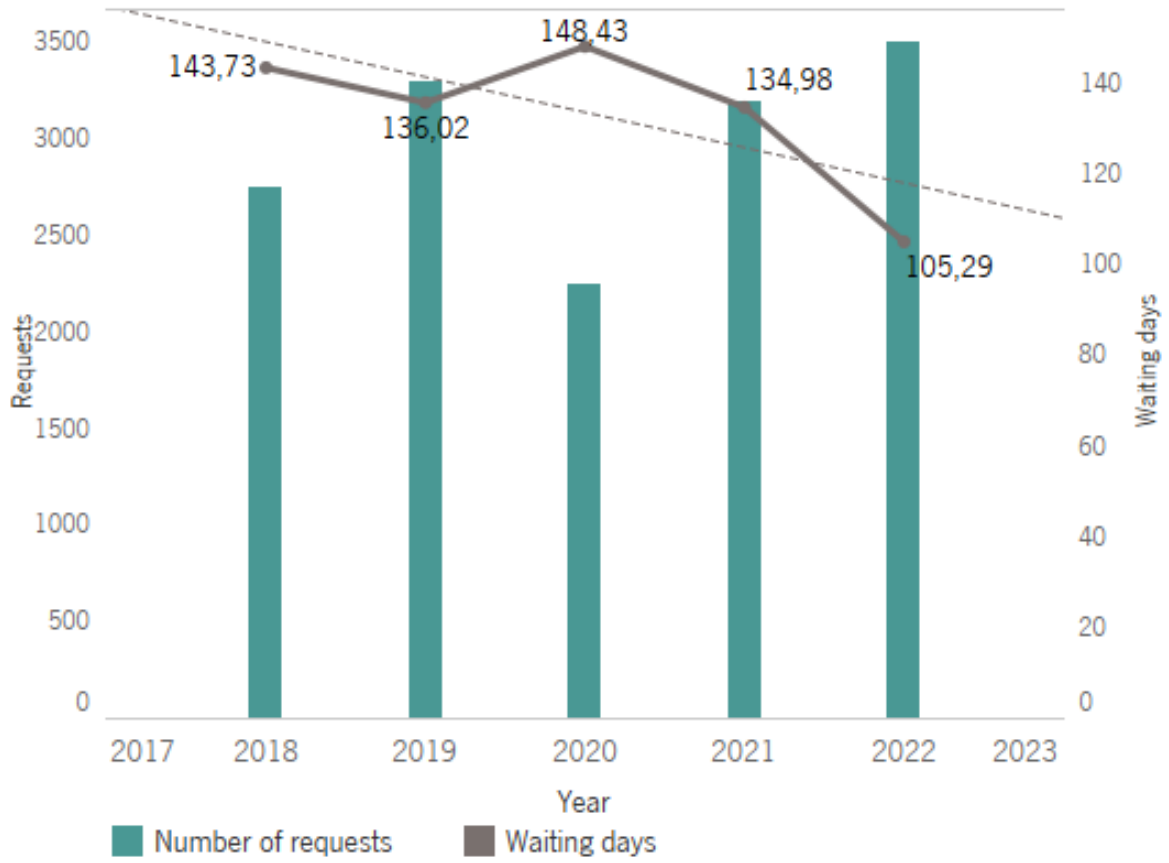


Figure 40: Tasks performed over time and outsourcing waiting times.

onwards, probably due to direct administrative outsourcing without the need for clinical triage.

6.3.2 Corneal transplant use case

The surgical procedure of corneal transplantation, also known as Keratoplasty, is frequently performed to restore vision affected by corneal damage. The accurate and timely management of patient data, achieved by EHR, promotes the success of such procedures. However, existing EHR systems often lack cohesion and consistency, resulting in challenges regarding data accessibility, sharing, and patient safety.

Recognising these issues, there is a growing demand for standardised EHR to guarantee data accuracy in healthcare institutions. Therefore, this use case advocates the adoption of openEHR to standardise corneal transplant registries, to improve the quality and interoperability of EHR, thereby simplifying data capture, sharing and analysis for healthcare providers.

Based on the proposed system, a systematic approach was taken to implementing standardised clinical records using openEHR specifications, involving collaboration with healthcare professionals to model archetypes, templates, forms, decision rules and WP. The resulting customised solution aims to optimise healthcare delivery for corneal transplantation while aligning with contemporary clinical practices.

By incorporating forms, DLMs and WPs, the solution was successfully integrated into a Portuguese hospital. Analysis of the data collected during the implementation period revealed improvements in task management and patient follow-up. Overall, the corneal surgery use case highlights the importance of adopting openEHR structures, particularly achieved by automating rules and processes to standardise corneal transplant records, demonstrating the implementation process and highlighting the benefits of standardised EHR in this field.

6.3.2.1 Introduction

The eye is a sensory organ that allows living organisms to receive and interpret visual information from their environment. For humans, sight is a primordial sense, influencing every aspect of daily life (WHO, 2019). The ability to see is intrinsically linked to the collaboration between the eyes, the brain and the nervous system (Bourne et al., 2021). Visual impairment occurs when there is a disturbance in the visual system, affecting one or more of its functions. Especially in less developed regions with limited access to healthcare, blindness represents a significant public health challenge (Singh et al., 2019). Its impact goes beyond physical limitations, affecting individuals' independence and social interactions, often leading to feelings of isolation and depression (WHO, 2022).

A WHO (2019) vision report revealed a staggering figure of approximately 2.2 billion people worldwide affected by visual impairment or blindness. This prevalence is not only worrying for its physical implications but also for its wider social and economic ramifications (Bourne et al., 2021). The economic cost of blindness includes reduced labour force participation, decreased productivity and increased healthcare spending, which burdens individuals and governments. Consequently, the knock-on effects of blindness extend to families, communities and society in general, emphasising the urgent need for approaches capable of tackling this global challenge (WHO, 2019).

Worldwide, the demand for ophthalmological care services is expected to increase dramatically over the next decade, without the presence of an assertive measure, which represents a significant challenge for the healthcare sector (Steinmetz et al., 2021). To meet this growing demand, innovative solutions are needed to guarantee the provision of quality ophthalmological services. The cornea stands out as an essential structure of vision, being the outermost transparent layer located at the front of the eye (Bourne et al., 2021). Acting as a transparent window, the cornea allows light to enter the eye and reach the retina, which is converted into electrical signals to be interpreted as visual information by the brain. To maintain clear vision, the cornea must remain transparent and free of any obstructions, such as scars or opacities, allowing light to reach the retina (Singh et al., 2019).

According to the WHO (2022), corneal opacities are the fourth leading cause of blindness worldwide and can be caused by certain diseases such as diabetic retinopathy and retrolental fibroplasia, which can affect the transparency of the cornea and lead to loss of vision. Fortunately, many cases of visual impairment can be resolved through corneal transplantation. This procedure offers effective rehabilitation for corneal blindness by replacing a damaged or diseased cornea with a healthy cornea from a donor. Due

to the absence of blood vessels in the cornea, the risk of graft rejection is significantly minimised, making corneal transplantation one of the most successful types of organ transplantation capable of restoring sight and improving patients' quality of life (Steinmetz et al., 2021; WHO, 2022).

The success of corneal transplantation depends on the accurate and timely management of patient information, from pre-operative assessment to post-operative care. EHR are essential for processing clinical data, offering a centralised view of patient records and improving communication between healthcare providers. Effective use of EHR can significantly improve the outcomes of corneal transplant procedures, leading to better patient outcomes and a more streamlined care process. By minimising errors and inconsistencies in data management, EHR play a vital role in reducing adverse events and ultimately improving corneal transplant success rates (Dobrow et al., 2019). However, traditional EHR systems often suffer from a lack of standardisation and consistency, resulting in fragmented management and documentation of corneal transplant records. This fragmentation leads to challenges in accessing and sharing information, increased risks of medical errors and compromised patient safety. In addition, the lack of standardised formats prevents healthcare professionals from accessing comprehensive and accurate patient data, leading to inefficiencies in patient care (Dobrow et al., 2019).

Therefore, the application of the openEHR-based system promises to overcome these challenges, guaranting the accuracy and consistency of patient data across all healthcare settings. The adaptability, flexibility and scalability of openEHR's modular approach make it an ideal solution for dealing with the complexities of health data management in organisations of all sizes. Hence, CDSS can improve the processes for managing and documenting corneal transplant records, ultimately improving care and outcomes for patients.

6.3.2.2 Methods

This use case presents a specific methodology that outlines the sequential process of transitioning corneal transplant registries in a Portuguese hospital to adhere to the openEHR specifications. Unlike conventional methods, openEHR distinguishes data from applications and services, offering an unprecedented level of adaptability. This facilitates seamless adaptation to changing requirements, technological advances, healthcare regulations and other external influences. Furthermore, by separating the data layer from the application layer, openEHR integrates a diverse set of health data from disparate sources. This integration ranges from basic patient information to complex clinical data, regardless of its original format.

In this use case, the methodology used adopts openEHR to contribute to ongoing efforts to improve the quality and safety of healthcare provided to patients through the adoption of standardised EHR systems. Therefore, Figure 41 illustrate the methodology adopted in this case, covering three phases: requirements collection, modelling, and deployment.

Initially, the aim was to perform a use case on the transformation of corneal transplant records in a specific hospital institution. Recognising the critical importance of direct communication with the medical team, efforts were focused on establishing a robust line of interaction to conduct a gathering of essential

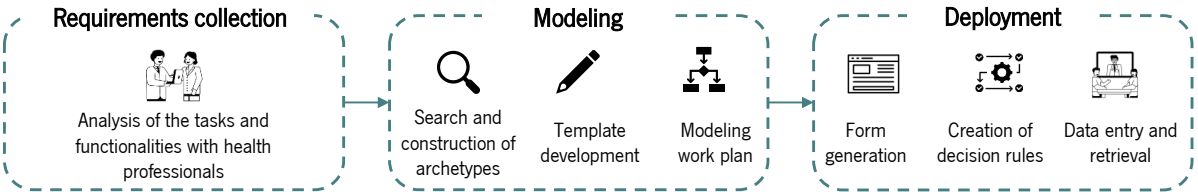


Figure 41: Methodological approach for the corneal transplantation use case.

requirements and prerequisites. These exchanges are fundamental to acquiring the primary knowledge needed to model the use case with the utmost rigour and thoroughness, ensuring the meticulous recording and documentation of all pertinent details relating to the care pathway of patients undergoing corneal transplantation.

Subsequently, modelling the openEHR structures began to support the registration and management of corneal transplant records, as well as the timely execution of the associated tasks. This modelling includes the development of archetypes, templates, forms, decision rules, and work plans. The following subsections will provide a detailed characterisation of the work carried out in each of the phases described in the methodology.

Requirements collection The process of gathering requirements is a fundamental step in the development of healthcare systems and applications, laying the foundations for ensuring that the needs and expectations of all stakeholders are comprehensively understood and integrated into the final solution. Consequently, the methodology initiates with stakeholder identification, involving healthcare professionals and IT experts. The selection of stakeholders was guided by the necessity to form a focus group, involving diverse staff members from the hospital institution related to the corneal transplantation workflow. The collaborative effort to gather requirements for enhancing corneal transplantation records with openEHR encompassed active engagement from medical staff, IT personnel from the hospital's IS department, and developers.

Following the creation of the working group, a series of meetings were organised to begin the requirements gathering phase. Stakeholders played a central role in providing information that guided the design and development of the openEHR structures. These sessions involved scrutinising current documentation processes and data management practices to identify areas for improvement. Structured to encourage active feedback, stakeholders shared ideas about existing workflows, specific needs, preferences, identified pain points and suggestions for improvement.

Through these discussions, it became apparent that the hospital's existing HIS for managing corneal transplant records had significant shortcomings, including data entry errors, loss of information, difficulty in sharing data between healthcare providers, and a lack of standardisation. Consequently, the main objective was to rectify these issues and implement a more robust and comprehensive information management system, using openEHR frameworks to mitigate the recognised problems. Collaboratively, the stakeholders outlined the scope, defined requirements and outlined use cases for the clinical domain to

be modelled.

The working group identified five key events in the corneal transplant process in which data recording actions could take place. These moments were meticulously analysed to ensure exhaustive and accurate data collection. Table 7 provides a detailed description of each key event that resulted in five forms. To facilitate identification, each form has an identification label. Subsequently, these forms will be linked to specific tasks within the corneal transplant workflow, serving as repositories for various patient tasks.

Table 7: Description of the five key events identified within the corneal transplantation process.

ID	Key Event	Description
F1	Corneal Transplantation Proposal	To insert the data concerning the corneal transplantation proposal such as type of transplant, laterality, diagnosis, priority, motive, among others
F2	Contact for Corneal Transplantation	To record the three possible contact attempts for corneal transplantation, including information such as phone number, date of contact, result, reason, and date of next contact.
F3	Schedule Anesthesia Consultation	To enter data regarding the scheduling of the anesthesia consultation. It contains the requesting service, the date of the appointment, the motive and additional information.
F4	Perform Anesthesia Consultation	To record the result of the anesthesia consultation, the executing service, the execution date of the appointment and observations.
F5	Manage Suspended Proposal	To register the result of the decision regarding suspended corneal transplantation proposals, either to reinstate to the list or to abandon, and the respective reason.

Modelling Forms provide a user-friendly, template-based interface for entering and retrieving clinical data, supporting the entry and visualisation of structured, semi-structured and unstructured data. These forms are customised and adaptable to various clinical scenarios. Essentially, archetypes constitute the fundamental elements of clinical data structures, templates define standardised structures for specific clinical records, and forms offer user-friendly interfaces for entering and retrieving clinical data. The process of developing openEHR forms, which enable data entry in certain tasks of the corneal transplant workflow, involves transforming archetypes into models and then into FE forms.

As already mentioned, the initial step consisted of meetings with domain experts to outline the scope of the clinical domain to be modelled and gather data requirements, following the guidelines of the Archetype Modelling Methodology (Beale, 2002). Key stakeholders included healthcare professionals familiar with openEHR, archetype development processes and clinical terminologies. After determining the scope of the modelling and identifying the relevant clinical concepts and data elements, the next step was to search the CKM for existing archetypes that aligned with the modelling scenario. The CKM acts as a repository

for openEHR archetypes and models, facilitating global governance and the collaborative development of domain knowledge artefacts.

Some archetypes were used directly, while others did not fully represent the data items and had to be adapted through specialisation. When there were no corresponding archetypes, new ones were created. The openEHR RM defines four main categories of archetypes: *COMPOSITION*, *SECTION*, *ENTRY* and *CLUSTER* (Beale & Heard, 2008). A *COMPOSITION* is a container class, while a *SECTION* is an organiser class, both containing *ENTRY* objects. The *ENTRY* class is further specialised into the *ADMIN_ENTRY*, *OBSERVATION*, *EVALUATION*, *INSTRUCTION* and *ACTION* subclasses, of which the last four are types of *CARE_ENTRY*. *CLUSTERS* are reusable archetypes that can be used in any *ENTRY* or *CLUSTER* (Beale & Heard, 2008). For the corneal transplant proposal, two archetypes were considered appropriate, namely, the service request (Figure 42), which is part of the *INSTRUCTION* subclass of the openEHR *ENTRY* class, and the anatomical location (Figure 43), which is part of the openEHR *CLUSTER* class.

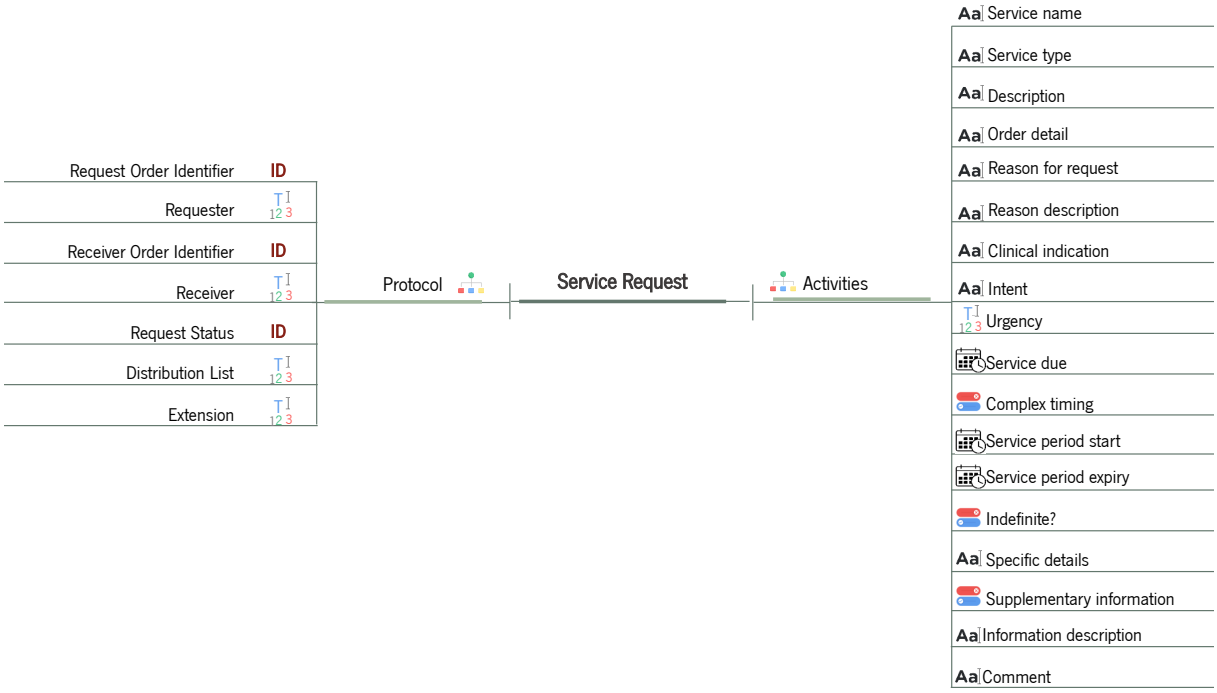


Figure 42: Data structure of the “Service Request” archetype.

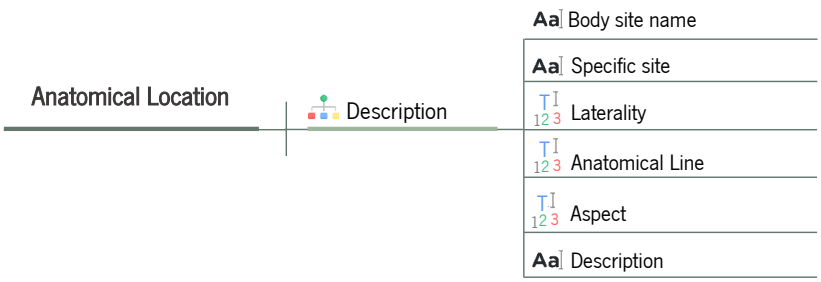


Figure 43: Data structure of the “Anatomical Location” archetype.

In addition, a third archetype was developed to encompass certain facets of the procedure, including risk assessment, complexity, counting previous surgeries and the need for an anaesthetic consultation. Called "Eye surgery details", this archetype belongs to the CLUSTER class. The mind map of this archetype is illustrated in Figure 44.



Figure 44: Data structure of the "Eye Surgery Details" archetype.

Once this phase has been completed, details of the relevant data restrictions - such as data types, cardinality, occurrences and specific data values - are specified for each archetype. In particular, SNOMED-CT terminologies were used to map the coded values of the *Laterality* element in the *Anatomical Localisation* archetype. Local terms were used for the remaining coded text items. The coded values created for each coded text item, are described in Table 8.

Once the necessary archetypes had been identified and developed, the AD tool was used to organise and restrict these archetypes into a model that reflected the requirements of the corneal transplant proposal. A COMPOSITION-type template was created, called *Corneal transplant proposal*, using the *Service request* archetype. Initially, the *Service Request* archetype was integrated into the content attribute. Subsequently, the template was altered to eliminate elements that were incongruous with the clinical context being analysed, such as *Type of Service*, *Request Detail* and *Intention*. The *Anatomical localisation* and *Eye surgery details* archetypes were imported into the "Specific details" group. In addition, specific elements - namely "Appearance", "Anatomical Line" and "Description" - from the "Anatomical Localisation" archetype were excluded from the template. To facilitate interpretation and manipulation, the template was exported as an OPT file and later converted into the JDT structure. Finally, the JDT template was injected into the FE to format the user interface form.

Deployment After completing the modelling and validation of all the openEHR structures that support corneal transplant EHR, the next step involved integrating them into an automated solution. This implementation phase involved integrating a set of tools from the openEHR ecosystem, including FE, WE and DLE. FE allowed healthcare professionals with modelling skills to customise the user interface forms. Users could adjust formatting elements such as colours, fonts and field visibility, adapting the forms to their specific needs. It also made it easier to associate functions and reference sets with the form fields, improving the form's functionality. Using FE, healthcare professionals have simplified data entry processes, creating intuitive forms optimised for their clinical workflows.

In turn, WE acts as a tool responsible for overseeing all workflows modelled by professionals, including materialisation, task status, decision management and assigning executors. This is achieved

Table 8: Description of the terminology codes assigned to each coded text item.

Archetype	Item	Code	Value
Anatomical Location	Laterality	SNOMED-CT::362503005	Left eye
Anatomical location	Laterality	SNOMED-CT::362502000	Right eye
Anatomical location	Laterality	SNOMED-CT::362508001	Both eyes
Eye surgery details	Risk	at0004	High
Eye surgery details	Risk	at0005	Moderate
Eye surgery details	Risk	at0006	Low
Eye surgery details	Complexity	at0007	High
Eye surgery details	Complexity	at0008	Moderate
Eye surgery details	Complexity	at0009	Low
Service request	Diagnosis	H16319	Corneal abscess
Service request	Diagnosis	H1830	Corneal membrane alterations
Service request	Diagnosis	H52219	Irregular astigmatism
Service request	Diagnosis	H18739	Descemetocele
Service request	Diagnosis	H18519	Corneal endothelial dystrophy
Service request	Diagnosis	H18719	Corneal ectasia
Service request	Diagnosis	H1820	Corneal edema
Service request	Diagnosis	T868499	Corneal graft (complication)
Service request	Type of transplant	08R83KZ_tt_d	Total transplantation (right eye)
Service request	Type of transplant	08R83KZ_tt_e	Total transplantation (left eye)
Service request	Type of transplant	08R83KZ_dalk_d	Anterior transplant DALK (right eye)
Service request	Type of transplant	08R83KZ_dalk_e	Anterior transplant DALK (left eye)
Service request	Type of transplant	08R83KZ_dsaek_d	Anterior transplant DSAEK (right eye)
Service request	Type of transplant	08R83KZ_dsaek_e	Anterior transplant DSAEK (left eye)
Service request	Type of transplant	08R83KZ_dmek_d	Anterior transplant DMEK (right eye)
Service request	Type of transplant	08R83KZ_dmek_e	Anterior transplant DMEK (left eye)

through the TP module, which defines a formal model for processing tasks and workflows. WE aims to convert graphical workflow models into executable plans which, when running, lead employees to carry out tasks. Essentially, WE offers an automated solution for managing and executing complex workflows

in the healthcare field.

In parallel, the DLE works as a logical decision engine in charge of processing clinical or operational rules and initiating designated events according to predefined conditions. Its fundamental role is to reinforce the logic of the forms and TPs, receiving requests from both the FE and the WE. By ensuring the accurate and consistent execution of decision rules, the DLE contributes to improving patient care and outcomes.

The FE and DLE integration process begins when a healthcare professional updates a form field. After any change in the value of a field, FE starts internal processing to check whether the field serves as a condition for any rule within the DLM associated with the current form. If this is the case, FE identifies each correlated rule and examines whether all the associated conditions have assigned values. Once all the conditions within a rule have been validated, the FE triggers a POST request to the DLE containing the input variables. This outlines a well-defined sequence of computational tasks necessary for the exact implementation of the specific set of rules modelled for each form.

Given the hospital's existing IT infrastructure, integrating the proposed solution proved to be a simple process, with no complex integration hurdles. To optimise the flow of work processes, FE was incorporated via an existing web application at the hospital. This web application provides healthcare professionals with a detailed overview of assigned tasks, allowing them to submit completed forms directly via the portal. The WE serves as the backbone for managing and activating the tasks accessible to medical staff via the professional portal. Consequently, the professional portal acts as a centralised HIS for task management and data collection, thus improving the clinical workflow.

To control access to corneal transplant tasks, specific user roles have been created within the healthcare professional demographic, each with designated capabilities and functions. These roles have been meticulously assigned to authorised personnel, ensuring that only qualified individuals can access and complete corneal transplant-related tasks. This hierarchical structure of roles and responsibilities ensures that the hospital's corneal transplant procedures are managed and executed by competent personnel. The collaboration between the healthcare institution and the research centre facilitated the exchange of knowledge and resources, which led to an easier implementation of the solution. This partnership has also fostered a culture of innovation and continuous improvement in the hospital's clinical practices, ultimately benefiting patients by improving the quality of care provided.

The implementation faced a major challenge in terms of the shortage of healthcare professionals with knowledge of openEHR and modelling. The team therefore carried out numerous demonstrations and provided extensive documentation to make it easier for users to adopt the tools. Despite these obstacles, the medical staff reacted very positively, reporting ease of adaptation and satisfaction with the tools provided.

6.3.2.3 Results

The openEHR ecosystem offers an integrated solution for managing healthcare data through a combination of different tools and technologies. The openEHR forms, DLM and WP work together to support the delivery of effective and optimised clinical care. These modules collectively uphold the integrity, accessibility and accuracy of patient data, while offering functionalities such as data validation, automated actions and real-time decision support to guide optimal patient care pathways. Their seamless integration makes it easier to organise and monitor the progression of clinical tasks, guaranteeing the timely and efficient execution of all necessary clinical procedures.

Work plan definition In recent years, the openEHR specifications have expanded significantly to meet the requirements of automating clinical processes, as the TP (Beale, 2017). TP facilitates the management of task plans and standardised clinical workflows. The core concept of TP revolves around a plan, or set of plans, designed to achieve specific objectives and involve an active subject. As part of the WP structure, the primary conceptual element is the WP, which includes one or more TP. A WP describes a sequence of tasks to be carried out in a specific order to achieve a clinical objective relating to a subject. It is important to note that, given the subject-centred nature of WP, each subject requires a unique instance. WP help organise and oversee the progress of clinical tasks, ensuring that all necessary steps are completed efficiently and on time. On the other hand, each TP within a WP explicitly describes the work to be carried out in a specific context by the main performer, along with other potential participants. In openEHR, the main performer refers to the individual or entity responsible for carrying out a particular clinical action, allowing clinical actions to be traced back to those responsible. The data collected through the forms and the decision support provided by the DLM can be used to define and update the WPs in real-time.

In this use case, a WP specifically adapted for corneal transplantation was developed to guarantee the implementation of the solution within the planned timeframe. The first TP outlined in this WP concerns the corneal transplant proposal, accessible to certain ophthalmologists in specific scenarios. In addition, two TP focusing on anaesthesia consultations were included: one for scheduling and one for carrying out the consultation, assigned to different professional groups. In addition, two more TP were designed: one related to the contact for the transplant, managed by the administrative staff, and the other related to the transplant procedure itself, supervised by the doctor who initiated it.

Figure 45 illustrates the initial TP in simplified form to make it easier to visualise and understand. Note that in this initial TP, the corneal transplant proposal form is filled in as the first actionable task. After submission, the sequence of events depends on the "Anaesthesia Consultation" field filled in on the "Corneal Transplantation Proposal" form. If it is deemed necessary, the patient will book and attend the anaesthesia consultation, followed by the transplant contact. Alternatively, if the anaesthetic appointment is not necessary, the patient is placed directly on the active waiting list for corneal transplant contact tasks. If successful, the transplant procedure follows; if not, the offer is suspended and the suspension

management tasks become available, to be handled by the corneal transplant ophthalmologists. In this example, all the dispatchable tasks are interconnected with other TPs, mainly with an executable task associated with one of the modelled forms.

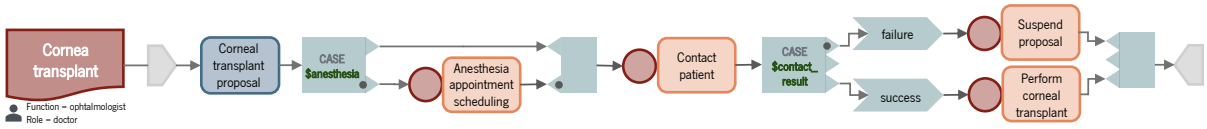


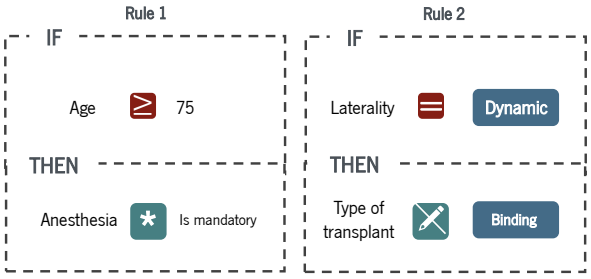
Figure 45: Representation of the workflow for the cornea transplant use case.

Construction of decision rules CDS plays a vital role in the openEHR architecture, serving to automate and improve decision-making processes. The DL serves as a formal language for codifying clinical knowledge and expressing decision-support logic through sets of rules. A DLM, through their structured modelling, encapsulate decision rules structured as defined in the DL specifications. These decision modules act as computerised instructions for decision-making, offering a standardised and automated approach to applying decision rules to patient data in the EHR system in real-time. Thus, the proposed DLE allow healthcare organisations to implement algorithms and rules designed to determine the best course of action for each patient. The DLM processing can guide clinical decision-making, trigger alerts or notifications for healthcare providers or initiate automated actions in the EHR.

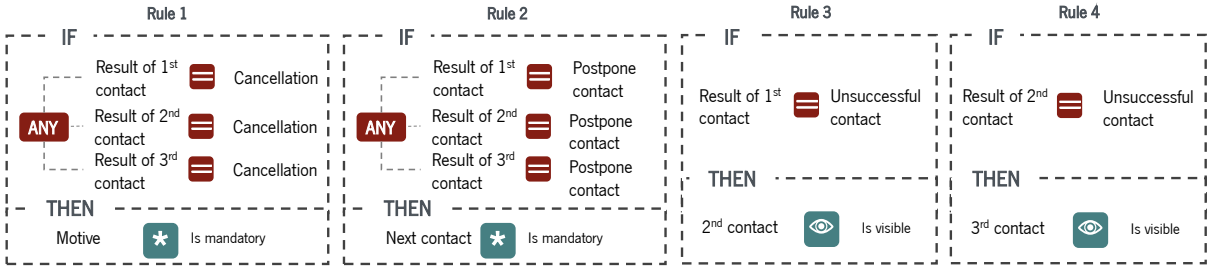
To guarantee the accuracy of corneal transplant records, it was necessary to develop decision rules that were dynamically applied to the user interface forms during runtime. DLM allows forms to automatically adapt to specific patient scenarios and the responses of healthcare professionals. Thus, according to the requirements gathered in the initial phase of the methodology, two DLM were developed for forms F1 and F2, respectively. Figure 46 describe the rules associated with each DLM, including the necessary conditions to trigger a certain action.

The initial rule of DLM1 consists of determining whether the patient should have anaesthesia in the procedure. In cases where the urgency of the proposal is high, an anaesthetic consultation is unnecessary. However, if the request is not urgent, the need for an anaesthetic consultation depends on the information provided in the *anaesthesia* field filled in by the doctor on the form. Rule 2 requires a dynamic operator to trigger the binding value. When laterality is defined, the values for the type of transplant are filtered. For example, if the laterality is for the right eye, only transplant types for the right eye are displayed.

Concerning DLM2 (Figure 46b), four rules were defined. The first rule contains four conditions in which any can be true, referring to the three contact attempts for patients on the waiting list. If the contact is cancelled in any attempt, the *motive* field is mandatory. The same applies to rule 2, where if the contact is postponed in any of the three attempts, the *next contact* field is mandatory. Only one condition was created for rules 3 and 4, referring to unsuccessful contact attempts. If the first contact attempt is unsuccessful (rule 3), then the section of the form for the second contact is visible. Consequently, if the second contact is unsuccessful (rule 4), then the third contact section is visible. In the case of is not



(a) DLM1: Cornea transplant.



(b) DLM2: Cornea contact list.

Figure 46: Rules created for the cornea transplant use case.

possible to contact the patient in any of the three attempts, a decision needs to be made regarding their status on the transplant waiting list. They can either be removed from the list, which means the waiting period ends, or they can be re-inserted on the transplant contact list.

The DLM rules designed to facilitate the critical decisions of the modelled WP were fundamental to ensuring the correct functioning of the corresponding implementations. By automating the adjustment of forms based on specific scenarios, the system offers decision support to healthcare providers, guiding them through the data entry process and clinical decision-making.

Performance analysis In a data-driven world, statistical analysis has become essential for obtaining information and drawing conclusions that may not be immediately apparent through simple visual inspections. Statistical analysis has particular significance in the field of healthcare research, where it can be used to evaluate the effectiveness and efficiency of IT solutions. In this sense, healthcare professionals can identify areas for improvement, including rationalising workflows, increasing user-friendliness and resolving technical glitches, ultimately leading to better outcomes for patients and a higher quality of care.

To assess the effectiveness and efficiency of the solutions implemented for managing corneal transplants, an analysis was carried out on data collected between 1 May 2022 and 31 March 2023. This analysis will include relevant indicators and graphical representations. The data collection procedure involved detailed planning and adherence to ethical guidelines to maintain the accuracy and validity of the data. Initially, the databases and tables of interest were identified. Subsequently, an anonymisation process was carried out to safeguard the identity and privacy of the patients, eliminating any personally identifiable information from the data. After anonymisation, relevant SQL queries were formulated to extract the necessary data. Finally, the extracted data was meticulously organised into descriptive statistics,

including indicators, tables and graphs, facilitating interpretation and conclusion.

Figure 47 shows key the results obtained in the corneal transplant process in a quantitative way. The application of this use case resulted in the creation of two openEHR forms, two DLM with six rules in total, and 830 tasks that indicates tasks accessible for healthcare professionals to fill in the corresponding forms. Out of 830, 530 tasks were completed, as tasks that were successfully submitted by healthcare professionals, indicating that the completion rate of the tasks is therefore 64%. In addition, 197 patients registered in the corneal transplant list.

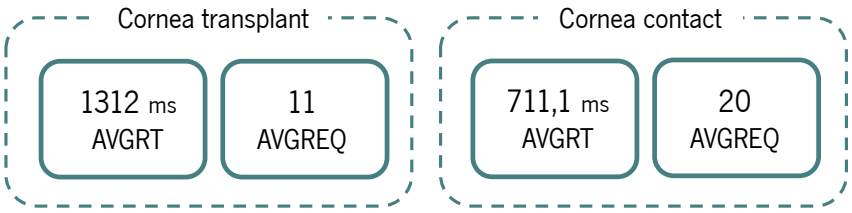


Figure 47: Results obtained for the corneal transplant flow.

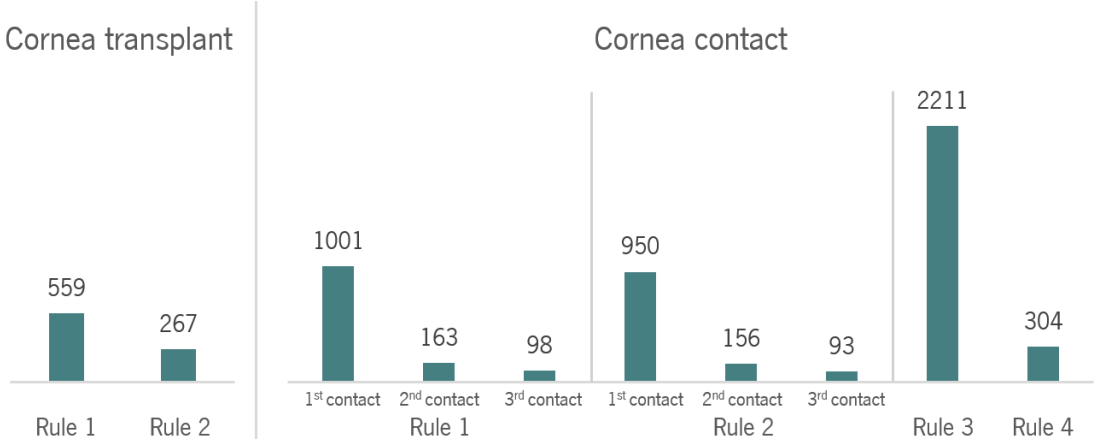
Regarding the performance of the DLE, Figure 48a represents the outcomes obtained with the application of the performance metrics. For the cornea transplant (DLM1), the AVGRT was 1312ms and for the cornea contact (DLM2) was 711,1ms. Approximately, DLM2 is 601ms faster than the DLM1. Although DLM2 has more rules created, DLM1 includes a binding rule. This means that when DLE receives a rule execution request, it must call an external service to obtain the necessary variable value. This external call can impact DLE's response time for that module. Regarding the AVGREQ, DLM1 averages 11 requests per day, while DLM2 averages 20 requests per day.

Furthermore, the number of rules executed by the DLE for each DLM was counted, as shown in Figure 48b. In DLM2, rule 3, which corresponds to the first attempt to contact the patient, was found to be the most frequently called rule. Comparing this with the number of calls for rule 4, it is evident that the first contact attempt is the most successful, as the number of calls for rule 3 is approximately 7.3 times lower than for rule 4. For DLM1, there is no apparent correlation between the rules in this module.

This study investigates the impact of a standardised approach on the corneal transplant workflow, which was previously hindered by poor automation and a high risk of data loss. Statistical analysis highlights the number of available and completed tasks and patients on the corneal transplant list. With a task completion rate of 64%, the results are promising but indicate room for improvement, potentially due to resource limitations and inadequate training of healthcare professionals. The workflow is also heavily influenced by external factors such as patient health and the availability of donor organs, affecting task completion times. Additionally, the implementation of the decision engine for rule execution has helped automate the process, demonstrating flexibility and effectiveness.



(a) AVGRT and AVGREQ of cornea transplant for both DLM.



(b) Count of rules executed for the modules of cornea transplant.

Figure 48: Results obtained for cornea use case.

6.3.3 Nutritional risk screening use case

In today's healthcare landscape, an increasing number of hospitalised patients are being recognised as being at risk of malnutrition. To deal with this problematic, CDSS are being adopted to assist the decision-making process. In this context, this use case explores an interoperable approach to support clinical pathway decisions for nutritional risk screening by utilising the openEHR standard. The study presents an architecture that integrates different openEHR components designed to define workflow tasks, create decision rules, and visualize forms through archetypes and templates. To facilitate the nutritional pathway implementation within a Portuguese hospital center, the clinical guidelines Nutritional Risk Screening (Nutritional Risk Screening (NRS) 2002) and Global Leadership Initiative on Malnutrition (GLIM) were employed. As a result, three forms and three decision modules were developed following the proposed architecture. This approach streamlines the integration of data from various sources and holds the potential to enhance coordination among healthcare professionals involved in a patient's care.

6.3.3.1 Introduction

The prevalence of malnutrition among adult inpatients has become an increasing concern in Portugal, with approximately 29% to 49% of hospitalised patients being malnourished (Marinho et al., 2021). This situation was particularly pronounced in 2020, amid the Covid-19 pandemic when infected patients admitted to hospitals were often at risk of malnutrition. Consequently, this risk nearly quadrupled the chances

of in-hospital mortality (Boaz & Kaufman-Shriqui, 2023).

According to previous studies, patients who received nutritional support during their hospitalisation had a significantly lower mortality rate compared to those who did not receive such support (Schuetz et al., 2019). This finding underscores the importance of providing adequate nutritional support to malnourished patients in healthcare facilities (Kaegi-Braun et al., 2021). As a result, CDSS play a significant role in clinical pathways, providing support in the decision-making process by automating processes, reducing task duration, and lightening the workload. These systems expedite specific workflow-related activities while simultaneously reducing clinical errors and easing the burden placed on healthcare processes (Sutton et al., 2020).

However, the adoption of CDSS comes with a set of challenges that can affect its overall performance. One of the main challenges highlighted is the lack of interoperability between systems. EHR extracted from heterogeneous systems often lack standardisation and structure, compromising semantic interpretation and integration between systems (Sutton et al., 2020). In addition, disorganised data hampers decision support by obstructing knowledge acquisition and representation. Clinical terminologies and standardised approaches have the potential to address this problem, but their adoption remains limited and slow despite the progress made over time (Middleton et al., 2016).

Thereby, this use case aims to provide an interoperable approach for the nutritional screening pathway operated in a Portuguese Hospital Center. The proposal is based on the openEHR specifications, an open data standard that enhances semantic interoperability between EHR systems. Three components were involved in this architecture, responsible for: defining the tasks in the nutritional risk workflow; visualising forms with standardised modelling; and automatically processing previously defined decision rules within the pathway. The ultimate goal is to create an integrated and interoperable environment based on standardised openEHR structures, which can also be applicable in different cases.

CDSS are increasingly in demand in health units to enhance the quality of services provided and streamline work tasks (Middleton et al., 2016). However, several challenges and failures hinder their adoption. One recurring issue in healthcare is the lack of interoperability in systems, which refers to the ability to communicate between heterogeneous systems (Weber & Ho, 2020). Therefore, clinical standards aim to overcome this obstacle by proposing open specifications or encoding techniques to enhance communication between systems (Sutton et al., 2020).

The openEHR standard is an open standard specification that promotes semantic interoperability and data standardisation through the structuring of EHR (Beale & Heard, 2008). One central concept of openEHR is the separation of knowledge and information through a two-level modelling architecture. The first level comprises the reference information model, and the second level deals with the clinical content represented by archetypes and templates (Beale & Heard, 2008).

The DL specifications offers a syntax and semantic framework for defining rule sets logically (Beale, 2021). Clinical pathways, workflows, and clinical practice guidelines require the expression of rules and the declaration of input variables. Thus, DL includes a multi-section module, the DLM, with a predefined structure capable of declaring variables, defining conditions and rules, and executing rule sets and output

variables. The overarching promise is to represent the decision logic independently from HIS and programming languages, making it flexible and shareable across different systems (Samwald et al., 2012).

6.3.3.2 Methods

The clinical pathway for nutritional screening involves multiple tasks and clinical guidelines that are recorded in heterogeneous HIS. This study aims to represent the nutritional risk screening pathway conducted in a Portuguese public hospital through a proposed interoperable approach and decision logic architecture. To achieve this, a four-step methodology was adopted, as illustrated in Figure 49.

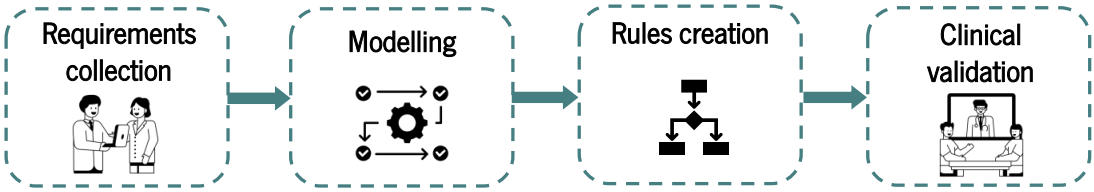


Figure 49: Applied methodology based on four steps for nutritional screening use case.

The process encompasses gathering clinical pathway requirements, modelling clinical knowledge, representing clinical rules, and validating the proposed approach. The various steps of the methodology involved the collaboration of IT experts and clinical specialists, including biomedical engineers, information systems engineers, doctors, and nurses.

Requirements collection Adult patients receiving hospital care are increasingly being diagnosed with malnutrition, which can be caused by impaired intake or assimilation of nutrients and leads to altered body composition, resulting in diminished physical and mental function and impaired clinical outcomes from disease. Malnutrition can be identified through various clinical methods (Reber et al., 2019). The requirements for this study follow the clinical pathway of nutritional risk screening implemented in a Portuguese Public Hospital. The clinical concepts and guidelines adopted are those recommended by the Portuguese National Health System (Amaral et al., 2020).

Within the first 48 hours of a patient's hospitalisation, a nutritional screening is conducted using a pre-defined scale based on the patient's age. This study focuses on the process for adult patients (those over 18 years old). The scale employed for this purpose is the Portuguese version of NRS 2002 (Amaral et al., 2020). The NRS 2002 tool allows healthcare practitioners to assess the likelihood of malnutrition in hospitalised patients through a combination of questions and measurements (Amaral et al., 2020; Reber et al., 2019). After validating the values entered into the tool, the result may indicate whether the patient is at nutritional risk.

If the patient is at nutritional risk, it becomes necessary to evaluate and determine the severity of the malnutrition. Additionally, the patient is referred for a nutritional consultation. To assess the diagnosis and severity of malnutrition, the GLIM tool is employed (Cederholm et al., 2019). Requirements were

collected through meetings with healthcare professionals responsible for overseeing this process, specifically doctors and nurses. Subsequently, a comprehensive examination of the process was conducted, including the identification of tasks carried out and variables utilised in each step.

Clinical knowledge modelling The foundation of the openEHR standard lies in the modelling of clinical knowledge through archetypes and templates (Beale & Heard, 2008). CKM serves as an openEHR community repository containing various available artefacts, including archetypes, templates, terminologies, and more (Hong et al., 2019). It serves as a collaborative space for managing and publishing clinical knowledge resources. Therefore, the initial step in the modelling phase was to search CKM for archetypes related to malnutrition. At the time of the search, three archetypes were available: the NRS 2002, the Malnutrition Screening Tool (MST), and the Malnutrition Universal Screening Tool (MUST), all of which were recommended by the European Society for Clinical Nutrition and Metabolism (ESPEN). Considering the objectives of this study and the identified requirements, the authors concluded that the NRS 2002 was the most suitable choice. Figure 50 visually represents the data structure within the NRS archetype using a mind map.

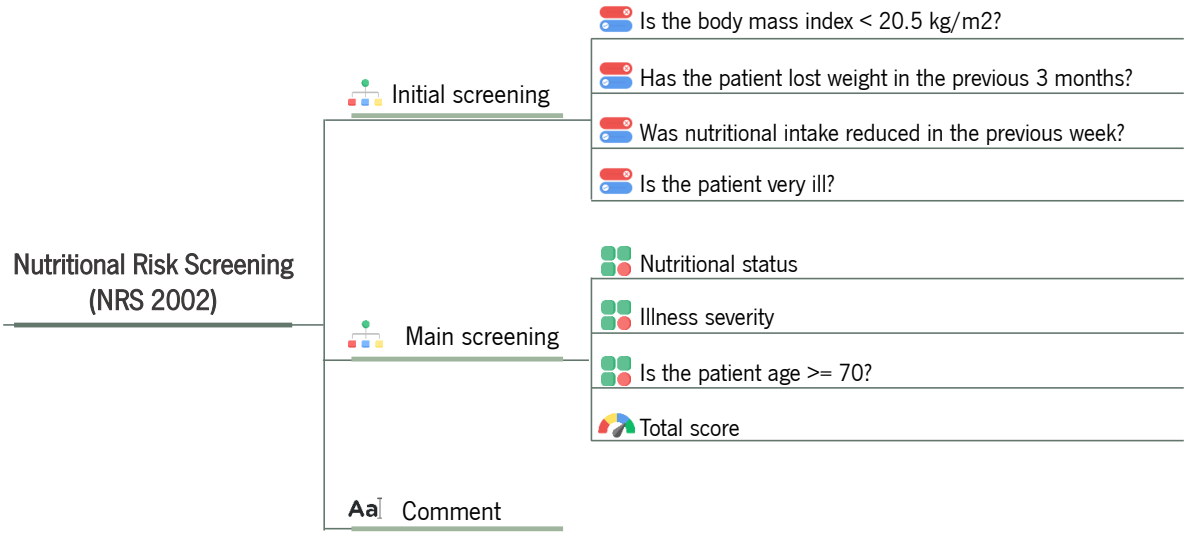


Figure 50: Data structure of NRS archetype.

The data structure captured by the NRS archetype was aligned with the Portuguese version (Amaral et al., 2020). In terms of the openEHR RM, the NRS archetype is classified as an *observation* type, primarily used for recording information obtained through direct observation or measurement. The chosen archetype was exported in its appropriate language and imported into the AD platform. AD is a web-based, open-source tool designed for visualizing and developing archetypes and templates. As previously mentioned, the archetype comprehensively covered the data requirements, with the only necessity being the translation of concepts into Portuguese (PT-PT), a language not yet available in AD for this archetype.

Although certain archetypes could be used directly, new archetypes had to be created when the required archetype was not available in the repository. Thus, the authors recognised the need to develop

an archetype from scratch for assessing the degree of malnutrition based on the GLIM criteria. The reason for this development was the absence of archetypes in CKM to serve this purpose. Established in 2016, GLIM is an international initiative and framework resulting from collaboration among four leading clinical nutrition societies in the world, namely ASPEN, ESPEN, FELANPE, and PENSA, addressing the critical needs of the healthcare community in dealing with malnutrition (Cederholm et al., 2019). Given its nature, the GLIM archetype also falls under the *observation* type. Figure 51 illustrates the data structure of the GLIM archetype.

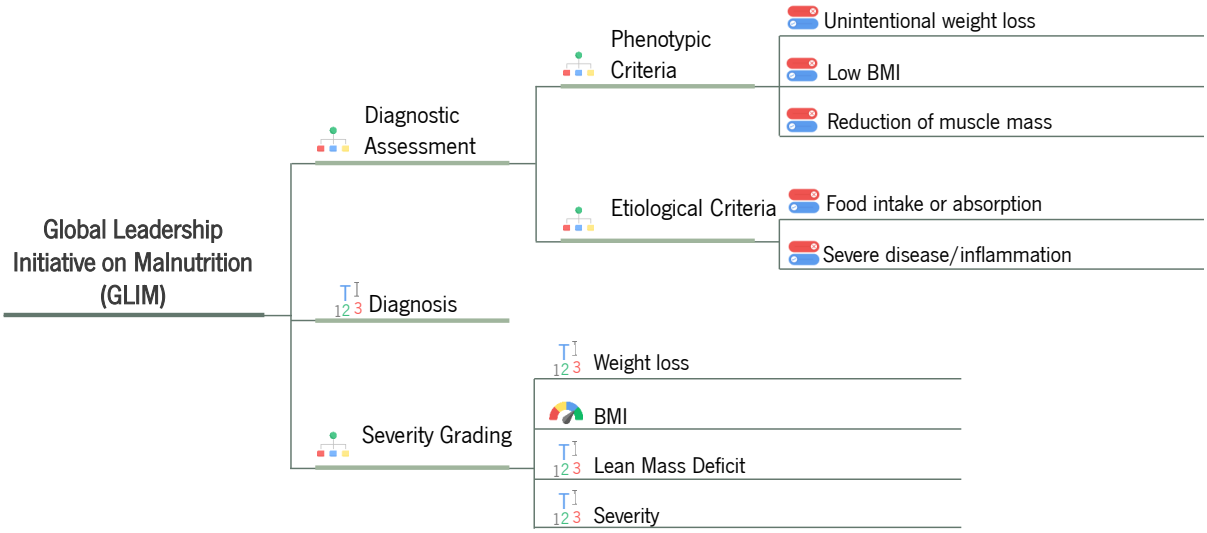


Figure 51: Data structure of GLIM archetype.

Furthermore, there was a need to model a predefined template for requesting an internal nutrition consultation. A CKM search led to the use of the published *service request* archetype, classified as an *entry instruction* type. The purpose of this archetype is to request a health service to be carried out by a healthcare professional. Figure 52 represents the data structure used for the nutritional consultation request archetype.

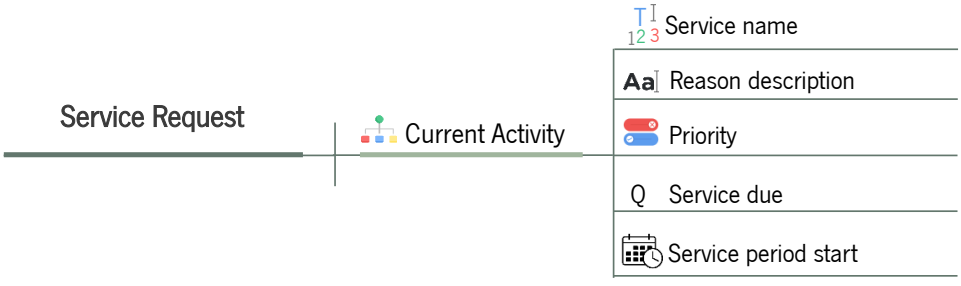


Figure 52: Data structure of service request archetype.

Following the identification and development of the required archetypes, the AD was used to arrange and restrict these archetypes into larger, functional structures, resulting in the creation of three distinct

templates. These templates were created using a *Composition* and included the integration of the modelled archetypes, the removal of elements unnecessary for the intended use cases, and the refinement of some existing constraints. After the templates were thoroughly modelled and validated, the export procedure was initiated, yielding an OPT file for each template.

In addition to modelling the clinical structures, the authors proceeded with the modelling of the clinical pathway. This modelling stage relies on openEHR's TP, a component of the Reference Model designed to enable healthcare systems to efficiently organize, monitor, and manage tasks. In prior research, the research team had already developed an algorithm capable of automating task processing and triggering decision points. Workflow modelling was also conducted within the AD tool, establishing an initiation process tailored to the requirements of the specific use case. The resulting WP derived from this modelling process was extracted and stored for future implementation.

Process validation The validation process took place throughout the development of this project. On one hand, the involvement of medical professionals was essential for validating clinical knowledge, especially in the collection of requirements, modelling medical concepts, and constructing the workflow. On the other hand, developers were responsible for ensuring the system's functionality, guaranteeing that all developed components were integrated and aligned with the project's objectives.

The primary focus of this project was aligned with the representation of clinical knowledge through decision rules. Using the proposed DLE, it became possible to create decision rules applicable to the modelled templates. These rules adhered to the documentation provided by the NRS 2002 and GLIM guidelines, ensuring the absence of any misguidance. For instance, rule conditions could only be established using variables from each archetype, corresponding to the data structure.

6.3.3.3 Results

The proposed architecture was designed based on a three-tier architecture. Organizing the system into three computing layers facilitates the understanding of the interaction between the components. Leveraging openEHR specifications allowed to design of an integrated interoperable architecture with three key components the WE, the FE, and the DLE.

These three components are in constant communication, with the DLE receiving requests from both the FE and the WE, and subsequently sending its processed responses. The FE is an application that represents templates through forms in an organized and visible manner. These forms can incorporate clinical and operational rules, such as rules that influence the structure of the form (e.g., making a field mandatory, visible, editable, etc.). The WE is responsible for processing workflows and task plans. Since these are workflow-oriented, some task plans necessitate a decision branch, requiring the processing of predefined rules by the DLE which can be clinical or administrative rules. In summary, the purpose of a decision module is to represent a protocol or guideline through a rule or a set of rules, which, when a certain condition is deemed true, triggers one or more events.

Hereupon, the DLE constitutes the logic layer of the artefact. As a knowledge-based system, the DLE comprises a knowledge base for storing DLM and an inference engine for processing these modules. A DLM includes mandatory and optional sections, which were adapted and stored as modules in JSON format. The mandatory sections encompass reference data that identifies the purpose of the created module, author data, type of integration, among other details. Furthermore, context variables are associated with the decision module, which may be of the input or output type, along with the expression of rules through conditions and related events. As for optional sections, the decision module may have associated preconditions, utilise other decision modules, and incorporate terminologies capable of coding and classifying clinical concepts.

Nutritional risk pathway Upon a patient's admission to a hospital, the assessment of their risk level is conducted. In more severe cases, the patient is admitted for an unspecified duration. During the initial 48 hours of hospitalisation, a series of diagnostic tests are performed to assess the patient's health status, including assessing the risk of malnutrition.

To illustrate the procedure carried out at the studied Portuguese hospital centre for assessing the nutritional status of hospitalised patients, a workflow was modelled using the openEHR TP specifications within the AD platform. This process involved identifying the key tasks to be executed based on their characteristics, definitions, types, and the resources employed. As a result, Figure 53 presents the workflow conducted by the inpatient team and the nutrition team in an automated and interoperable manner.

The process commences with the nutritional risk assessment task plan that includes the NRS form, which was previously modelled according to the openEHR specifications and is associated with the first performable task. After the form is completed and the task is fulfilled, a decision point (represented by a decision group) is reached to determine the next course of action. This is achieved by sending a request to the DLE, which executes the pre-defined rules within the form and conveys the obtained result to the WE, which subsequently determines the appropriate decision branch to follow.

If the result is negative, signifying that the patient is not at nutritional risk, the patient will undergo a reassessment every 7 days until their discharge from the hospital. This recurring assessment is depicted through a *repeat_spec* of *task_repeat* type associated with the task group. The repetition period is set at 7 days, and the termination condition is either a positive result in the NRS or the patient's discharge. Conversely, if the patient is identified as being at nutritional risk (yielding a positive result), two parallel tasks are initiated: a referral task for an in-hospital nutrition consultation and a medical evaluation conducted using the GLIM form.

These two tasks involve a hand-off to different performers within the current Work Plan. As for the GLIM evaluation, a new task plan is implemented, presenting the GLIM form to the internal medicine doctors. The GLIM assessment can result in three potential outcomes: mild malnutrition, moderate malnutrition, or severe malnutrition. Simultaneously, the nutrition consultation dispatchable task is linked to the in-hospital consultation triage task plan, which in turn is connected to the in-hospital consultation response.

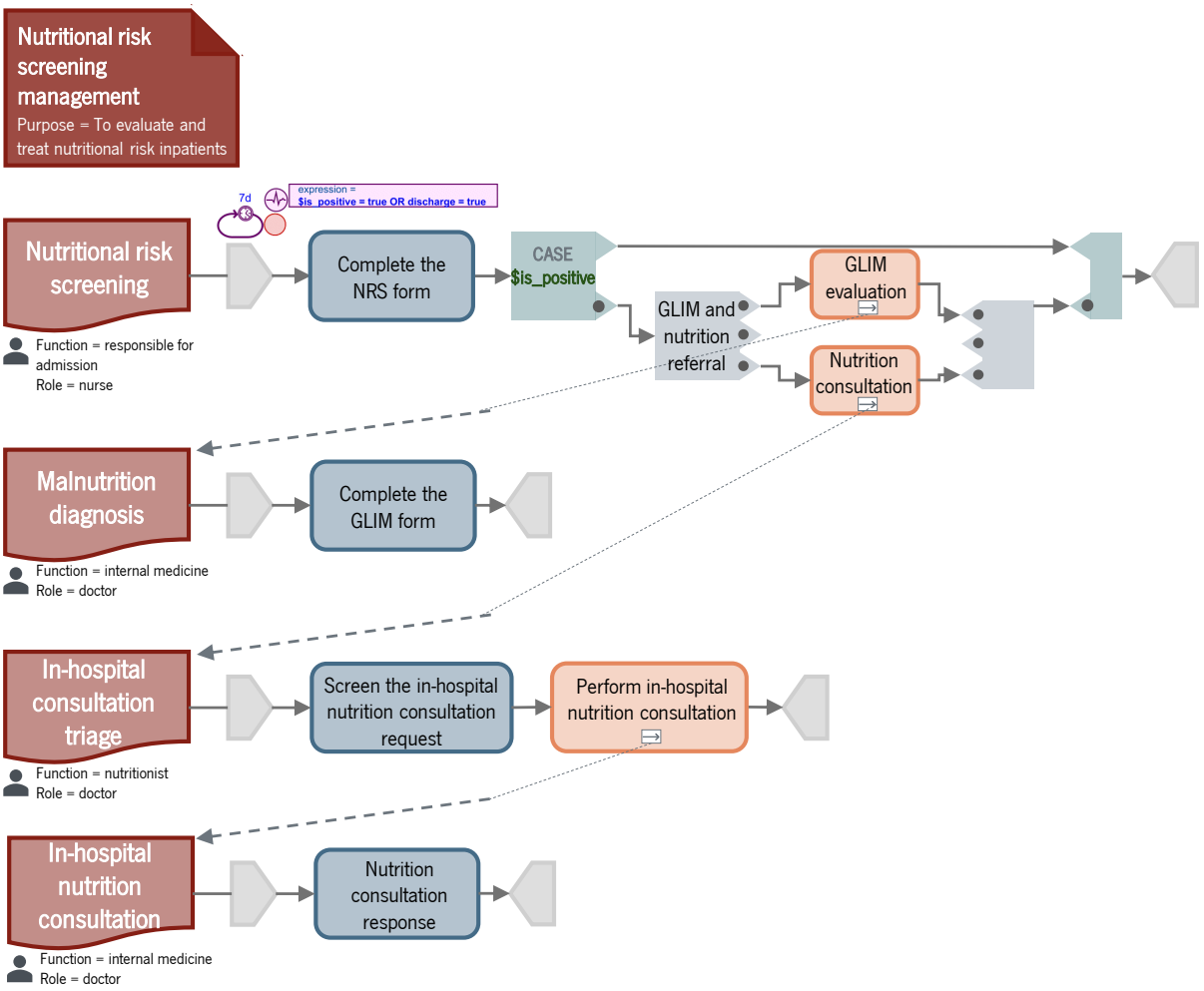


Figure 53: Workflow modelled for nutritional screening pathway.

Nutritional risk forms One of the significant outcomes of clinical knowledge modelling is the creation of openEHR forms, which play a significant role in simplifying the completion of certain tasks in the nutritional screening workflow. These forms are derived from the modelled templates and serve as essential tools to help healthcare professionals carry out their responsibilities effectively.

After exporting the templates in OPT, it was necessary to convert them into JSON data format, a widely used key-value pair structure in software development, to facilitate reading and manipulation. Each JDT structure was then integrated into the FE tool. Modelling experts customized the user interface forms within this tool to ensure they met the desired requirements and were user-friendly.

Nutritional risk assessment is based on an evaluation of an individual's current nutritional status and an assessment of the potential for deterioration in this status. This deterioration is primarily attributed to increased nutritional demands caused by metabolic stress associated with the individual's prevailing clinical condition (Reber et al., 2019).

The NRS form consists of two main sections: the initial screening and the main screening. The initial screening section comprises four questions related to the patient's current health condition, focusing

on parameters such as BMI, weight loss, decreased food intake, and the severity of their health status. Notably, these questions solicit binary responses, specifically 'yes' or 'no,' as each of these data elements is defined with the *DV_BOOLEAN* data type.

When the form is initially presented to the healthcare practitioner, only the initial screening section is visible and available for completion. The main screening section is revealed only if the patient is determined to be at nutritional risk. Therefore, the visibility of the main screening section depends on an affirmative response to at least one question within the initial screening section. This logic is implemented using decision rules, which will be described later in this document. When such a rule is triggered, the form employs an internal mechanism to toggle the visibility of the second section.

The main screening section is the core component for conducting the nutritional risk assessment. The evaluation is based on three *DV_ORDINAL* data type fields. This data type includes a fixed value set that associates a score with each possible response. These fields are related to the patient's nutritional status, the severity of their illness, and their age. Both nutritional status and severity of illness share the same value set, which comprises categories such as absent, mild, moderate, and severe. However, it's essential to understand that these categories hold distinct interpretations within their respective contexts. Table 9 outlines the meaning of the value set for each field.

Table 9: Description of the value sets associated with Nutritional Status and Severity of Illness.

Value	Nutritional Status	Severity of Illness
Absent score: 0	When the nutritional status of the patient is considered normal.	When the patient has normal nutritional needs.
Mild score: 1	When the patient has had weight loss greater than 5% in 3 months OR food intake below 50-75% of needs in the previous week.	When the patient sustains a hip fracture or chronic patients, in particular with acute complications: cirrhosis, chronic obstructive pulmonary disease (COPD), chronic hemodialysis, diabetes, oncology.
Moderate score: 2	The patient had weight loss greater than 5% in 2 months OR BMI on the scale of 18.5-20.5 + deterioration in general condition OR food intake of 25-60% of needs in the previous week	When the patient has 'major' abdominal surgery, stroke, severe pneumonia, or hematological malignancy.
Severe score: 3	The patient had weight loss greater than 5% in 1 month (greater than 15% in 3 months) OR BMI below 18.5 + deterioration in general condition OR food intake of 0-25% of needs in the previous week	When the patient has traumatic brain injury, bone marrow transplant, or intensive care patients (APACHE greater than 10).

Regarding the patient's age, if the age is 70 years or older, the value is set to 1; otherwise, it's set to 0. Based on the data entered into these fields, a cumulative score is computed in a *DV_COUNT* data type field named *total score* (the calculation will be explained in the next section). Additionally, there's an open text field of the *DV_TEXT* data type for nurses to write comments regarding the risk of malnutrition.

As per the defined WP, the first stage involves conducting nutritional screening using a validated tool such as NRS-2002. If the NRS assessment is positive, it is necessary to diagnose and classify the severity of malnutrition following the GLIM criteria. This approach provides standardised criteria for diagnosing and classifying malnutrition, aiming to improve the assessment and management of malnourished individuals worldwide.

The diagnostic assessment of malnutrition includes etiologic criteria and phenotypic criteria. Etiologic criteria are related to reduced food intake or assimilation, disease burden, and inflammatory conditions. Phenotypic criteria are associated with non-volitional weight loss, low BMI, and reduced muscle mass. For detailed criteria, please refer to Table 10.

Table 10: Description of the etiologic and phenotypic criteria.

Phenotypic Criteria			**Etiologic Criteria**	
Weight Loss	Low BMI	Reduced Muscle Mass	Reduced Food Intake or Assimilation	Disease Burden and Inflammatory Condition
>5% within past 6 months or > 10% beyond 6 months	<20 kg/m^2 if < 70 years or <22 kg/m^2 if > 70 years Asia: <18,5 kg/m^2 if < 70 years or <20 kg/m^2 if > 70 years	Reduced by validated body composition measuring techniques	≤50% of ER >1 week, or any reduction for >2 week, or any chronic GI condition that adversely impacts food assimilation or absorption	Acute disease/injury or chronic disease-related

The form is divided into two sections: one for capturing etiologic criteria and the other for phenotypic criteria. Each field represents a criterion and uses *DV_BOOLEAN* data type, allowing binary responses ('yes' or 'no'). Subsequently, the Diagnosis field is a *DV_CODED_TEXT* data type, filled with 'malnourished' if the patient meets at least one etiologic and phenotypic criterion, indicating the presence of malnutrition. Otherwise, it's marked as *not malnourished* if these criteria are not met, indicating the absence of malnutrition. If the patient is malnourished, another section appears to assess the severity of malnutrition. This section contains three *DV_CODED_TEXT* fields, namely weight loss, lean mass deficit, and severity. In addition, a *DV_COUNT* field is contemplated to record the BMI of the patient. Regarding the severity, there are two options available: 'stage 1 - moderate malnutrition' and 'stage 2 - severe malnutrition'.

In addition to documenting GLIM criteria, a positive NRS assessment triggers a referral for an in-house clinical nutrition consultation. The from for internal consultation request includes the requested medical speciality as *DV_CODED_TEXT* (pre-filled as clinical nutrition), the urgency level as *DV_BOOLEAN*, consultation deadline as *DV_QUANTITY*, reasons for the request as *DV_TEXT*, and the request date as *DV_DATE* (auto-filled).

Nutritional decision rules The proposed DLE allows the automatic execution of rules and guidelines integrated into a specific clinical workflow. Based on the DL specification (Beale, 2021), rules have a predefined structure through a combination of variables and conditions. The inference engine of the proposed architecture comprises three types of rule processing, such as rule production, decision table, and scores. Once the rules are established, a JSON file comprising the decision logic data is stored in the knowledge base.

In this proposal, the rules created can be associated with modelled workflows and forms. Following the predefined nutritional pathway, a decision point is stipulated in the flow corresponding to the response to the NRS result, which, depending on the result, may follow different paths. For this case, the WE solicits a request from the DLE, where it executes the rule and returns the response with the result of the case in question. Moreover, three DLM were created associated with the three forms developed, to determine the rules applied to clinical and administrative concepts. Below it is described the three modules created for this use case.

- DLM 1: NRS

The DLM1 of this use case was created following the NRS guideline and modelled through the ODIN language, in accordance with the DL specifications, as demonstrated in appendix B.1. When opening the form, a request is sent to the DLE, where it checks the veracity of the request and returns with a response. In this case, two rule were created, as shown in Figure 54.

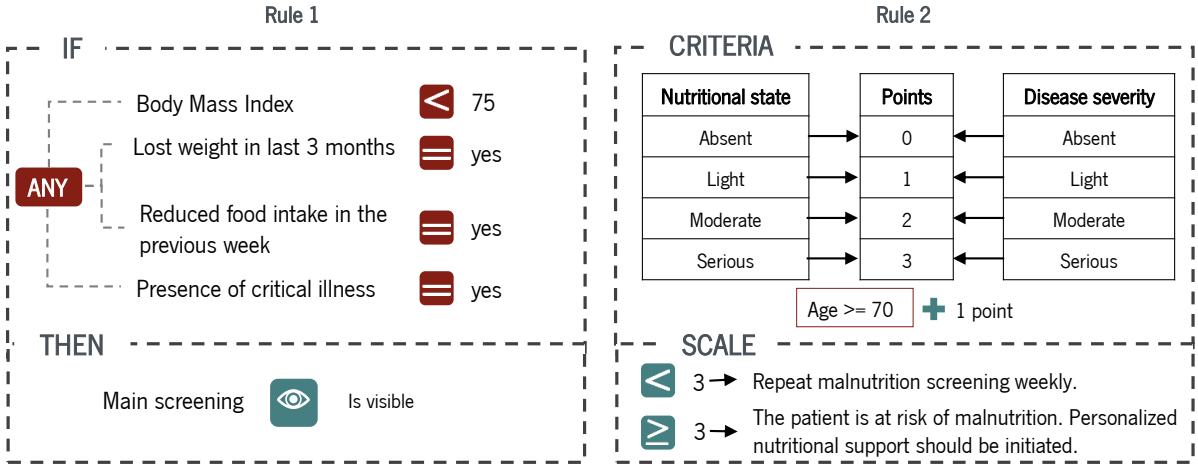


Figure 54: Decision rules of DLM1 for the NRS guideline.

First, a rule was created for initial screening. This is a rule production type with four associated conditions, where at least one of them must be true (ANY operator). Notably, the first condition is calculated automatically, as the BMI is a calculation variable that is computed using pre-defined data from the SPO. The DLE sends a request to the data proxy service to retrieve the patient's latest weight and height records and calculates the BMI based on a predefined formula. Once the calculation is completed, the DLE sends the result to the form, and the field is then locked, preventing further editing. The remaining conditions

are Boolean values entered by the user, typically the responsible nurse. If at least one of the conditions is true, the main screening section becomes visible for completion.

If rule 1 is considered valid, rule 2 is invoked. Rule 2 is associated with the main screening section of the form, and is a score rule. Being a score type rule, variables have associated values that will trigger an output according to the total sum of the point values. In this case, the nutritional status and disease severity are two variables with assigned point values based on their levels. For example, if the nutritional status is moderate, it's awarded 2 points; if the disease severity is severe, it's awarded 3 points. Additionally, there's a third variable in this case, which assesses the patient's age, giving an additional point if they are over 70 years old. The scoring scale defined for this case is as follows: if the total score is less than 3, the patient is not considered at nutritional risk but will undergo weekly screening until discharge from the hospital. If the total score is greater than or equal to 3, the patient is at nutritional risk, triggering an internal nutrition consultation and requiring the completion of the GLIM form.

- DLM 2: GLIM

In line with the clinical pathway described above, when a patient is identified as having nutritional risk, it is imperative to fill out the GLIM form. To facilitate this process, DLM 2 was developed, encompassing clinical rules for the GLIM form. As depicted in Figure 55, two production rules were created: one for assessing diagnostic criteria and another for determining the severity of malnutrition. These rules utilise the fields within the form, aligning with phenotypic and etiologic criteria.

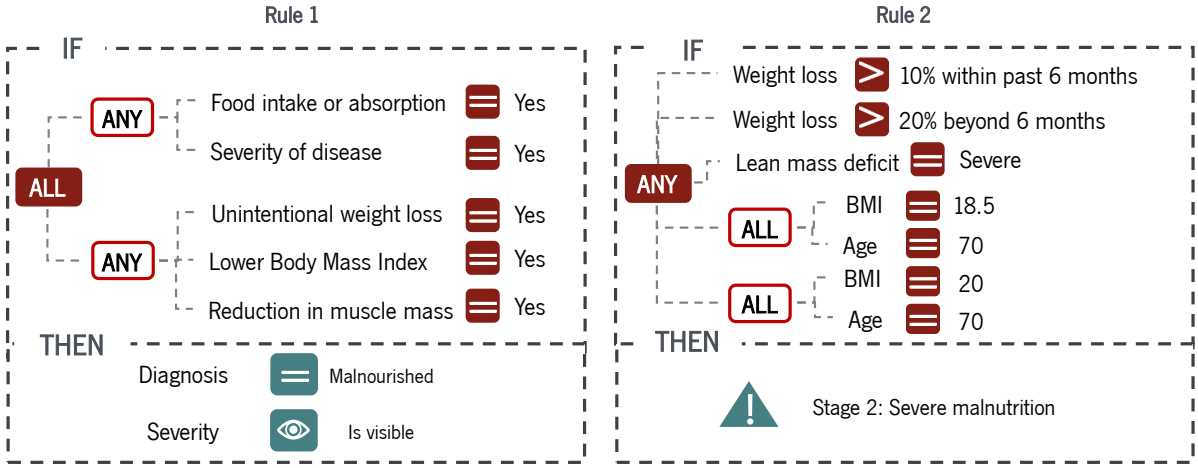


Figure 55: Decision rules of DLM2 for GLIM guideline.

For rule 1, there is an interplay between two sets of rules, each containing conditions for both phenotypic and etiologic criteria. In this configuration, if at least one condition in each set is true, the patient is diagnosed as malnourished, subsequently revealing the *assessment* section. In rule 2, the severity of the patient's malnutrition is determined through the use of five conditions, where two of them are a set of another two conditions (connected by the 'ALL' operator). For the weight loss variable, the values must be more than 10% within the last 6 months or more than 20% beyond 6 months. The Lean mass deficit

must be considered severe. The BMI must be less than 18.5 for patients under 70 years old or less than 20 for patients over 70 years old. Notably, the BMI variable is calculated automatically, and the patient's age is checked in this context through the SPO service. If any of the specified conditions are true, the patient is classified as having severe malnutrition.

- DLM 3: Internal consultation request

The third DLM is linked to the Internal Consultation form, which is completed when the patient is identified as being at nutritional risk based on the NRS result. The rule in this DLM is a decision table with a single variable. If the *priority* field has a boolean value *yes*, as illustrated in figure 56, the time to execute the order (*service due* field in the form) is automatically set to *24h* as output. This means that if the consultation is urgent, it must take place within 24 hours; otherwise, it should be conducted within 72 hours.

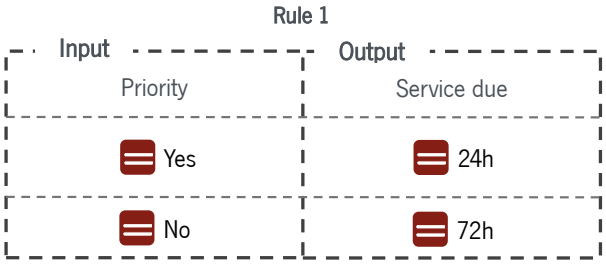


Figure 56: Decision rules of DLM3 for internal consultation request.

Additionally, automatic completion has been established for specific form fields. For instance, the *service name* field is pre-filled with *nutrition*, and the *reason description* field is populated with the message *Patient identified with nutritional risk*, with the option to make edits. The initial fields in the order are automatically set to the current date and time.

6.3.4 Obstetrics use case

Obstetrics comprises the clinical process of all obstetric care for pregnant women, such as, monitoring pregnancy, childbirth and the postpartum period. This clinical process encompasses a great deal of data and consequently involves complex decisions at the different stages of obstetrics. The adoption of CDSS in obstetrics promises to improve this process due to its complexity and the identification of the best guidelines for each patient, since the processes differ according to the patient status. Therefore, this use case presents the workflow conducted in a Portuguese health center in the obstetrics service. Particularly, the flow will focus on the area of obstetric hospitalisation, addressing tasks related to monitoring pregnancy, childbirth, and labor.

6.3.4.1 Introduction

Pregnancy and childbirth are important developmental periods in a woman's life (Kamali et al., 2018). Effective communication during care transitions, particularly between obstetric triage and labor teams, is crucial to avoid errors and inefficiencies, as poor handoffs can delay treatments, miss critical health information, and reduce satisfaction among staff and patients (O'Rourke et al., 2018). Access to relevant information during pregnancy is crucial for expectant mothers to reduce adverse outcomes. According to WHO (2014), about 800 women die daily from pregnancy or childbirth-related complications, with higher maternal mortality in rural and low-income communities due to inequities in healthcare access (Kamali et al., 2018). Providing appropriate information helps women make informed decisions, improving their psychological outcomes and quality of life, and leading to more effective disease management strategies. Most maternal deaths stem from preventable or treatable causes, highlighting the importance of proper prenatal care (Kamali et al., 2018; Kyei-Nimakoh et al., 2017).

The adoption of EHR systems is transforming patient care by facilitating high-quality and safe healthcare delivery. However, issues with workflow integration have slowed EHR adoption in some specialty care settings (Lowry et al., 2015). Standardising health information exchange and interoperability is crucial for maximising the benefits of EHR. By creating HIS with a common data structure, healthcare organizations can achieve semantic interoperability, enabling seamless data sharing across various applications and improving overall care coordination (Bacelar-Silva et al., 2013). O'Rourke et al. (2018) believes that implementing a standardised system can improve communication workflow in obstetric services.

Therefore, this use case aims to address the processes performed within the obstetric service in the Portuguese hospital centre to overcome the problems faced with the previous approach. The flow is focused on the inpatient department, where the delivery, labour, admission, history and puerperium diary will be considered.

6.3.4.2 Methods

The methodology adopted for this use case followed a four-phase approach, as shown in Figure 57. As this use case was the last to be developed, the stages of the methodology followed similar steps to the previous use cases.

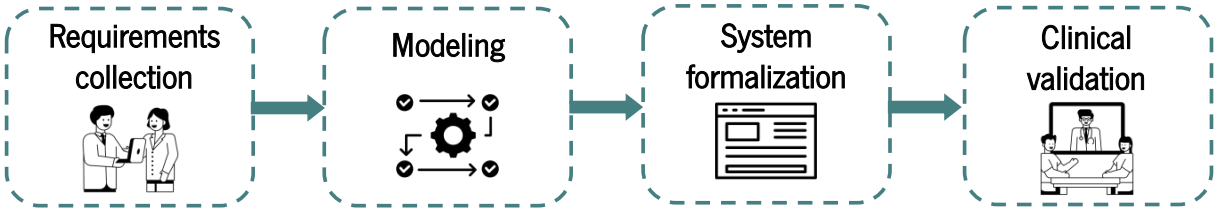


Figure 57: Methodology adopted for obstetric use case.

A four-step methodology was adopted, incorporating requirements collection, modelling, system formalisation, and clinical validation. This approach ensured that the system met the specific needs of

healthcare providers and patients while maintaining high standards of clinical accuracy and usability.

Requirements collection The initial step involved gathering comprehensive requirements through a focus group comprising healthcare professionals, IT specialists, and domain experts. This diverse group provided valuable insights into the practical needs and challenges faced in clinical settings. Through structured discussions and brainstorming sessions, a set of requirements were identified, as well as desired features to the workflows. The focus group also highlighted specific failure points in current systems, which guided the development of targeted solutions.

Modelling With the requirements defined, modelling of the data structures was conducted using openEHR archetypes and templates. Archetypes represent reusable clinical concepts, while templates are combinations of these archetypes selected for a specific clinical scenario. In this sense, three templates were modelled to record information relating to the patient's admission, labour and childbirth. The structures were modelled in AD, using existing archetypes in the CKM repository and creating new ones when necessary. The focus group reviewed and refined these templates, ensuring that they correctly represented the clinical processes and terminologies.

Forms, workflow and rules creation The next step was system formalisation, where the templates were converted into practical components, including forms, rules, and tasks. Forms were designed based on the templates created in the modelling phase, ensuring they captured all necessary data points for the respective obstetric purpose. Rules were created for each form, compassing different decision models. Tasks were defined inside the workflow modelling to streamline and automate the clinical processes. The focus group played a crucial role in validating these components, providing feedback on usability and functionality.

Validation The final step was clinical validation, where the system was tested in the real clinical environment of the obstetric service of the Portuguese Hospital Centre. Healthcare professionals from the focus group conducted a series of pilot tests, using the system in their daily routines. This phase aimed to verify that the system met clinical needs, integrated seamlessly into existing workflows, and improved overall efficiency and patient care. Feedback from this phase was used to make necessary adjustments, ensuring the system was ready for broader implementation.

6.3.4.3 Results

This section will present the results regarding the application of the proposed system in this use case. The outcomes are regarding the workflow performed, the developed forms through archetype modelling, rules creation, and the use of a prediction module.

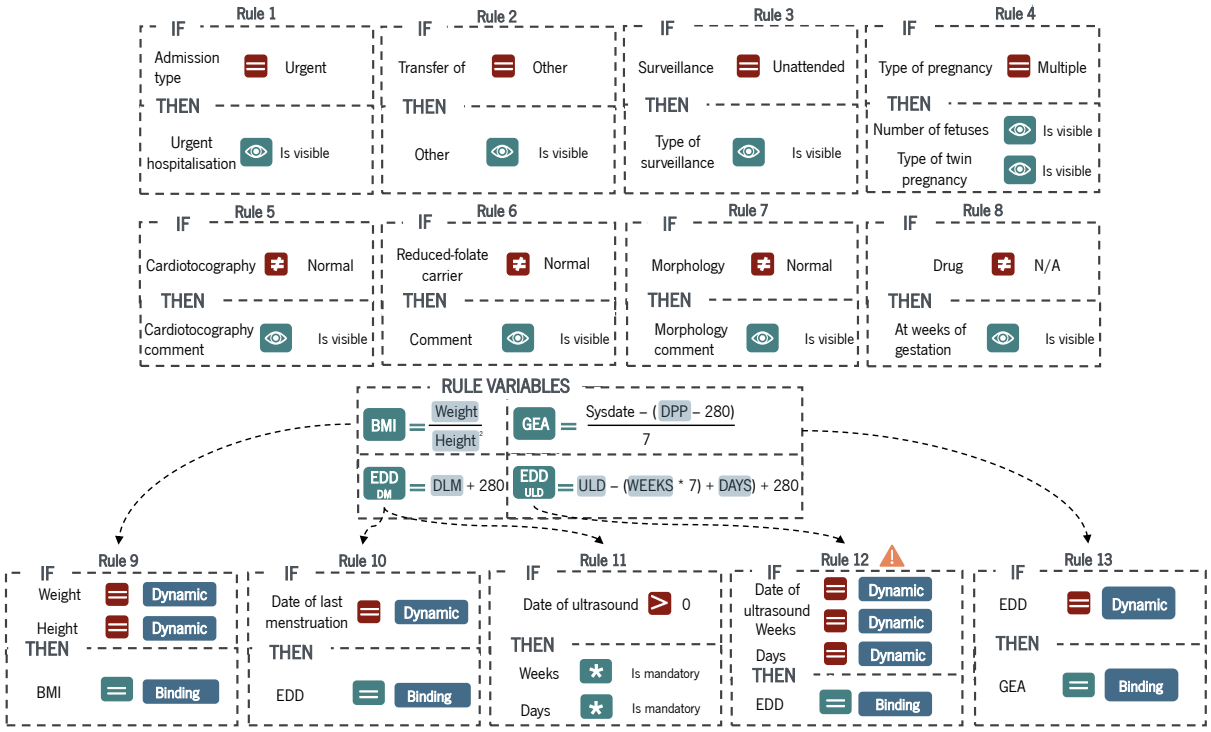
Decision logic formalisation Different workflows are carried out in the obstetrics department of the Portuguese Hospital Centre. The application of the proposed system covered eight task plans and forms, ranging from the woman's first pregnancy appointment to her hospital discharge after giving birth. Specifically, the first consultation, subsequent consultations, admission, labour, delivery, abortion, puerperium diary, and antecedents. However, in order to comprise this work, this use case will only consider three processes: the patient's admission, labour, and the childbirth. The three work plans led to the creation of three openEHR forms that were modeled in advance. Consequently, three decision modules were developed to be associated with each of these forms.

- DLM 1: Admission

The patient's admission to the obstetrics department begins when the woman is going into labour. A set of rules are defined to automate this process. The obstetrics department's previous system defined the rules internally in the legacy system's programming code, and also through direct database queries. This had a negative impact on the flexibility of the healthcare professionals in relation to the system, as they had no autonomy to create new rules or make changes when necessary. The rules created for DLM1 is demonstrated in Figure 58.

DLM1 was created in order to automate the filling in of some composite data on the patient's admission form. Using production rules, thirteen rules were created, as illustrated in Figure 58a. In general, most of the rules have been created to automate filling in the admission form. The first rule checks the type of admission, where if it's of the urgent type the *urgent hospitalisation* section is visible on the form. The second rule makes the *other* text field visible if the transfer type is not one of those listed. For rule 3, if the patient is not supervised, the surveillance type field becomes visible. Rule 4 determines whether the type of pregnancy is multiple, if so, the fields for specifying the *number of foetuses* and the *type of twin pregnancy* become visible on the form. Rules 5, 6 and 7 determine whether there are any abnormalities in the pregnancy by checking the cardiotocography scan, the reduced folate carrier, and morphology. If the results are different from normal, a text field is visible for comments. Rule 8 checks whether drugs have been used, if this is different from not applicable, it is necessary to specify at which weeks of gestation they were used.

The following rules used rule variables to calculate a certain value. Some of the calculations required the use of the data binding service, SPO, to provide the current value of the necessary variables. In the case of rule 9, the rule variable BMI was created to calculate the muscle mass index using the patient's current weight subtracted by her height squared. The weight and height values are supplied by the SPO and the DLE calculates it using the values received, and fills in the BMI field with the final result. Rules 10, 11 and 12 are related to the calculation of Expected Date of Delivery (EDD), where two ways have been defined: one outlined in rule 10 and the other in rule 12. Rule 12 takes precedence over rule 10. To do this, rule 11 is triggered first to check if the date of the first ultrasound scan has been filled in. If so, the fields relating to the number of weeks and days of gestation become mandatory and rule 12 is



(a) Production rules for DLM1 of the obstetrics use case.

Rule 14

Criteria

Consistency	Dilation	Position	Effacement	Hodge Plans	Points
Firm	0 cm	Posterior	0 to 30%	Above I	0
Medium	1 to 2 cm	Mid position	40 to 50%	I	1
Soft	3 to 4 cm	Anterior	60 to 70%	II	2
-	> 5 cm	-	> 80%	Superior to II	3

Scale

Total score

(b) Score rule for DLM1 of the obstetrics use case.

Figure 58: Admission decision rules for the obstetric use case.

triggered. Rule 12 calculates the expected date of delivery using the date of the ultrasound scan, where this date is subtracted by the number of weeks multiplied by 7, plus the number of days, and then 280 is added to the total value. If the date of the first ultrasound is not specified, then EDD is calculated through rule 10, using the date of the last menstrual period, where this date is added to 280, which is the number of days until the baby is born. Finally, rule 13 calculates the pregnant woman's gestational age (GEA) by subtracting the current date with the EDD minus 280 days and dividing everything by 7.

Figure 58b demonstrates the rule 14 created through the score decision model. Using the score type, a rule was defined to calculate the bishop index. This rule used five variables, namely consistency, dilation, position, extinction and hodgepodge. Each variable has an associated point that was imported from the archetype used in the modelling phase. DLE imports and interprets the values of the openEHR modelled structures and automatically saves the associated score according to the variable value selected by the user. In the end, the total score is added up and the bishop index form field is assigned the value.

- DLM 2: Chilbrith

One of the clinical processes in obstetrics is childbirth, which involves the expulsion of the fetus and the identification of characteristics of both the fetus and the mother. This process determines how the labour process was carried out, for example, using specific instruments or medication to help with the pain identified in the procedure and, if necessary, moving on to a caesarean section. A decision module was therefore developed to support this clinical process, as shown in Figure 59. Subsequently, the logical model called Childbirth or delivery was developed to help the form create different rules that will be used throughout its completion.

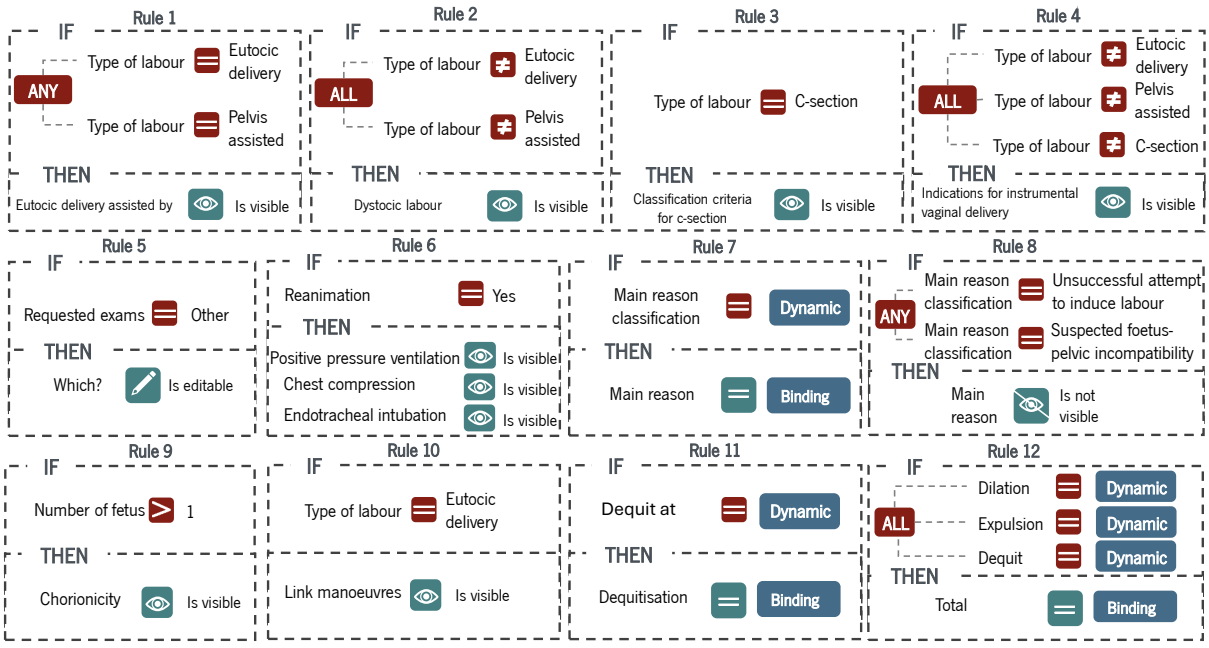


Figure 59: Chilbrith decision rules.

For DLM2, only production rules were created. Rules 1 to 4 and rule 10 are applied to the type of delivery. For rule 1, the types must be eutocic or assisted pelvis for the *eutocic delivery assisted by* field be visible. Otherwise, the dystocia section becomes visible (rule 2). In rule 3, the type of birth must be Caesarean section for the *classification criteria for c-section* to be visible. In rule 4, for the *indication for instrumental vaginal delivery* section to be visible, the type of delivery must be different from eutocic delivery, assisted pelvis and caesarean section. Additionally, rule 10 defines the *link manoeuvres* field visible if the type of delivery is eutocic.

Rule 5 has been created for exam requests, where, if the exam is not in the list of values, the *which?* text field becomes editable. Rule 6 determines whether there is reanimation in childbirth, if so, the *positive pressure ventilation*, *chest compression*, and *endotracheal intubation* fields become visible. Rule 7 has dynamic values for the main reason classification, determining the list of possible values for the *main reason* field. Rule 8, on the other hand, states that if the main reason classification is equal to *unsuccessful attempt to induce labour* or *suspected feto-pelvic incompatibility*, the *main reason* field will no longer be visible. Rule 9 defines the number of foetuses, if it is greater than 1, the coronicity field is visible. Using data binding, rules 11 and 12 were created through API calls prepared to retrieve real-time values from external sources. In particular, rule 11 provides information on dequitisation and rule 12 calculates the total value obtained through dilation, expulsion and dequit.

- DLM 3: Labour

The first DLM is alluded to the childbirth, in other words, it refers to the details of all the contractions and dilations of the woman's uterus. In short, labour seeks to establish all the guidelines for the birth process. With this in mind, a form was created to register the information about the delivery procedure. The labour logic model illustrates a rule that supports one part of filling in the form Figure 60.

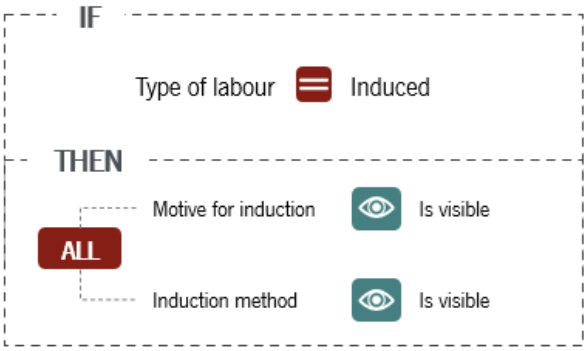
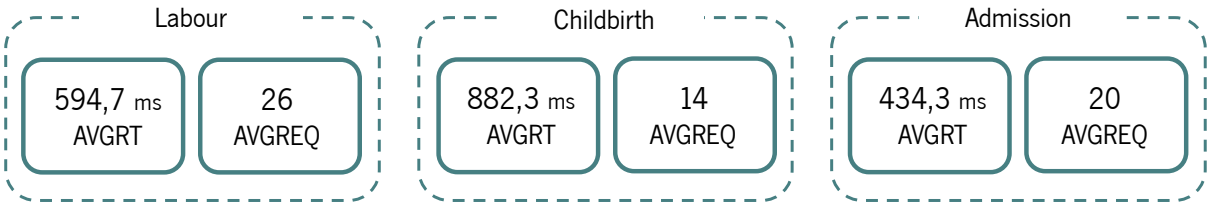
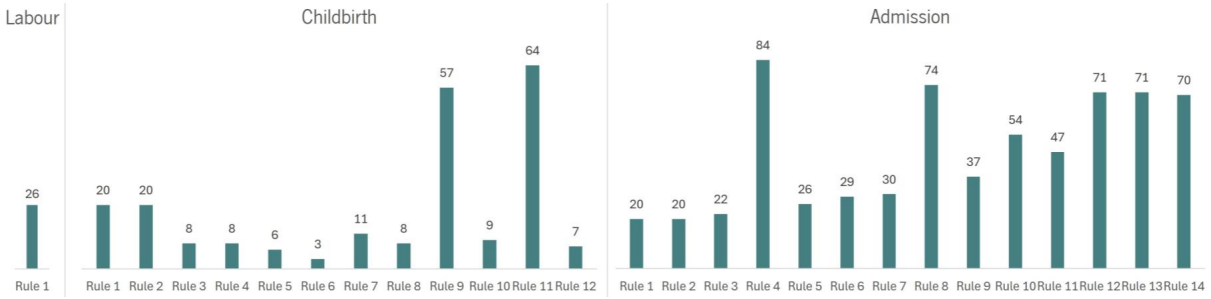


Figure 60: Labour decision rules.

Therefore, the DLM rule uses a field variable "Tyoe of labour" and, if this has the value "Induced", the field "Method of induction" and "Reason for induction" will be visible to fill in on the form. For DLM3 in the obstetrics use case, only one rule needed to be created since most of the information is already documented on the childbirth form.



(a) AVGRT and AVGREQ of obstetric use case for both DLM.



(b) Count of rules executed for the modules of obstetric.

Figure 61: Results obtained for the obstetric use case.

System indicators Key indicators from the output obtained with the application of the obstetric process were identified. Figure 61 represents the outcomes obtained regarding the performance of the DLE. The three modules created have different average response times, with admission having an AVGRT of 434.4ms, labor 594.7ms, and delivery 882.3ms, as demonstrated in Figure 61a. The average number of requests per day (AVGREQ) varies between 26, 14 and 20, for labor, delivery and admission, respectively.

As the obstetrics use case was the most recent study to be developed, there are still few quantitative records of its use. Figure 61b shows the number of calls made in each rule for each module created. For DLM1, the most called rules were Rule 4, Rule 8 and Rule 12. Regarding the rules created for the type of birth in DLM2, the most frequently called were Rule 9 and Rule 11.

Prediction module To enhance this use case, the prediction module of the proposed artifact was utilised. A need was identified to automate the rule creation process based on historical data from the legacy system. Consequently, the objective is to develop semi-automatic rules using ML techniques, leveraging the historical data. The type of labor decision was selected for demonstration purposes. Figure 62 illustrates the process undertaken to implement the prediction module.

The initial phase of the process involved identifying and retrieving historical records from the legacy system. This included admission data, labor data, and antecedent records, all stored in semi-structured Extensible Markup Language (XML) formats. The essential components were extracted from each source. Following the data extraction, the next step was to analyze these sources to determine which variables would be used for forecasting.

Based on the literature review (Irwinda et al., 2021; Meier et al., 2019; Tarimo et al., 2021), eight variables were identified as influencing the decision on the type of delivery. These variables include

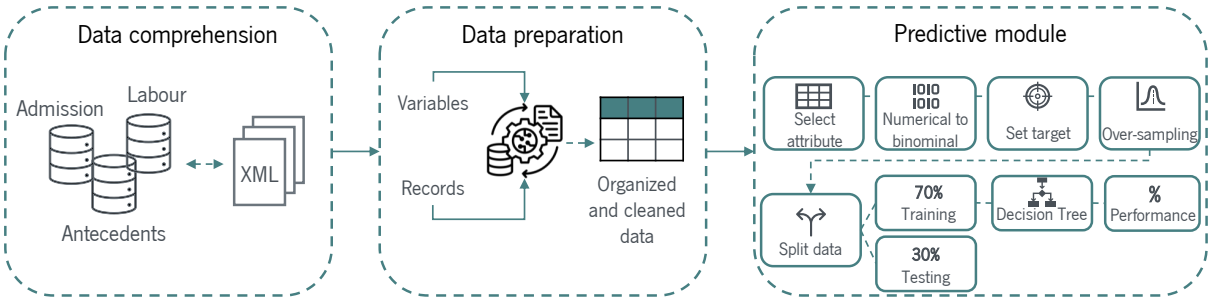


Figure 62: Process conducted for the prediction module of the obstetrics use case.

the woman's age, height, number of weeks of gestation, type of pregnancy (unique or multiple), baby's presentation, number of previous labours, number of previous c-sections, and Bishop score. The second phase involved preparing, cleaning, and transforming the extracted data. This process focused on filtering out blank and null values, as well as out-of-context records. When attribute values didn't match the expected data types (e.g., text values in integer fields), necessary transformations were performed. The most challenging aspect was handling free-text data, which was often inconsistent and lacked significance.

An ML tool was employed to conduct the forecasting process, utilising a sequence of dedicated operators for data preparation, analysis, and evaluation. First, the the selected dataset was imported, serving as the basis for the subsequent analysis. Next, the attributes from the dataset that influence the output were choosen. To improve the model's accuracy and efficiency numerical attributes were converted to binominal (binary) format, ensuring compatibility and interpretability with the model's algorithm. The output variable was defined as the target for prediction, guiding the learning process. Following the process, an over-sampling technique was applied to handle class imbalances in the dataset. By generating synthetic samples for the minority class, this method ensures a more balanced and fair training process. The dataset was split into training and testing sets with a 70%-30% ratio for training the model on one portion of the data while evaluating its performance on another. After refining the model, a decision tree algorithm was used to generate the rules based on the selected attributes. Consequently, the model was applied connecting the trained decision tree model to the test data for evaluation.

The performance of the model was assessed, providing various metrics to evaluate the model's predictive accuracy and overall execution. As a result, an analysis was made, in order to analyse the performance of the prediction module. Table 11 shows the results obtained in terms of accuracy, sensitivity, and precision.

Table 11: Performance of the prediction model for the obstetrics use case.

Metric	Value
Accuracy	80.27%
Sensitivity	72.25%
Precision	73.15%

The outcomes predicted by the model indicated an accuracy of 80.27%, which reflects how correct its predictions were compared to the actual outcomes. Sensitivity measures the proportion of actual positive cases (true positives) correctly identified by the model, with a sensitivity of 72,25% suggesting that the model identified positive instances. The precision signifies the accuracy of positive predictions made by the model, indicating how many of the predicted positive instances are actually correct, corresponding to 73.15%. Overall, the prediction model performs reasonably positive in all the metrics evaluated. The value obtained in accuracy suggests that the model makes correct predictions in most cases. However, there is some room for improvement in both sensitivity and accuracy, indicating potential areas for optimisation to improve the model's performance.

With regard to the rules derived from running the model, the decision tree model was responsible for this process. The aim was to identify trends in delivery type based on a set of conditions involving variables, operators, and values, resulting in rules. As a result, Figure 63 displays a snippet of the outputs produced by the prediction model.

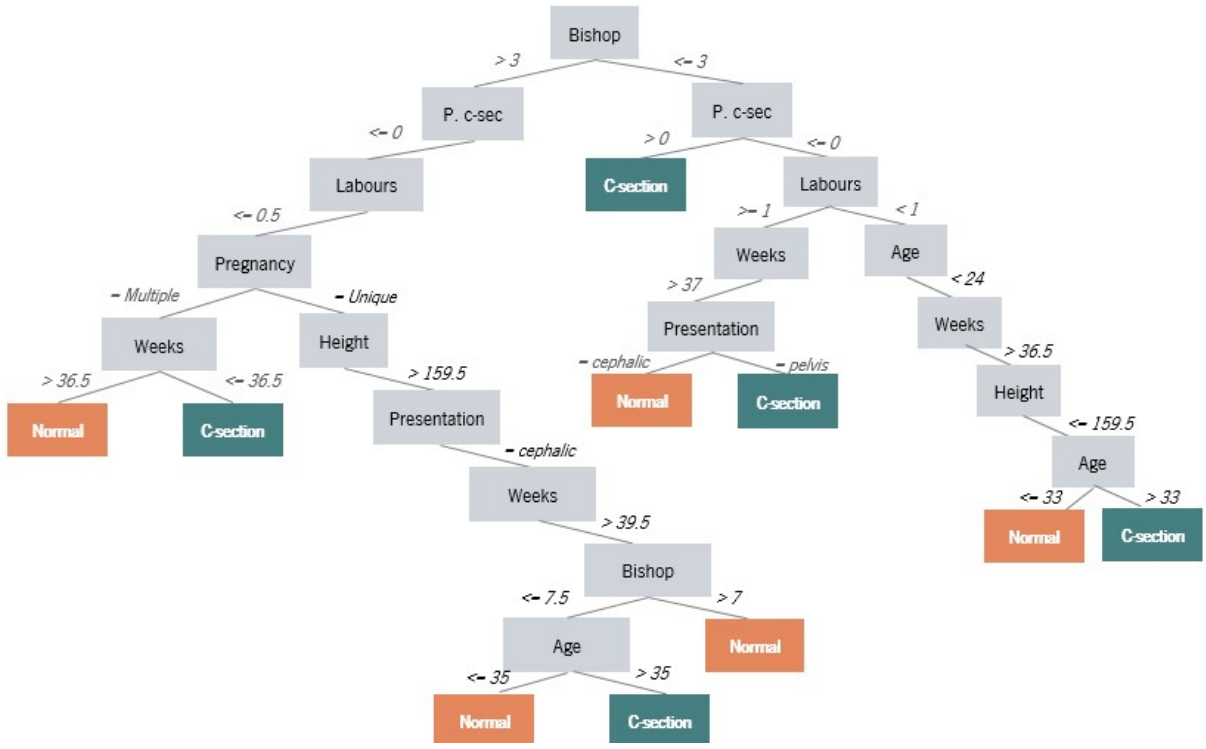


Figure 63: Generated rules with the application of the prediction model.

Running the model generated a huge number of branches associated with the decision tree. By defining configuration parameters, the generation of rules was restricted, presenting combinations that were more focused on the purpose. Additionally, the algorithm displays the number of occurrences that each result is based on. This allows for evaluating both the trend and the accuracy of the results. Using the simplest branch of the example presented, the rules obtained can be interpreted as: IF the Bishop Index (input variable) is less than or equal (operator) to 3 (value) AND the number of previous c-sections

(inpupt variable) is greater than (operator) 0 (value), THEN the type of delivery (output variable) will be caesarean section (output value).

The goal of developing this component was to determine if semi-automatic rules could be generated from a set of records from legacy systems. Based on the rules generated by the model, the work effort is reduced, since there is no need to build rules from scratch, requiring only validation by professionals in the field. The current level of automation for this module is semi-automatic, as it requires final validation by domain experts. Following these steps, the prediction process was conducted to guarantee robust and accurate results. The careful selection of attributes, the treatment of unbalanced data and the optimisation of parameters were crucial to the develop the predictive model.

6.4 Concluding remarks

The purpose of this chapter is to demonstrate the application of the proposed system in a real-world environment. Both cases involve innovative approaches to structuring clinical data and automating processes. Several phases were included for each case, from modelling the necessary openEHR structures to their implementation in a Portuguese hospital, covering task planning, rule definition and forms.

For the imaging exams use case, information was collected on the screening process of more than 6800 imaging exam requests. The relevance of the solution was supported by the statistical analysis carried out, showing a significant reduction in waiting times for outsourcing management, with around 30,857 fewer waiting days on average in 2022 compared to 2019. These results had a significant impact on the hospital involved, as it allowed for the computerisation of a previously paper-based process. This proved the viability of the proposed approach also applied to administrative processes.

The second use case demonstrated the effects of the intervention on the corneal transplant workflow, which was previously characterised by inadequate automation and an increased risk of data loss. The results revealed that out of 830 tasks available, 530 were completed, which indicates that the task completion rate is 64%. The number of tasks available and completed can help measure the workload of healthcare professionals and assess the system's ability to cope with the demands of the workflow. A higher ratio of completed tasks to available tasks indicates that the system is working efficiently and effectively. A lower completion rate, on the other hand, may suggest potential bottlenecks or areas for improvement in the system's design or implementation. As most of the tasks available in the workflow studied concern the 'Corneal Transplant Contact', which represents the active waiting list for corneal transplantation, the completion of the workflow depends on external factors such as the patient's health and the availability of donor organs. These dependencies directly affect the time needed to complete the tasks and, consequently, the total workflow.

The development of the nutritional risk screening use case was motivated by the importance of caring for inpatients at nutritional risk, requiring faster and more personalised care. The current process carried out in the hospital in question for this workflow is disintegrated and not automated. When a patient is

admitted, their nutritional risk is assessed using legacy systems and paper forms. Decision rules, such as scores, are defined by queries in the database itself, created by IT programmers. As the workflow is not operated automatically, the request for exams or services is made individually through heterogeneous systems. Consequently, this study emerged as a motivation to overcome the identified barriers, by applying a standardised and automated workflow. This use case is currently in the testing phase and does not have quantitative results of its application in real operation. However, it was possible to simulate its application in the respective workflow and it proved to be adaptable and easy to use, promising satisfactory results.

Finally, the most recent application of this research was conducted in the obstetrics department, involving several parallel processes and tasks that need to be coordinated. Although the proposed artefact was used in eight different work plans, only three processes were detailed to centralize the work, particularly the patient admission, labour and childbirth. This use case was the most demanding, as it involved identifying requirements within a highly complex environment, leading to the creation of a comprehensive set of varied rules. In addition, this use case allowed for experimentation with a knowledge generation module by predicting rules. While these predictions were not implemented, it was possible to demonstrate that the system is capable of generating semi-automatic rules, requiring the final validation of a healthcare professional.

Overall, the Portuguese Hospital Centre where this work was conducted boasts substantial resources and a strong technological infrastructure. Despite the computerisation of work processes, some issues were encountered. One of the limitations found in the hospital was the use of different and incompatible systems, which led to communication failures and data loss. In contrast, modelling in openEHR allows data to be structured and standardised, promoting semantic interoperability between systems and distinguishing clinical concepts from patient demographic information. Besides, the lack of automated decision processes had a direct impact on the performance of healthcare professionals where, sometimes, were forced to verify the transmission of information, the veracity of data and scheduling or medical requests, resulting in wasted time in patient care. Although this issues have a direct impact on the technology, professionals and the organisation, it is important to highlight it also affect the well-being of patients, even indirectly.

In essence, the proposed approach is flexible and capable of process rule-based guidelines integrated with workflows and standardised forms. Besides, by incorporating a decision logic component, healthcare professionals can easily create rules and guidelines without relying on IT developers. The separation of data and knowledge modelling enables independent development and implementation of different cases, providing more flexibility, collaboration between different stakeholders, and allowing work to be done outside the traditional software development process. This provides a more collaborative environment, enabling healthcare providers to actively participate in developing rules and guidelines without interfering with system coding or database services.

Part IV

Evaluation and Discussion

7

Enhancing an Effective Clinical Decision Support System

This chapter covers the process of analysing and validating the proposed artefact through a threefold evaluation. Firstly, a data analysis relating to the performance of the proposed system is provided. A cross-mapping of the use cases is presented next, in which the results and knowledge obtained from different clinical scenarios are synthesised to identify common patterns, challenges and areas for improvement. Finally, the previously developed MSM is applied to the proposed CDSS in order to assess its level of maturity. Analysing these results makes it possible to assess the system's effectiveness in terms of its capabilities and functionalities. In short, this chapter aims to explore the effectiveness of the system by bridging the gap identified. With this evaluation, areas for improvement are identified throughout the continuous development process.

7.1 Contextualisation

In healthcare, it is increasingly required that organisations adopt a component to support the decision-making process, whether it is independent or integrated into a HIS. HIS have enabled the representation of the cognitive activities of health professionals in a computable form capable of collecting, storing, and processing EHR (Ngafeeson, 2014). CDSS are required as an integral part of HIS to aid in decision-making processes, reduce errors and work malpractices, and improve the quality of services provided. Despite the continued adoption of DSS in healthcare, most developed systems fall short of their intended function (Muhiyaddin et al., 2020).

Previous studies on CDSS demonstrate improvement in preventive services, appropriate care delivery, and clinical and cost-related outcomes. Nonetheless, increasing provider adherence to CDSS recommendations is essential for optimising its effectiveness, with ongoing research into the factors that influence adherence. Although evidence underscores supporting the effectiveness of CDSS, certain studies have revealed limited improvements in procedural outcomes, indicating variability in effectiveness across different contexts (Murphy, 2014). Additionally, the previously conducted SLR (chapter 4) indicated persistent

limitations in CDSS implementation, contributing to its low effectiveness.

Other studies highlight this problem by identifying specific issues and concerns that may contribute to it. To identify common obstacles hindering the effectiveness of a CDSS implementation, six studies were analyzed based on specific criteria: (i) the type of literature review (systematic or narrative), (ii) publication within the last decade (with a preference for more recent publications), (iii) publication in a Q1 or Q2 journal, and (iv) articles in English as open access. Following the selection of eligible studies, the focus of CDSS concerns centered on technological aspects, excluding those influenced by social or organisational factors.

First, a careful analysis was carried out to identify the concerns addressed in each publication. This selection was followed by an intersection of topics to rank the concerns according to the frequency with which they appear in the literature. As a result, the top five concerns most frequently mentioned in the publications under consideration were the ones selected. Hence, Table 12 displays the five selected concerns that impact the effective performance of CDSS.

One of the primary concerns in the implementation of CDSS involves managing and representing knowledge. To provide reliable recommendations, a CDSS must have access to a thorough and standardized knowledge repository. This necessitates extracting and organising clinical data in a structured format conducive to sharing, reuse, flexibility, and adaptability across diverse systems. Failing to establish a robust knowledge base can result in data scarcity, redundancy, or loss, along with misguided prescriptions and tasks. Moreover, the absence of standardized data storage can increase dependence on manual, paper-based processes, impeding and contradicting the system's intended functionality.

Another significant challenge is integrating CDSS into clinical workflows. Clinical workflows and pathways must be defined automatically and linked to decision points. However, the modeling of complex and specific workflows associated with patient care can prove difficult. Disruptions or fragmentation in the workflow can escalate the workload for healthcare professionals, impacting their ability to effectively manage patient care. This can lead to non-optimised logistics and a rise in error rates, compromising the overall quality of care provided.

Decision rules should be based on medical knowledge and synchronized with care processes. Automating the processing of rules, protocols, and guidelines aims to streamline the retrieval and analysis of clinical data. However, if decision rules are not accurately created or maintained, CDSS can result in information overload, providing incorrect or unguided recommendations. Such outcomes can confuse and potentially compromise patient safety.

Ensuring interoperability and data sharing is crucial for the efficacy of CDSS. Information exchanged among various systems must be both trustworthy and secure. Utilising standards and terminologies enhances the exchange of semantically interpretable data, avoiding data loss, communication failures between systems, and misinterpretation of shared information. Otherwise, the system risks insecurity and unreliability, increasing the likelihood of errors and costs, and ultimately compromising patient safety.

Lastly, user acceptance and satisfaction are critical factors in decision support and any information system. When healthcare professionals lack trust in or fail to adapt to the system, it can lead to limited

Table 12: Concerns found in CDSS literature (adapted from (Hak and Santos, 2024)).

ID	Concern	Contextualization	Impact	References
P1	Knowledge management and representation	Having a reliable and robust knowledge base is essential for system maintenance. Extracted clinical data must be processed and stored in a structured and standardized format, to promote sharing, reuse, and adaptability to different systems	Data deprivation; duplication or loss of information; misguided prescriptions and tasks; increase paper processes	(Greenes et al., 2018; Kawamoto & McDonald, 2020; Laka et al., 2021; Papadopoulos et al., 2022; Sutton et al., 2020)
P2	Clinical workflow integration	Workflow are essential for representing specific and complex tasks associated with a care process. Workflow modelling is important to increase professional autonomy, as well as having an interrupted and fragmented workflow. This will increase work overload, affecting the performance of health professionals in managing patient care	Workload in healthcare professionals; non-optimised logistics; increased error induction	(Bright et al., 2012; Kawamoto & McDonald, 2020; Laka et al., 2021; Sutton et al., 2020)
P3	Automatic creation of decision rules	Decision rules must be based on knowledge oriented to care processes. Automated processing of rules, protocols, and guidelines will facilitate processing and access to clinical information	Information overload; incorrect and unguided recommendations	(Bright et al., 2012; Kawamoto & McDonald, 2020; Laka et al., 2021; Sutton et al., 2020)
P4	Interoperability and sharing	Ensuring that the information shared is reliable and secure is extremely important. Low use of standards and terminologies can contribute to data loss, failure in communication between systems, and semantic misinterpretation of exchanged information	Insecure and unreliable system; increased errors and costs; compromised patient safety	(Greenes et al., 2018; Kawamoto & McDonald, 2020; Papadopoulos et al., 2022)
P5	Healthcare professional acceptance	User satisfaction is an important point to consider. Healthcare providers need to trust and adapt to the system, otherwise their resistance will lead to limited usability and low implementations	Wasted care time; reduced patient satisfaction; disgruntled professionals	(Bright et al., 2012; Laka et al., 2021)

usability and low implementation rates. This resistance can lead to wasted care time, lower patient satisfaction, and disillusioned healthcare professionals, resulting in the underutilisation of CDSS and its potential being not full utilised.

Overall, the ineffectiveness of CDSS may relate to various concerns beyond the five mentioned. A review of the literature examining CDSS performance revealed several concerns, from which five were

chosen based on their relevance to CDSS technology-related problems. Addressing these concerns is essential for mitigating the potential opposite effects on healthcare settings, as systems with low efficacy can jeopardize patient and healthcare professional safety.

7.2 Evaluation

The previous SLR conducted (chapter 4) revealed a gap in the effectiveness of CDSS implementation, where the reviewed systems did not progress beyond stage 2 (of 4) of the maturity model. This opened up a research opportunity to investigate possible approaches that could help increase the effectiveness of a CDSS. To this end, a decision logic component was proposed to bridge this gap. Following the openEHR DL specifications (Beale, 2021), the artefact aims to represent clinical knowledge through different ways of expressing rules and guidelines.

In order to assess the feasibility and potential of the artefact developed, an evaluation will be conducted covering three topics. Firstly, an analysis of the system's data will be presented concerning its overall performance. Next, a cross-mapping between the use cases developed will be demonstrated to identify the functionalities obtained at each point in time. Ultimately, the proposed CDSS will be evaluated to determine whether it fulfils the criteria of an effective CDSS, according to theMSM.

7.2.1 Data analysis

Evaluating the performance of a CDSS is a critical factor in ensuring its rapid utilisation in a healthcare environment. One of the main performance points is the response time of the system, which has a direct impact on the efficiency of clinical workflows and the ability of healthcare professionals to make timely decisions. Response time is the duration between requesting information and receiving recommendations from the CDSS. In the rush and complexity of hospital environments, a system needs to have a short response time, as it allows doctors to quickly access relevant information and make informed decisions without causing delays in patient care.

Optimising response time involves the efficiency of the data processing algorithm, the complexity of the decision rules, and the underlying infrastructure that supports the system. In addition, a CDSS with fast response times can increase satisfaction and acceptance among health professionals. Healthcare providers are more likely to incorporate decision support tools into their practice if they find them efficient and seamlessly integrated into their workflow. To this end, two indicators were developed to evaluate the performance of the proposed decision logic system. Firstly, the AVGRT metric is responsible to calculate the response time of the system. AVGRT is calculated using the following formula:

$$\text{AVGRT} = \frac{\sum_{i=1}^{N} R_i}{N}$$

R_i corresponds to the response time of the ith request, and N is the total number of requests. This formula sums up all response times for each request and divides by the total number of requests to find the average response time. Then, another metric was defined to calculate the AVGREQ per day:

$$\text{AVGREQ} = \frac{\text{Total number of requests}}{\text{Count of unique dates}}$$

AVGREQ is calculated as the total number of requests divided by the total number of days covered by the knowledge base. In other words, it is calculated the count of unique dates out of the number of orders for the day. This metric is used to estimate the expected number of daily requests made to the system, allowing for the analysis of trends over time and enabling effective monitoring and control.

After the design and development of the DLE, the system was implemented and tested using real-world applications in a Portuguese Hospital Centre. Performance data was stored and analysed over a one-year period. The results, as depicted in Figure 64, represent the outcomes obtained based on the applied performance metrics.

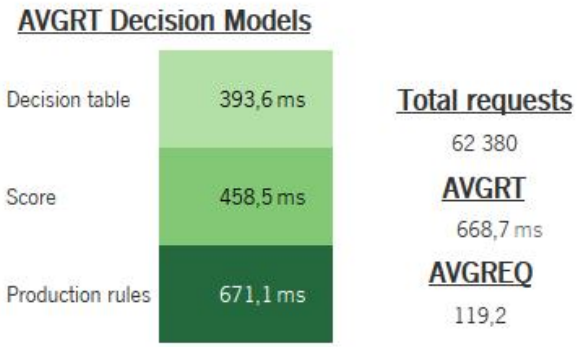


Figure 64: Values resulting from performance indicators.

During the one-year period, the DLE handled 62380 requests for different services. The AVGRT was 668.7ms, and the AVGREQ was 119.2. Additionally, a comparison of response times for the different models was also conducted, represented in a heat map in Figure 64. The AVGRT for decision table processing was 393.6ms, for scores was 458.5ms, and for production rules was 671.1ms. Despite the similar processing nature of these models, the differences in response times lack concrete evidence. However, the higher number of production rules compared to other models likely contributes to the increased response time.

According to Nielsen (1994), a response time of up to 1.0 second is the limit for maintaining an uninterrupted flow in the system interaction. The results show that the average response time for the system varies between 0.1 and 1.0 seconds, staying within the acceptable limit. Therefore, it can be concluded that the response time of the DLE system is appopriate for its intended use. The application of the metrics highlight the system's ability to manage a substantial volume of requests efficiently over an extended period.

Continuous monitoring and optimisation of response times are crucial to ensuring the ongoing performance of a CDSS. Regular updates and improvements to the system's algorithms and infrastructure can help maintain fast response times while adapting to changing clinical needs and technological advances. In short, the performance of a CDSS, particularly its response time, plays a vital role in facilitating timely and informed decision-making in healthcare. By prioritising efficiency and optimising system capabilities, the CDSS can effectively support healthcare providers in delivering high-quality services to patients.

7.2.2 Cross-checking use cases

Currently, the proposed artefact has been tested and implemented in a Portuguese Hospital Center, particularly covering four workflows, namely: imaging exam; corneal transplantation; malnutrition; and obstetrics. The implementation process is common in all cases and involves the participation of IT specialists and healthcare professionals. In a nutshell, the workflow is defined first, defining the decision points, tasks, and performers. The workflow is modelled according to the openEHR specifications and is then processed by the WE service. Subsequently, clinical knowledge structures are modelled using openEHR archetypes and templates, which are then processed by the FE and visualised as forms. Finally, decision modules are created, composing of a set of rules that will be processed by the DLE and then integrated with both the workflow and the forms.

Essentially, the implementation of the use cases in the Portuguese Hospital Center, demonstrated the ease of the proposed solution in defining decision modules oriented to clinical contexts. The previous approaches implemented at the Portuguese Hospital were done using legacy systems, where rules were defined in the systems programming code and database queries. Furthermore, the circuit was not integrated or interoperable with other systems, making it difficult to automate the process. It is worth noting that the proposed artefact allows the creation of rules through a web interface, enabling healthcare professionals and the stakeholders involved in the care process to define their workflow with integrated decision modules, autonomously and flexibly.

The proposed artefact was developed in parallel with the application of the demonstration cases. Many functionalities were developed based on the requirements imposed for each case. In addition, the temporal development of the use cases is directly related to the state of maturity of the prototype. The first use case (UC1) involved imaging exams, the second focused on cornea transplantation (UC2), the third addressed malnutrition (UC3), and the final use case was obstetric care (UC4). To identify the characteristics of the DLE at each stage of its development and implementation, a cross-checking was conducted between the functionalities present in each use case, as shown in Table 13.

Three main components of the DLE design were selected: the type of input variables, the operators forming the rule conditions, and the type of decision model. In general, all use cases covered field input variables, text condition operators, and rule-based decision models. Field variables were used to create rules linked to form fields. Text operators were used to compare two text values, determining if they were equal or not equal. The most commonly used decision model was the production rules model, due

Table 13: Cross-checking system functionalities with use cases.

UC	DLM	Input variables			Condition operators				Decision models		
		Field	SPO	Calculation	Text	Numeric	List	Dynamic	Rule	Score	Decision table
UC1	DLM1	X			X				X		
UC1	DLM2	X			X				X		
UC2	DLM1	X	X		X	X		X	X		
UC2	DLM2	X			X				X		
UC3	DLM1	X			X	X			X	X	
UC3	DLM2	X			X	X			X		
UC3	DLM3	X			X				X		X
UC4	DLM1	X		X	X	X			X	X	
UC4	DLM2	X			X	X	X	X	X		
UC4	DLM3	X			X				X		

to its simple knowledge representation, which fulfills most case logic. The intersection of these three components appears in all cases, especially in UC1, DLM2 of UC2, and DLM3 of UC4, as these are simpler modules that do not involve additional components.

The other types of variables considered were subject type and calculation variables. For DLM1 of UC2, it was necessary to associate subject variables, where their values were recorded in an external source, requiring communication between DLE and SPO. For UC4 DLM1, calculation variables were created to determine the value of a variable using mathematical formulas, combining variables, values, and operators.

As far as condition operators are concerned, numeric types were the second most used, particularly in DLM1 of UC2, DLM1 and DLM2 of UC3, and DLM1 and DLM2 of UC4. These modules primarily employed numerical comparison operators, such as greater than, less than, equality, or range of values. DLM1 in UC2 and DLM2 in UC4 used dynamic value operators to bind external data to the required variables through API calls or data queries via the binding service.

Regarding decision models, the score typology was used in DLM1 of UC3 and DLM1 of UC4. By using variable values, the system was able to calculate the total score defined by the respective rule. Conversely, UC3 DLM3 was one of the few cases where the decision table representation was used. This was evident due to demonstration cases did not have varying values for a given set of variables, eliminating the need for decision tables. For most of these cases, production rules and scores sufficed. Despite the implemented use cases, test cases were conducted prior to system implementation to evaluate the viability of decision tables, proving their potential for future use.

In short, the diverse implementation of the use cases confirmed the feasibility of the proposed artefact. The implementation of the system across all use cases showcased its adaptability and flexibility for diverse clinical context. This effort involved a team of ITengineers and healthcare professionals, which sometimes led to challenges, particularly in defining requirements and modeling clinical knowledge. Continuous

training sessions were held to address the healthcare professionals' lack of experience with the system, ensuring its correct use. Overall, the use cases demonstrated the successful implementation of the artefact and its alignment with scenario needs, validating the logical decision system.

7.2.3 MSM evaluation

When a CDSS does not produce the desired results, several causes are likely, such as an incorrect definition of the problem, a poor evaluation of the alternatives, or inadequate implementation. The proposed alternative may not be successful, leading to a new analysis of the problem, the evaluation of alternatives, and the selection of a new alternative. Thus, evaluation is a crucial factor in the process, as decision-making is a continuous and never-ending process.

To evaluate the developed artefact, the MSM (presented in section 4.4) was selected. This model was developed to identify a gap between the state of the art and the desirable maturity stage of a CDSS to assess its effectiveness. The MSM is based on the four phases of the Decision-Making theory developed by Simon 1960. Consequently, the model has four stages, with stage 4 being where the prestige maturity level is reached, as demonstrated:

- **Stage 1:** Intelligence;
- **Stage 2:** Intelligence + Design;
- **Stage 3:** Intelligence + Design + Choice;
- **Stage 4:** Intelligence + Design + Choice + Implementation.

Each stage has a set of associated criteria, at least one of which must be implemented to advance to the next stage. The phases and the respective criteria of the model are defined in the MSM. To provide a clear assessment, a cross-reference of the functionalities implemented in the developed system was made based on the criteria of each phase of the model, as shown in Table 14.

Table 14: Cross-checking MSM criteria.

Phase	Condition 1	Condition 2	Condition 3	Condition 4
Intelligence	X		X	X
Design	X		X	
Choice		X	X	-
Implementation	X	X	X	X

The first phase, Intelligence, focuses on gathering and analysing information. To meet the criteria of this phase, the proposed system has been designed to access the history of past decisions, enabling

to learn from previous cases and patterns. Additionally, the system can access structured and available clinical information, allowing it to accurately characterise each patient's situation.

Moving on to the Design phase, the focus is on generating alternative solutions. The proposed system meets the required criteria by incorporating clinical context variables, which provide a comprehensive understanding of the unique circumstances surrounding each case. Modelling techniques and procedures are the base of the openEHR standard, as it helps to develop various alternatives to address a given clinical situation. By employing models or sets of models, the system learns to make decisions for complex situations.

The next phase is Choice, which evaluates and selects the best alternative based on specific criteria or models. The proposed system stimulates and evaluates each available option, carefully weighing the merits of each. Through the application of computational models, the desired operation of the chosen solution is guaranteed through the simulation, optimisation, and validation of various clinical scenarios, enhancing the accuracy and effectiveness of the system. This stage plays a critical role in the decision-making process, determining the most appropriate course of action.

Finally, the Implementation phase entails the execution of the selected solution. The proposed system successfully applies the chosen option in a real clinical environment, seamlessly integrating with the existing infrastructure. Monitoring and evaluation mechanisms were adopted to continuously assess the system operation. Data collected during this phase helps us refine and optimise future decision-making processes. Additionally, our system can record past decisions, providing a valuable historical record.

Cross-checking was developed by carefully respecting each criterion of each phase for the functional operations of the proposed system. Thus, based on Table 14, for the proposed system there are 3 criteria in phase 1 (Intelligence), 2 criteria in phase 2 (Design), 2 criteria in phase 3 (Choice), and 4 criteria in phase 4 (Implementation). Since the system passes at least one criterion in every phase, the value of Si for each stage will be: $S_1 = 1$; $S_2 = 1$; $S_3 = 1$; $S_4 = 1$. Thus, the calculation of the formula is:

$$\text{MSM} = S_1 + S_2 + S_3 + S_4 = 1 + 1 + 1 + 1 = 4$$

In conclusion, the maturity level of the proposed CDSS is 4, indicating that the system reached the most mature stage of theMSM (Stage 4). Achieving this level of maturity attests to the effectiveness and reliability of our system in supporting clinical decision-making. TheMSM approach allowed to ensure that the DLE system meets the necessary requirements at each phase, ultimately leading to an effective and robust decision-making tool for clinicians. The thorough evaluation and validation process have instilled confidence in the capabilities and performance of the system, highlighting its potential to enhance clinical outcomes and improve patient care.

Overall, this formula provides a straightforward way of measuring the maturity level of a system based on its compliance with the criteria defined for each phase. It helps track the progress of the system's maturity over time and identifies the areas where improvements are needed to reach a higher maturity level.

7.3 Discussion

Healthcare institutions have seen a digital transformation over the years. However, clinical workflows are still in need of optimisation. One of the main challenges facing the health sector is the lack of interoperability between HIS. This problem is further exacerbated by the lack of standardisation of EHR. OpenEHR has been recognised as a solution for achieving semantic interoperability in HIS, but despite its benefits for modelling clinical knowledge, its use for clinical workflows has not yet been fully explored. The proposed decision logic system was developed based on the openEHR, specifically in DL specifications, and can be applied to modelling clinical and administrative workflows.

The artefact offers indications on the design and implementation of the openEHR ecosystem, namely the development of work plans, forms and rules, as well as their interaction. It demonstrates an automated and structured workflow capable of reducing waiting times as well as streamlining decision-making processes. Despite the benefits of adopting a CDSS, the literature review identifies existing concerns that prevent CDSS from becoming effective. The previous SLR conducted showed that most of the developed CDSS still lack resources, as they do not go beyond the Design phase of the decision-making theory, showing systems ineffectiveness.

Based on the evaluation performed through the MSM, the proposed system has reached stage 4 of maturity, indicating it is in the implementation phase. Consequently, this supports that creating a logical model by adopting the openEHR standard allows to create more effective CDSS, validating the RQ defined in this doctoral work. To further substantiate this conclusion, Table 15 highlights the contributions achieved by implementing the developed artefact, considering the MSM criteria and the identified concerns (in Table 12).

One of the critical problems identified in the adoption of a CDSS is knowledge management and representation. By adopting the openEHR standard for creating logical models, healthcare professionals can access a comprehensive and standardized framework to represent clinical knowledge. This allows for better management and retrieval of relevant information, thus enhancing decision-making effectiveness. The maturity model criteria that directly align with addressing this problem include having access to the history of past decisions, structured and available information capable of accessing specific clinical information, and the ability to record past decisions. Besides, the openEHR-based knowledge base allows information to have a version-control structure that is easy to access.

Another concern in CDSS adoption is the integration of clinical workflow. The use of the openEHR standard facilitates the integration of the CDSS with existing clinical workflows. The CDSS can seamlessly integrate with the healthcare professional's workflow, ensuring efficient decision-making processes. Automatic creation of decision rules is another identified concern in CDSS adoption. The developed artefact empowers healthcare professionals to develop decision rules that accurately reflect their clinical expertise, leading to more effective CDSS. The ability to define variables associated with specific contexts facilitates the creation of standardised rules and allows for better workflow coordination. This is achieved by defining variables in the DLM and integrating them with care pathways and through external data binding services.

Table 15: Contributions obtained considering the criteria met and the concerns identified (adapted from (Hak and Santos, 2024)).

Phase	Criteria	Concern	Contribution
Intelligence	C1, C4	P1, P3, P5	The process of capturing and storing EHR data is designed to meet local requirements and is formulated to enable easy and rapid access to subject-oriented information.
	C3	P1, P4	Semantic interoperability ensures that EHR can be shared and processed across heterogeneous systems while maintaining consistency of meaning and interpretation.
Design	C1	P2, P3	The ability to define associated elements with a specific context (as variables, tasks, or rules) promotes autonomy in healthcare providers and allows better workflow coordination.
	C3	P1, P2, P3, P4, P5	Clinical modeling allows healthcare providers to create their guidelines and protocols without the need to interfere with programming codes or databases.
Choice	C2	P2, P5	Decision models are created and represented in the system, offering health professionals a structured way to approach complex medical scenarios and make supported choices
	C3	P1, P3	Clinical content representation in a consistent and reliable format, enables the processing of different decision models (namely rules statements, decision tables and scores).
Implementation	C1	P2, P5	Data modeling capabilities enable organisations to tailor their knowledge to their specific service domains and local requirements, providing the flexibility needed for customization
	C2, C3	P1, P2, P5	Knowledge acquisition within the system provides a collaborative environment to promote teamwork and cooperation between professionals in system management and use.
	C4	P1, P3, P4	A longitudinal health record is established, which captures and manages patient health information over time. This comprehensive record includes historical data, and ongoing observations, and tracks changes and updates throughout the patient's healthcare

The use of modeling techniques is the basis of the proposed artefact. The openEHR standard provides a robust framework for modeling techniques and procedures. In DLM modelling, different models can represent clinical guidelines or sets of rules. the system represents clinical content in a consistent and reliable format, enabling the processing of different decision models (namely rule statements, decision tables, and scores). Decision models are created and processed in the DLE through the models covered by the inference engine. The different representations of logic and their chaining enable users to verify which is most appropriate for the desired purpose, ensuring that the system adequately represents the decision logic automatically. As a result, healthcare professionals can design and implement task execution processes and rule creation using logical models that automate workflows, eliminating the need for IT specialists to modify the system. This grants healthcare professionals independence, flexibility, and

autonomy, making it easier to represent clinical knowledge.

Interoperability and sharing are crucial aspects of any CDSS. Data is collected from the system's knowledge base, together with the EHR and openEHR repositories, to promote continuous monitoring and evaluation. This system facilitates collaboration among healthcare professionals and provides them with accurate and up-to-date information to make clinical decisions effectively A longitudinal EHR is created, which captures and manages the patient's health information over time. This comprehensive record includes historical data and ongoing observations and tracks changes and updates throughout the patient's care. This is achieved by building the knowledge base and the openEHR repository, keeping it current through its versioning control structure

Lastly, the acceptance of a CDSS by healthcare professionals is critical to its effectiveness. By adopting the openEHR standard, healthcare providers can work with a standardized and familiar framework, making the transition and acceptance of the CDSS. The maturity model criterion on the ability to record previous decisions in MSM, responds to this concern by providing healthcare professionals with a transparent and accessible record of their previous decisions, promoting trust in the CDSS.

Overall, it is believed that the proposed approach benefits healthcare by increasing efficiency in the work performed, improving data management, and streamlining decision-making processes. At the moment, this artefact has been tested and implemented in four clinical contexts in a Portuguese Hospital Center, particularly in the workflows of imaging exams, cornea transplant, malnutrition, and obstetrics, where all showed positive results. Before implementing the new approach, the services mentioned were managed by legacy systems from heterogeneous sources, making communication difficult and challenging to represent clinical knowledge. Furthermore, clinical rules were created directly in the system programming and through database queries, creating dependency on IT developers.

Therefore, continuous evaluation for improvement and growth is necessary to guarantee the optimisation and effectiveness of the proposed approach. Nevertheless, some limitations must be outlined. Although the proposed system has already been implemented in real healthcare institutions, more complex cases must be applied, particularly testing the chain of rules and decision models. Besides, the concerns identified focused on the influence of technology on developing more effective CDSS. However, other perspectives, such as organisational and social concerns, may be limiting the development of effective CDSS. Future work should explore these issues to contribute to the growth of CDSS effectiveness.

By aligning the maturity model criteria with the functionalities provided by the openEHR standard, the results show how the adoption of this standard addresses the problems and concerns identified in the adoption of the CDSS. Overall, the openEHR standard improves knowledge management and representation, facilitates clinical workflow integration, enables automatic creation of decision rules, improves interoperability and sharing, and promotes healthcare professional acceptance. Therefore, it is believed that the openEHR standard strengthens the effectiveness of CDSS and contributes to better healthcare decision-making processes. Thereupon, there is a continuous incentive to develop studies and report results to contribute to the body of knowledge of the scientific community in IS, covering DSS in healthcare.

Part V

Conclusions and Final Remarks

8

Conclusion

8.1 Overview of the work performed

Healthcare is a highly complex and constantly evolving field, continually responding to innovative technologies capable of supporting new treatments, emerging diseases and changing regulatory landscapes. At its heart is the imperative to provide quality care to patients amidst numerous competing demands and requirements. This doctoral thesis represents an endeavour in the field of CDSS with the aim of contributing new knowledge to the scientific community. Central to this work is a multi-faceted approach that encompassed: a systematic review of the published literature, the design and implementation of a rule-based CDSS using a logic engine, four use cases demonstrations, and the development and application of a maturity model.

The SLR presented in Chapter 4 served as a basis for identifying research gaps and areas that need to be further explored in the field of CDSS, aligned with objective O.1 of this work. By rigorously analysing the selected studies, trends in the use of CDSS were identified, along with an assessment of their maturity level. The reviewed literature indicates that CDSS are not meeting the objectives set during their design phase. Consequently, it was concluded that the developed CDSS are not being effective in their implementation.

Furthermore, one of the contributions of this doctoral thesis was the development and application of a maturity model to assess CDSS readiness and performance, aligned with objective O.2. Inspired by Herbert Simon's decision-making theory, the MSM establishes four stages of maturity based on the phases of decision theory, providing a structured model for assessing the capabilities, processes and results of the CDSS at various stages of development. Based on a set of criteria proposed for each stage, it becomes possible to identify strengths, weaknesses and areas for improvement, thus guiding a CDSS to become effective.

Based on the knowledge gained from the SLR, this work centred on the design and implementation of a rule-based CDSS, explored in Chapter 5, aligned with objectives O.3 and O.4. This involved utilising rules and algorithmic logic to represent clinical knowledge and exploring different model processing, such as production rules, decision tables, and scores. The pillar for building the artefact's knowledge base was

based on the application of the openEHR DL specification. In addition, the entire system was designed to process openEHR structures and integrate and interoperate with other services.

To demonstrate the application of the system in a real environment, aligned with objective O.5, Chapter 6 presents use cases as practical scenarios from various healthcare contexts. Incorporating evidence-based guidelines, best practices, and domain-specific knowledge, the proposed CDSS has proven to improve the accuracy and efficiency of decision-making and processes in clinical contexts. Notwithstanding, the adoption of openEHR archetypes and templates proved to maintain the consistency and accuracy of clinical data, offering greater flexibility compared to traditional methods of clinical documentation, which often rely on free-text entries that can pose challenges in understanding and interpretation across different patients and clinical contexts. Through this approach, healthcare organisations can simplify the representation of clinical data and allow doctors to adapt the patient-specific information presentation more dynamically (Beale, 2002). This ensures that clinical data remains consistently structured and semantically interoperable, facilitating accurate interpretation and sharing across various clinical systems.

Finally, in Chapter 7, the proposed artifact is evaluated using the developed MSM, in alignment with objective O.6. The criteria for each phase of the model are cross-checked to determine if the proposed CDSS can achieve the highest level of maturity, thereby proving its effectiveness. The proposed CDSS enables the automatic processing of decision rules through the proposed DLE. Through the evaluation, the DLE proves to be capable of reducing the risk of errors and variability in decision-making, promoting more consistent patient care. Integrating the DLE into clinical workflows simplifies processes and improves the quality and consistency of patient data, leading to better patient outcomes. This integration ensures that the information entered consistently aligns with established clinical guidelines and best practices, facilitating real-time decision support.

Concerning the initially defined RQ, it was concluded that adopting logical models and open standards enables the creation of more effective CDSS. The evaluation conducted using the MSM confirmed that the proposed system achievement of stage 4 maturity signifies a high level of effectiveness. Overall, the work carried out in this doctoral thesis represents a significant advance in the field of CDSS research and development. By integrating an SLR, the design and implementation of a CDSS based on an open standard, and the development and application of a maturity model, the thesis contributes to the broader goal of improving clinical decision-making and enhancing patient care outcomes.

8.2 Contributions to the scientific community

In research, sharing work over time is crucial for gaining visibility, emphasising topic importance, and obtaining feedback. Through the conducted work and obtained results, this research showed significant contributions to the scientific and technical community, covering from literature review to artefact evaluation. This doctoral study has produced knowledge that advances CDSS research, identifying the gap between the state of the art and the desirable CDSS effectiveness.

Leveraging existing literature (as Greenes et al., 2018; Sutton et al., 2020) enabled a comprehensive examination of CDSS effectiveness. Additionally, as openEHR DL specifications are recently published (Beale, 2021), it allows an up-to-date artefact orientated towards recent problems. As far as is known, there are still no published studies that address CDSS based on DL, which makes this work innovative and enriching for the scientific community. Therefore, this research not only supports future studies but also aids professionals in building complex and effective CDSS, steering away from traditional approaches.

One of the main motivations for carrying out this work was the continuous encouragement to publish articles contributing to IS research, particularly in the CDSS field. Consequently, this doctoral work has been disseminated through articles published in journals and presented at conferences, as detailed in Table 16.

Moreover, participation in scientific events was also an achievement. In 2022, the work proposal of this PhD thesis was selected to be presented in the European Research Center for Information Systems (ERCIS) Doctoral Consortium. Also in 2022, this work was selected to attain the InterHealth Summer School, where insights into data structuring and sharing techniques were gained, including an openEHR lecture. Both events provided valuable opportunities for receiving feedback on the work's progress and exchanging knowledge with peers. In addition, participation in the European Conference on Information Systems (ECIS) was extremely important, enabling this work to be presented to a vast and important community for IS research.

8.3 Future work

The future work of this doctoral thesis encompasses several key areas aimed at advancing the CDSS and its applicability in various clinical contexts. These areas include applying the system in different clinical contexts, exploring alternative decision models for the rule-based CDSS and improving the user interface for better usability and adaptability.

Firstly, the application of the CDSS in various clinical contexts represents a crucial avenue for future research. By broadening the scope of the application beyond the use cases discussed, more complex cases should be considered that will allow the evaluation of the system's effectiveness and usefulness in different specialities and care contexts to be extended. This means adapting the CDSS to meet the specific needs and requirements of each clinical context, as well as assessing its impact on clinical decision-making, workflow efficiency and patient outcomes.

Secondly, it is necessary to explore alternative decision models for the DLE processing algorithm. While rule-based approaches have been satisfactory for the scenarios applied, the integration of ML techniques is promising for increasing the accuracy and adaptability of decision-making. Future research could focus on developing and evaluating ML algorithms for rule processing, taking advantage of large-scale historical datasets to train predictive models and optimise decision support capabilities.

Table 16: Scientific publications.

Title	Year	Publisher	Type	State	Chapter
Effective Clinical Decision Support by Means of the Adoption of OpenEHR Standard	2024	European Conference on Information Systems (ECIS)	Core A conference	Published	Chapter 7
Towards effective clinical decision support systems: A systematic review	2022	PlosOne	Scimago Q1 Journal	Published	Chapter 4
Standardizing Corneal Transplantation Records with openEHR: Case Study	2024	JMIR Medical Informatics	Scopus Q1 journal	Published	Chapter 6
Towards an Effective Clinical Decision Support System in Intensive Medicine	2022	Procedia Computer Science	Conference proceedings	Published	Chapter 2
Rule-based Clinical Decision Support System using the OpenEHR Standard	2022	Procedia Computer Science	Conference proceedings	Published	Chapter 5
Electronic Health Records Structuring Based on the OpenEHR Standard	2022	IGI Global	Book chapter	Published	Chapter 5
Steps towards an Healthcare Information Model based on openEHR	2021	Procedia Computer Science	Conference paper	Published	Chapter 5
An OpenEHR adoption in a Portuguese healthcare facility	2021	Procedia Computer Science	Conference paper	Published	Chapter 6
Clinical Decision Support Using Open Data	2020	WorldCIST 2020	Conference paper	Published	Chapter 3
OpenEHR logic module: a tool for creating decision rules	2021	Procedia Computer Science	Conference paper	Published	Chapter 5
A Maturity Model for Omnichannel Adoption in Health Care Institutions	2023	Heliyon	Scimago Q1 journal	Under Review	Chapter 4
Automation of Hospital Workflows Using International Standards: a Case Study with Imaging Exams	2023	International Journal of Medical Informatics	Scimago Q1 journal	Under Review	Chapter 6

In addition, improving the user interface for creating and managing clinical rules is essential to increase usability and facilitate seamless integration into clinical workflows. Carrying out usability tests and collecting feedback from users are crucial aspects of identifying usability problems and areas for improvement. This may involve redesigning the user interface to simplify rule creation and management processes, incorporating user-friendly functionalities and visualisation tools, and implementing adaptable interfaces that can accommodate diverse user preferences and workflow requirements. In addition, there

is also scope for further exploration of the MSM through its application in the proposed CDSS.

In short, future work on the PhD thesis will centre on advancing the CDSS through application in different clinical contexts, exploring alternative decision models for rule processing, improving the user interface for greater usability and conducting adaptability tests to ensure continued relevance and effectiveness in supporting clinical decision-making. Through these efforts, the CDSS aims to contribute to improving patient care outcomes and strengthening decision-making capabilities in various healthcare contexts.

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A

SLR Group Outcomes

Table 17: Outcomes of knowledge representation and management.

Study	Outcome	Total	Value
Catalani et al., 2014, Akhloufi et al., 2019, Tamburrano et al., 2020, Kim et al., 2020, Lin et al., 2006, Rao and Turoff, 2000, Van Valkenhoef et al., 2013, Hu et al., 2006, Michalowski et al., 2003, W. Yao and Kumar, 2013, Lussier et al., 2007, Corny et al., 2020, Altay and Alatas, 2020, Yoo et al., 2020, Hamedan et al., 2020, Holmström et al., 2020, Chin et al., 2020, Niazkhani et al., 2020, Berge et al., 2017, Wasylewicz and Scheepers-Hoeks, 2018b, Smit et al., 2017	Rule-based module	21	40,39%
Catalani et al., 2014, Akhloufi et al., 2019, Dalaba et al., 2014, Sim et al., 2017, Bernasconi et al., 2019, Menon et al., 2020, Arain et al., 2020, Séroussi et al., 2013, Akçura and Ozdemir, 2014, Johnson et al., 2014, W. Yao and Kumar, 2013, Lam Shin Cheung et al., 2020, Downie et al., 2020, F. Xu et al., 2020, Torres Silva et al., 2020, Miller et al., 2019, Wasylewicz and Scheepers-Hoeks, 2018a, Bond et al., 2017, Strockbine et al., 2020, Smit et al., 2017	Clinical practice guidelines	20	38,46%
Catalani et al., 2014, Jiang et al., 2019, Dalaba et al., 2014, Sim et al., 2017, De Lima Marinho et al., 2019, Bernasconi et al., 2019, Kim et al., 2020, Rao and Turoff, 2000, Michalowski et al., 2003, Johnson et al., 2014, Corny et al., 2020, Altay and Alatas, 2020, Yoo et al., 2020, Wu et al., 2020, Choi et al., 2020, Chin et al., 2020, Lichtenegger et al., 2020, Vargason et al., 2016, Berge et al., 2017, B. Xu et al., 2018	Algorithmic logic	20	38,46%
Kim et al., 2020, Lin et al., 2006, Hu et al., 2006, W. Yao and Kumar, 2013, Lussier et al., 2007, Yoo et al., 2020, Downie et al., 2020, F. Xu et al., 2020, Schaaf et al., 2020, Q. Xu et al., 2020, Chin et al., 2020, Niazkhani et al., 2020, Wasylewicz and Scheepers-Hoeks, 2018b	Knowledge base	13	25%
Jiang et al., 2019, Berrouiguet et al., 2016, Piri et al., 2017, Hu et al., 2006, Piri, 2020, Hamedan et al., 2020, Choi et al., 2020, F. Xu et al., 2020	Variable-based	8	15,39%
Lin et al., 2006, Rao and Turoff, 2000, W. Yao and Kumar, 2013, Downie et al., 2020, F. Xu et al., 2020, Torres Silva et al., 2020, Wasylewicz and Scheepers-Hoeks, 2018b	Inference engine	7	13,46%
Breitbart et al., 2020, Van Valkenhoef et al., 2013, Piri, 2020, Lussier et al., 2007, Ucuz et al., 2020	Standardized clinical terminologies	5	9,62%
Jiang et al., 2019, Hamedan et al., 2020, Niazkhani et al., 2020	If/then statements	3	5,77%
Michalowski et al., 2003, Altay and Alatas, 2020, Berge et al., 2017	Data mining techniques	3	5,77%
Jiang et al., 2019, Akçura and Ozdemir, 2014	Bayesian network	2	3,85%
Piri et al., 2017, Piri, 2020	Neural networks	2	3,85%

Table 18: Outcomes of technological features.

Study	Outcome	Total	Value
(Jiang et al., 2019), (Akhloufi et al., 2019), (Dalaba et al., 2014), (Arain et al., 2020), (Séroussi et al., 2013); (Piri et al., 2017); (Lin et al., 2006); (Piri, 2020); (Michalowski et al., 2003); (W. Yao & Kumar, 2013); (Lam Shin Cheung et al., 2020); (Downie et al., 2020), (Lee & Lee, 2020); (Choi et al., 2020); (F. Xu et al., 2020), (Schaaf et al., 2020), (Holmström et al., 2020), (Lichtenegger et al., 2020), (Niazkhani et al., 2020), (Torres Silva et al., 2020), (Miller et al., 2019), (Wasylewicz & Scheepers-Hoeks, 2018a), (Bond et al., 2017), (Smit et al., 2017)	Recommendation and suggestion	24	46,15%
(Sim et al., 2017), (Berrouiguet et al., 2016), (De Lima Marinho et al., 2019), (Bernasconi et al., 2019), (Menon et al., 2020), (Van Valkenhoef et al., 2013), (Akçura & Ozdemir, 2014), (Hu et al., 2006), (Lam Shin Cheung et al., 2020), (Hamedan et al., 2020), (Ucuz et al., 2020), (Chin et al., 2020), (Torres Silva et al., 2020), (Vargason et al., 2016), (Berge et al., 2017), (B. Xu et al., 2018), (Wasylewicz & Scheepers-Hoeks, 2018a), (Strockbine et al., 2020)	Information management and monitoring	18	34,62%
(Dalaba et al., 2014); (Sim et al., 2017), (Tamburrano et al., 2020), (Menon et al., 2020), (Séroussi et al., 2013), (Johnson et al., 2014), (W. Yao & Kumar, 2013), (Lussier et al., 2007), (Corny et al., 2020), (Lam Shin Cheung et al., 2020), (Yoo et al., 2020), (Chin et al., 2020), (Niazkhani et al., 2020), (Torres Silva et al., 2020)	Alerts, notifications and reminders	14	26,92%
(Catalani et al., 2014); (Sim et al., 2017); (Breitbart et al., 2020); (Falciglia et al., 2020); (Akçura & Ozdemir, 2014); (Piri, 2020); (Corny et al., 2020); (Lam Shin Cheung et al., 2020); (Downie et al., 2020); (Chin et al., 2020); (Niazkhani et al., 2020)	Error reduction	11	21,15%
(Jiang et al., 2019), (Berrouiguet et al., 2016), (Menon et al., 2020), (Kim et al., 2020), (Lin et al., 2006), (Lam Shin Cheung et al., 2020), (Wu et al., 2020), (Holmström et al., 2020)	Assessment	8	15,38%
(Piri et al., 2017), (Piri, 2020), (Altay & Alatas, 2020), (Lam Shin Cheung et al., 2020), (Hamedan et al., 2020), (Ucuz et al., 2020), (Wu et al., 2020), (Choi et al., 2020)	Prediction	8	15,38%
(Arain et al., 2020), (Van Valkenhoef et al., 2013), (Corny et al., 2020), (Q. Xu et al., 2020), (Holmström et al., 2020), (Lichtenegger et al., 2020), (Torres Silva et al., 2020)	Process automation and prioritization	7	13,46%
(Akçura & Ozdemir, 2014), (Lussier et al., 2007), (Yoo et al., 2020), (Q. Xu et al., 2020)	Events	4	7,69%
(Tamburrano et al., 2020), (Breitbart et al., 2020), (Rao & Turoff, 2000), (Lichtenegger et al., 2020)	Standardization	4	7,69%
(Falciglia et al., 2020), (Wu et al., 2020), (F. Xu et al., 2020)	Calculation and scoring	3	5,77%
(Catalani et al., 2014), (Tamburrano et al., 2020)	Cost and time reduction	2	3,84%

Table 19: Outcomes of system integration.

Study	Outcome	Total	Value
(Dalaba et al., 2014), (Breitbart et al., 2020), (De Lima Marinho et al., 2019), (Bernasconi et al., 2019), (Kim et al., 2020), (Séroussi et al., 2013), (Lin et al., 2006), (Michalowski et al., 2003), (Lussier et al., 2007), (Downie et al., 2020), (Lee & Lee, 2020), (Hamedan et al., 2020), (Ucuz et al., 2020), (Wu et al., 2020), (Choi et al., 2020), (F. Xu et al., 2020), (Schaaf et al., 2020), (Q. Xu et al., 2020), (Holmström et al., 2020), (Lichtenegger et al., 2020), (Torres Silva et al., 2020), (Vargason et al., 2016), (Miller et al., 2019), (B. Xu et al., 2018), (Wasylewicz & Scheepers-Hoeks, 2018b), (Bond et al., 2017), (Smit et al., 2017)	Standalone CDSS	27	51,92%
(Catalani et al., 2014); (Jiang et al., 2019); (Berrouiguet et al., 2016); (Sim et al., 2017); (Menon et al., 2020); (Falciglia et al., 2020); (Arain et al., 2020); (Piri, 2020); (Johnson et al., 2014); (Chin et al., 2020); (Berge et al., 2017)	EHR	11	21,15%
(Rao & Turoff, 2000), (Van Valkenhoef et al., 2013), (Hu et al., 2006), (W. Yao & Kumar, 2013), (Altay & Alatas, 2020)	Specific HIS	5	9,62%
(Tamburrano et al., 2020); (Akçura & Ozdemir, 2014), (Yoo et al., 2020), (Niazkhani et al., 2020)	CPOE	4	7,69%
(Akhloufi et al., 2019); (Corny et al., 2020), (Strockbine et al., 2020)	CPOE and EHR	3	5,77%
(Piri et al., 2017), (Lam Shin Cheung et al., 2020)	EMR	2	3,84%

Table 20: Outcomes of type system.

Study	Outcome	Total	Value
(Akhloufi et al., 2019), (Berrouiguet et al., 2016), (Arain et al., 2020), (Séroussi et al., 2013), (Lin et al., 2006), (Johnson et al., 2014), (W. Yao & Kumar, 2013), (Lam Shin Cheung et al., 2020), (Downie et al., 2020), (Q. Xu et al., 2020)	Web-based application	10	19,23%
(Catalani et al., 2014), (Jiang et al., 2019), (Tamburrano et al., 2020), (Menon et al., 2020), (Rao & Turoff, 2000), (Akçura & Ozdemir, 2014); (Piri, 2020); (Holmström et al., 2020), (Strockbine et al., 2020)	Specific computerized tool	9	17,31%
(Dalaba et al., 2014), (Falciglia et al., 2020), (Van Valkenhoef et al., 2013), (Hamedan et al., 2020), (Schaaf et al., 2020), (Chin et al., 2020), (Vargason et al., 2016), (Miller et al., 2019)	Software application	8	15,38%
(De Lima Marinho et al., 2019), (Corny et al., 2020), (Wu et al., 2020), (Choi et al., 2020), (Berge et al., 2017)	Machine learning-based	5	9,62%
(Altay & Alatas, 2020), (Lee & Lee, 2020), (Ucuz et al., 2020), (F. Xu et al., 2020)	AI-based	4	7,69%
(Breitbart et al., 2020), (Bernasconi et al., 2019), (Yoo et al., 2020), (Torres Silva et al., 2020)	Web and mobile application	4	7,69%
(Michalowski et al., 2003), (Lussier et al., 2007), (Lichtenegger et al., 2020)	Mobile application	3	5,77%
(Piri et al., 2017), (Wasylewicz & Scheepers-Hoeks, 2018b)	Data Analytics	2	3,85%
(Bond et al., 2017), (Smit et al., 2017)	Knowledge-based	2	3,85%
(Niazkhani et al., 2020)	User interface	1	1,92%
(B. Xu et al., 2018)	Cloud computing	1	1,92%
(Kim et al., 2020)	Data-layer infrastructure	1	1,92%
(Hu et al., 2006)	Image retrieval expert system	1	1,92%
(Sim et al., 2017)	Web-based application and data analytics	1	1,92%

B

Modelled Decision Logic Modules

Listing B.1: Decision logic module for nutritional risk screening use case.

```
dlm NRS.v0.1.0

definitions -- Descriptive
    | lang and translations meta-data, as for archetypes
    language = { original_language: [ISO_639-1::en]  };
    | description meta-data, as for archetypes
    description = {
        lifecycle_state: "unmanaged",
        original_author: {
            name: "Francini Hak",
            email: "id8966@alunos.uminho.pt",
            organisation: "University of Minho"
            date: "2023-08-02",
            details: {
                purpose: "Calculating the nutritional risk of a
                    hospitalised patient",
                use: "It should be used in hospital settings",
                misuse: "Should not be used in children (<18 years)" } } };

[use
    BMI: Body_mass_index.v1.0.2]

[preconditions
    isHospitalized]

[definitions -- Reference
    <constant definitions>]

input -- Administrative State
    age: Integer
```

```
input -- Historical State
    <historical subject variables>

input -- Tracked State
    BIM_low: Boolean
    weight_loss: Boolean
    food_reduction: Boolean
    critical_illness: Boolean

rules -- Conditions
    BMI_low_yes:
        Result:= BMI_low = true
    weight_loss_yes:
        Result:= weight_loss = true
    food_reduction_yes:
        Result:= food_reduction = true
    critical_illness_yes:
        Result:= critical_illness = true

rules -- Main
    possible_risk: BMI_low_yes or weight_loss_yes or food_reduction_yeS or
       critical_illness_yes : screening_final_score
    nutritional_state: Text
        Result := case nutritional_state in
            ==============
            Absent:     0,
            --------------
            Light:      1,
            --------------
            Moderate:   2,
            --------------
            Serious:    3
            ============== ;
    disease_severity: Text
        Result := case disease_severity in
            ==============
            Absent:     0,
            --------------
            Light:      1,
            --------------
            Moderate:   2,
            --------------
            Serious:    3
            ============== ;
    age_greaterThan_70: Boolean
```

```
        Result := case age in
            ==============
            |<70|:      0,
            --------------
            |70|:       1
            ==============
rules -- Output
    screening_final_score: Integer
        Result.add (
            nutritional_state,
            disease_severity,
            age_greaterThan_70 );
    result_NRS: Text
        Result := choice of
            ================================================================
            screening_final_score in |<3|: #Repete screening weekly,
            ----------------------------------------------------------------
            screening_final_score in  |3|: #The patient is at nutritional
               risk
            ================================================================
                ;
definitions -- Terminology
    terminology = {...};
```