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From Real-World Data to Clinical Visualization: Developing a Data Model for Wound Care

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Abstract

Introduction: The rapid expansion of digital health is changing healthcare, integrating clinical research and everyday practice. Real World Data from Electronic Health Records is the cornerstone for generating Real World Evidence that informs decision-making. Chronic wounds require continuous monitoring and intervention, and traditional wound assessment remains inefficient and subjective. The openEHR standard offers a solution for creating persistent, longitudinal health records. However, the true value of such data is unlocked only when it is effectively reused. Bridging the gap between robust clinical data capture and its effective secondary use remains a challenge, and one effective approach is the development of analytical packages and visualization dashboards that can provide actionable insights.

This work aims to design and validate a dual-purpose data model for wound care that supports both primary data collection in clinical practice and secondary use for analytics and visualization.

Methodology: This work followed a methodology of sequential, interdependent tasks, including clinical modelling, semantic mapping, and data visualization. The initial phase established the clinical requirements for a comprehensive wound dataset. Subsequently, the core information model was designed using the openEHR standard, with archetypes and templates authored in Archetype Designer and validated against the Clinical Knowledge Manager (CKM). The resulting model's technical conformance was validated using a data repository based on the Open-Source EHRbase platform. To ensure semantic interoperability, existing terminology bindings from validated archetypes were leveraged, complemented by a manual mapping of additional concepts to standard clinical vocabularies, including Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), using the SNOMED CT Browser and the Observational Health Data Science and Informatics (OHDSI) Athena platform. Finally, the model's dual-purpose utility was validated by developing an interactive Apache Superset dashboard to translate the structured data into actionable clinical and management insights.

Results: An archetype-based openEHR model for wound care was developed, comprising 53 data points across key clinical domains such as patient demographics, risk assessment scales (e.g., Braden), wound characteristics (e.g., dimensions, tissue type), and treatment protocols. To enable a holistic patient view for secondary use, the model's design anticipates interoperability with ancillary systems. This approach resulted in a consolidated dataset of 107 data points for the visualization dashboard, integrating contextual clinical variables from sources such as laboratory information systems (e.g., inflammatory markers) and pharmacy records. The hybrid mapping approach, combining pre-validated archetype bindings with targeted manual curation, ensured semantic fidelity. An interactive, two-panel dashboard ("Clinical" and "Management") was successfully implemented in Apache Superset, providing dynamic visualizations of key indicators designed to address clinical challenges such as tracking wound progression, identifying infection risks, and evaluating treatment effectiveness, thereby demonstrating the value of the collected data for quality monitoring.

Conclusion: This work presents a conceptual and methodological framework for integrating primary and secondary data use in wound care through a dual-purpose information model. It demonstrates how leveraging openEHR for robust data persistence, combined with standardized terminologies and modern business intelligence tools, can enhance interoperability and unlock the value of real-world data. The proposed solution provides a scalable foundation to support data-driven decision-making, ultimately contributing to improved clinical outcomes and more efficient healthcare management.

Resumo

Introdução: A rápida expansão da saúde digital está a transformar os cuidados de saúde, integrando a investigação clínica e a prática diária. Os Dados do Mundo Real (RWD) provenientes dos Registos Eletrónicos de Saúde são essenciais para a geração de Evidências do Mundo Real (RWE) que fundamentam a tomada de decisões. As feridas crónicas exigem monitorização e intervenção contínuas, e a avaliação tradicional de feridas continua a ser ineficiente e subjetiva. A norma openEHR oferece uma solução para a criação de registos de saúde persistentes e longitudinais. No entanto, o verdadeiro valor desses dados só é desbloqueado quando são eficazmente reutilizados. Colmatar a lacuna entre uma robusta captura de dados clínicos e a sua eficaz utilização secundária continua a ser um desafio, e uma abordagem eficaz é o desenvolvimento de pacotes analíticos e de dashboards de visualização que possam fornecer informações com aplicação prática no dia a dia clínico.

Este trabalho visa conceber e validar um modelo de dados de dupla finalidade para o tratamento de feridas, que suporte tanto a recolha primária de dados na prática clínica como a sua utilização secundária para análise e visualização.

Metodologia: Este trabalho seguiu uma metodologia de tarefas de modo sequencial e interdependentes, incluindo modelação clínica, mapeamento semântico e visualização de dados. A fase inicial estabeleceu os requisitos clínicos para um conjunto de dados abrangente sobre feridas. Subsequentemente, o modelo de informação central foi projetado usando o padrão openEHR, com arquétipos e modelos criados no "Archetype Designer" e validados com o "Clinical Knowledge Manager" (CKM). A conformidade técnica do modelo resultante foi validada usando um repositório de dados baseado na plataforma de código aberto EHRbase. Para garantir a interoperabilidade semântica, foram aproveitadas as ligações de terminologia existentes de arquétipos validados, complementadas por um mapeamento manual de conceitos adicionais para vocabulários clínicos padronizados, incluindo a Nomenclatura Sistematizada de Medicina – Termos Clínicos (SNOMED CT), utilizando o SNOMED CT Browser e a plataforma Athena da "Observational Health Data Science and Informatics" (OHDSI). Finalmente, a utilidade de duplo propósito do modelo foi validada através do desenvolvimento de um painel interativo Apache Superset para traduzir os dados estruturados em informações clínicas e de gestão acionáveis.

Resultados: Foi desenvolvido um modelo openEHR para tratamento de feridas, baseado em arquétipos, que integra 53 elementos de dados de domínios clínicos essenciais, como dados demográficos do paciente, escalas de avaliação de risco (por exemplo, Braden), características da ferida (por exemplo, dimensões e tipo de tecido) e protocolos de tratamento. Para permitir uma visão holística do paciente para uso secundário, o desenho do modelo prevê a interoperabilidade com sistemas auxiliares. Esta abordagem resultou num conjunto de dados consolidado de 107 elementos de dados para o painel de visualização, integrando variáveis clínicas contextuais de fontes como sistemas de informação laboratorial (por exemplo, marcadores inflamatórios) e registos de farmácia. A abordagem de mapeamento híbrido, que combina ligações de arquétipos pré-validadas com curadoria manual direcionada, garantiu a fidelidade semântica. Um *dashboard* interativo de dois painéis ("*Clinical*" e "*Management*") foi implementado com sucesso no Apache Superset, fornecendo visualizações dinâmicas de indicadores chave, concebidos para abordar desafios clínicos como o acompanhamento da progressão da ferida, a identificação de riscos de infeção e a avaliação da eficácia do tratamento, demonstrando assim o valor dos dados recolhidos para a monitorização da qualidade.

Conclusion: Este trabalho apresenta uma estrutura conceptual e metodológica para integrar o uso de dados primários e secundários nos cuidados de feridas, através de um modelo de informação de dupla finalidade. Demonstra como a exploração do openEHR para uma persistência robusta de dados, combinada com terminologias padronizadas e ferramentas modernas de *business intelligence*, pode melhorar a interoperabilidade e desbloquear o valor dos dados do mundo real. A solução proposta oferece uma base escalável para suportar a tomada de decisões orientada por dados, contribuindo, em última análise, para a melhoria dos resultados clínicos e uma gestão mais eficiente dos cuidados de saúde.

Preamble

This dissertation is submitted for the Master's degree in Medical Informatics and arises from my background as a nurse with a longstanding interest in informatics. Clinical practice has made clear the centrality of electronic health records across the continuum of care and, in particular, how data quality and structure shape safety, efficiency, and coordination among teams. This experience motivated me to expand the intersection between nursing and information systems, seeking to turn care data into information that is useful and timely.

It focuses on validating the potential of electronic health records for secondary use of data and decision-oriented visualization, with an emphasis on wound care. This clinical domain exposes persistent challenges: heterogeneous documentation, fragmented indicators, interoperability and difficulty in tracking longitudinal progression. The proposed response relies on structured data models and visualizations that translate clinical complexity into clear dashboards, supporting more consistent decisions and enabling comparisons across settings.

Accordingly, this dissertation seeks to contribute a data model and a set of visual representations that strengthen documentation quality, facilitate outcome monitoring, and promote continuous improvement in both chronic wound care and medical informatics-related fields. The path presented here aligns personal motivation with needs identified in practice, aiming to bring data-driven practice closer to everyday care, generate evidence from real-world data for clinicians and managers, and strengthen the digital maturity of health services.

Scientific and Financial Results

A poster within the scope of this project was presented at the 18th Young Researchers Meeting of the University of Porto (IJUP 2025) and published in the conference's abstract booklet:

- Palheira, H., Canelas-Pais, M., Taveira-Gomes, T. (2025). Exploring Data Models: Use of Real-World Data and OMOP Standards for the Development of a Wound Management Dashboard [Poster]. IJUP – 18º Encontro de Jovens Investigadores da Universidade do Porto, Porto, Portugal.

A copy of the poster is available in Annex 1.

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Acronyms

ADL	Archetype Definition Language
AI	Artificial-Intelligence
AQL	Archetype Query Language
BI	Business Intelligence
CDR	Clinical Data Repository
CKM	Clinical Knowledge Manager
DARWIN EU	Data Analytics and Real-World Interrogation Network
EHDS	European Health Data Space
EHR	Electronic Health Records
EMA	European Medicines Agency
ETL	Extract, Transform, Load
FCUP	Faculty of Sciences of the University of Porto
FDA	U.S. Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
FMUP	Faculty of Medicine of the University of Porto
IoMD	Internet of Medical Devices
IoT	Internet of Things
KPI	Key Performance Indicators

LOINC	Logical Observation Identifiers Names and Codes
NICE	National Institute for Health and Care Excellence
NPWT	Negative Pressure Wound Therapy
OHDSI	Observational Health Data Science and Informatics
OMOP CDM	Observational Medical Outcomes Partnership Common Data Model
OPT	Operational Template
OSS	Open-Source Software
RCT	Randomized Controlled Trials
RWD	Real-World Data
RWE	Real-World Evidence
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
SUS	System Usability Scale
WHO	World Health Organization

Introduction

1. Introduction

1.1 The Digital Transformation of Healthcare

Since the turn of the twenty-first century, health systems have been increasingly forced to deliver higher-quality care to larger, older, and more complex patient populations while containing costs. Within this context, Digital Health has emerged as the most significant driver of transformation. Digital Health and this transformation are also shaped by the complex convergence of technological innovation, changing patient expectations, emerging global health challenges, and the implementation of strategic policy initiatives. This ongoing process aims to leverage digital technologies to improve health outcomes, enhance efficiency, and ensure more accessible and equitable care [1] [2] [3]. The WHO also recognizes digital health's critical role in achieving universal health coverage. The concept now reaches far beyond classic e-health, including Internet-enabled medical devices (Internet of Things - IoT and Internet of Medical Devices - IoMD), cloud-based software as a medical device, big-data platforms, robotics, health information systems, infodemics, interoperability, telemedicine, blockchain, health data and the deployment of artificial-intelligence (AI) in decision-support systems as an example [4] [3].

In parallel, the U.S. Food and Drug Administration (FDA) offers the perspective on the scope of Digital Health, which succinctly defines it as integrating everything from mobile medical apps to advanced analytics and convergence of people, information, technology, and connectivity to improve health care and health outcomes. This concise definition emphasizes the diversity and range of technologies under the Digital Health umbrella. It highlights that Digital Health includes everyday tools and applications to manage health, and is not limited to sophisticated, large-scale health information systems. Mobile medical apps, wearable devices, telemedicine platforms, and patient portals are just a few examples of the technologies that contribute to the expanding landscape of DH. Additionally, the FDA's mention of "advanced analytics" stresses the crucial role of data processing and interpretation in extracting valuable insights from the vast amounts of health-related information collected. This facet emphasizes the growing importance of artificial intelligence, machine learning, and other computational tools in Digital Health. [5]Ref: FDA-DH-2024 [5].

Digital Health is increasingly recognized as a vital element of modern healthcare systems. It includes various technologies and applications designed to enhance patient care, advance public health, and foster medical innovation. This approach is reflected in official definitions and regulatory frameworks.

The European Health Data Space (EHDS) provides a significant example; it formalizes the establishment of a secure infrastructure to facilitate cross-border data exchange. This critical provision enables healthcare providers and researchers across European Union (EU) member states to share and access health data in a safe and controlled manner. Furthermore, the EHDS legislation also emphasizes the importance of enabling secondary data use for research purposes. This dimension of the regulation opens opportunities for conducting large-scale studies, analysing population health trends, and accelerating the development of new treatments and therapies. The EHDS aims to create a robust and interconnected European healthcare ecosystem to improve data access and use [6]

1.2 Challenges in Chronic Wound Monitoring

Wounds, both acute and chronic, are an increasingly important global challenge. Despite major advances in medicine and healthcare, their impact on society remains substantial, affecting a large number of people worldwide. These conditions are highly prevalent and have severe consequences on patient’s quality of life, while also placing a considerable financial burden on healthcare systems.

Its prevalence is globally escalating, driven by demographic and epidemiological trends the aging of the population and the increasing incidence of chronic comorbidities, such as diabetes mellitus, obesity, and cardiovascular diseases [7] .

Martinengo et al. present epidemiological data revealing a prevalence of 2.21 cases per 1000 inhabitants for chronic wounds of mixed aetiology [8,9]. This highlights the complexity of these conditions, which frequently result from the interaction of various etiological factors, such as venous insufficiency, arterial disease, neuropathy, and systemic comorbidities like diabetes mellitus. Within this scenario, a specific subgroup emerges with relevance: chronic leg ulcers. These represent the vast majority of observed chronic wound cases, with a prevalence of 1.51 per 1000 inhabitants [9]. This suggests that leg ulcers constitute a substantial challenge. Their chronicity and propensity for complications negatively impact the quality of life of affected individuals and impose a considerable burden on healthcare resources.

Traditionally, wound management was viewed as a reactive practice, dependent on subjective assessment and the individual clinician's experience, but this is currently changing, driven by the convergence of digital technologies.

Digital health technologies offer promising solutions for chronic wound monitoring. However, they still face several challenges, as accurate wound measurement and comprehensive assessment remain difficult [10], digital tools can simplify documentation and empower healthcare professionals, but at the same time their implementation may encounter resistance and face adoption complexities [11]. To address these issues effectively, the integration of such technologies into clinical workflows requires a careful analysis of user needs and practical constraints [12]. Thus, it makes particular sense that the development of smart mobile systems designed to optimize wound care management should involve continuous and in-depth communication with healthcare professionals throughout the entire design process [10].

Wearable technologies introduce new possibilities for real-time wound monitoring and active healing. However, selecting appropriate data visualizations is essential to engage patients meaningfully [12,13] without overwhelming them with unnecessary information and unsuitable for their health literacy level.

Despite these obstacles, digital wound assessment technologies continue to demonstrate potential benefits in clinical practice, particularly in enhancing care quality and facilitating knowledge transfer among stakeholders [11,12].

1.3 Dissertation Structure

This dissertation is organized into eight main chapters:

- Chapter 1, Introduction, establishes the context of digital health, highlights the current challenges in chronic wound care, and introduces the need for a standardized data model.
- Chapter 2, Objectives, defines the core aim of the work.
- Chapter 3, Justification, provides the theoretical background and literature review, justifying the selection of openEHR and Open-Source tools by examining the state-of-the-art in digital health and data standards.
- Chapter 4, Materials and Methods, details the methodology, covering the structural data modelling with openEHR, semantic mapping to standard terminologies, and the development of the visualization dashboard.
- Chapter 5, Results, presents the tangible outputs of the project, including the final openEHR operational template, the semantic mappings, and the functional interactive dashboard.
- Chapter 6, Discussion, interprets the results, analysing the implications of the model's design, the choice of terminologies, and the challenges faced in the context of improving data quality and interoperability.
- Chapter 7, Conclusion, summarizes the main contributions of the research.
- Chapter 8, Future Work, suggests potential future research directions, including clinical implementation of the model and the development of advanced analytical capabilities.

The dissertation concludes with a list of References and Annexes that provide supplementary information and supporting materials.

Objectives

2. Objectives

In this work, we develop and validate a scalable data model for wound management that, from its origin, can serve two complementary purposes: i) the structured and semantically consistent persistence of records in care context, and ii) the capacity for their secondary reuse through real-time visualization and analysis. To this end, we explore and select openEHR archetypes, and, based on them, we create a clinical wound template that supports standardized data collection. Our final objective is to develop and provide an interactive dashboard in Apache Superset, with customizable filters and dynamic interaction, to support informed decision-making and continuous monitoring of outcomes in wound care.

Justification

3. Justification

3.1 Background

Digital Health is an evolving, interconnected ecosystem characterized by technological diversity, regulatory complexity, and immense potential for transforming healthcare. The harmonization of data exchange standards, the advancement of analytical capabilities, and the continued development of user-friendly applications will be essential in driving the successful adoption and implementation of Digital Health technologies worldwide.

To ground these concepts in practice, Table 3.1.1 synthesizes the principal drivers currently shaping Digital Health and their advancements, presenting the effects and significance for real-world data (RWD), real-world evidence (RWE). The table prioritizes drivers that influence data capture and quality, semantic and technical interoperability, and the secondary use of data within EU, WHO, and FDA frameworks, and is illustrative of how this ecosystem continues to evolve.

Table 1: A summary table of the key drivers advancing the digital health transformation, illustrating the convergence of technological advancements, societal needs, and major policy initiatives such as the European Health Data Space (EHDS)

KEY DRIVER	DESCRIPTION	SOURCE
Advanced Analytics and AI	Expanding data collection during routine clinical practice from EHRs and real-world sources. Handling vast amounts of data with AI/ML to identify health risks, assist with diagnosis, treatment, and monitoring, and support decision making. Providing a comprehensive picture of clinical factors to complement traditional clinical trials.	[1] [14] [15]
Advanced Mobile Technologies and Connectivity	Utilizing fifth generation (5G) wireless and cloud technologies for substantial device connectivity. Offering scalable, flexible IT infrastructure through cloud computing. Enhancing data collection and real-time monitoring with the Internet of Things (IoT) and Internet of Medical Devices (IoMD).	[16] [17]

Ethics, Literacy & Society	Promoting a human-centered, inclusive digital transformation through initiatives like "Europe's Digital Decade". Reshaping knowledge, relationships and power dynamics in healthcare. Emphasizing the need for responsible innovation, equity and inclusion. Protecting privacy and empowering users through enhanced digital health literacy.	[18] [19] [20]
Impact of Global Crises	Accelerating the adoption of tele-health, surveillance and mobile solutions in response to pandemics. Exposing gaps in health infrastructure and governance.	[21]
Healthcare Delivery and Efficiency	Setting ambitious public-service digitalization goals for 2030, such as 100% citizen access to e-health records. Improving healthcare delivery, efficiency and effectiveness, reducing operating costs, and ensuring accessibility with innovative solutions. Utilizing telehealth and telemedicine for resource-efficient, patient-oriented care, particularly in managing chronic diseases. Acting as innovation multiplier for public health and enabling personalized, timely data access. Supporting the transition to continuous, comprehensive care. Offering cost-effective solutions for managing the ever-growing prevalence of comorbid conditions and help to control healthcare expenses.	[18] [1] [21] [15] [22] [14]
Patient-Centricity and Empowerment	Facilitating patients participation in decision-making regarding their healthcare decisions. Enabling personalized and precise treatments, by delivering the "right data to the right person at the right time for the right purpose".	[1] [22]
Policy, Governance & Standardization Efforts	Ensuring data integrity and confidentiality through principles such as blockchain and zero-trust principles to. Establishing interoperability to allow data to flow freely across systems without loss of meaning. Establishing data sharing as a fundamental requirement for effective digital health. Implementing sustainable financing strategies, such as public-private partnerships, to support digital health initiatives. Developing national digital-health strategies, with 83% of WHO-Europe states having them in place. Establishing the EU AI Act (Reg. EU 2024/1689) as the first comprehensive, risk-based framework for trustworthy AI. Mandating interoperable EHRs and secure data use through the European Health Data Space (EHDS) Regulation, leveraging infrastructure like MyHealth@EU. Tracking funding and progress through governance cycles, such as the EU's 'State of the Digital Decade' report.	[1] [22] [21] [20]

3.1.1 Concerns and Challenges With Electronic Health Records

EHRs have become fundamental in 21st-century healthcare, driven by their potential to improve care coordination, enhance the accessibility of clinical information, and enable large-scale analyses of patient data [23]. The health benefits of EHRs quickly become evident. Combined with political decisions, these advantages have driven widespread adoption and implementation, enabling rapid access to medical histories and supporting data-driven clinical decisions. However, alongside these benefits, EHRs have also introduced challenges and raised concerns that have become the focus of recent research. One of the main issues identified is the documentation burden placed on healthcare professionals. A study conducted among clinicians in the United States found that they spend between one-third and half of their daily working hours interacting with EHR systems rather than engaging directly with patients, this wave represents a significant loss in care delivery capacity [23]. In addition to the documentation burden, there is evidence that the usability of EHR systems is often perceived as inferior when compared to other technologies. Studies report System Usability Scale (SUS) scores frequently falling below 50 points, which is considered unacceptable [24]. This low usability is mainly attributed to complex interfaces, the presence of irrelevant information, and duplicated records, often resulting from the recurrent practice of copying and pasting previous notes and the repeated use of templates. Moreover, navigation within these systems is often inefficient due to intricate window structures, an excessive number of clicks, and continuous scrolling, all of which hinder effective system use [24,25]. The challenges, therefore, go beyond the sheer volume of information that must be recorded, the misalignment of workflows with clinical practice, and the poor usability of the systems. A reinforcing loop emerges, further aggravating the problem, as clinicians struggle to access records that are often unstructured, fragmented, and dispersed across multiple systems due to limited interoperability [23,24].

Interoperability refers to the ability of multiple healthcare systems and applications to share and exchange information in a continuous and secure manner. In theory, full interoperability would allow a patient's EHR to move freely across systems, hospitals, and clinics, eliminating data silos and ensuring that all stakeholders, including healthcare professionals and patients, can access the necessary information at the right time and in the appropriate format. Beyond the clear improvements in information exchange among clinicians, greater interoperability would lead to a reduction in duplicated records and diagnostic procedures. More importantly, it would contribute to better clinical outcomes and improved quality of care [25–28].

The security of health data and the protection of patient privacy represent another central concern in the use of EHRs. On one hand, electronic systems must ensure that only authorized individuals can access confidential patient information and that such data is neither altered nor lost. On the other hand, cybersecurity threats have been increasing in both frequency and sophistication, making the healthcare sector a frequent target for attackers. In fact, the healthcare industry has become the leading victim of both external attacks and internal incidents, whether malicious or accidental.[27,29,30]. Cyberattacks such as hacking, malware, and ransomware are the leading cause of security breaches in healthcare, followed by unauthorized internal disclosures by staff or partners. These incidents can result in serious consequences, including ransom demands and system downtime, which disrupt clinical operations and may encourage further attacks. To address these risks, healthcare organizations must implement administrative, physical, and technical safeguards. This involves conducting system audits, assigning dedicated security personnel, training staff, securing physical access to equipment, and using technologies like encryption, firewalls, antivirus software, and cloud-based systems to protect data and maintain service continuity [27,29,30].

Data quality EHRs is critical for effective and safe healthcare delivery and refers to the level which recorded information is accurate, complete, consistent, up-to-date, and fit for use. EHRs are expected to provide readable and structured data. Poor data quality can lead to reduced care quality, and compromised patient safety new challenges emerge, including input errors, omissions, and inconsistencies that are not always immediately detectable. The value of EHRs in supporting clinical decision-making and epidemiological research depends directly on the quality of the data they contain. Unfortunately, several studies have documented persistent deficiencies in this area. One critical issue is the completeness of records, missing data are frequent, whether due to clinician oversight or technical limitations in integrating information from multiple sources. Data are frequently fragmented across systems, formats, and modules. Efforts like the OMOP Common Data Model aim to improve data integration, but still, relevant information is often buried in free-text fields, attachments, or underused system modules, which is a barrier to the construction of a comprehensive clinical picture

3.1.2 The Role RWD and RWE in the Digital Transformation of Healthcare

In the current context of digital transformation in healthcare, we observe an increasing interest for data sources that go beyond traditional randomized controlled trials (RCTs). It is within this scenario that RWD and RWE emerge for deepening our knowledge of health and clinical practice [31,32]. RWD generally refers to health-related data routinely collected from real-life clinical settings and everyday patient experiences, outside of controlled clinical trials. Such data can come from diverse sources – for example, EHRs, insurance claims databases, disease registries, pharmacy records, wearables and mobile health apps, patient-reported outcomes, and even social determinants of health or environmental exposures. When analysed appropriately, these raw data are distilled into RWE – meaning clinical evidence regarding the usage, benefits, or risks of medical interventions derived from analysis of RWD [32–34]. In simple terms, RWD is the input (the factual observations from routine care), and RWE is the output – the actionable knowledge gained from rigorously analysing those real-world observations [5,35]. Together, RWD and RWE offer a powerful window into how treatments and health programs perform in actual practice, across heterogeneous patient populations and settings that lie beyond the reach of traditional trials [33].

One of the motivations for using RWE lies in its ability to complement and, in certain aspects, overcome the inherent limitations of RCTs [15,32]. Although RCTs are considered the gold standard for evaluating the efficacy of interventions in selected populations and controlled environments, their results can be challenging to generalize to the vast and heterogeneous real-world patient population [15,32,34]. RWE provides a more comprehensive and representative picture of what truly occurs in large-scale clinical practice, allowing us to gain valuable insights into the long-term safety and efficacy of medications and treatments, for instance [15,32,36].

Despite its potential, the transition from RWD to RWE have their challenges. The main obstacles include the heterogeneity and poor quality of data derived from routine clinical practice, which are often not collected for research purposes [15,32,36,37]; the lack of interoperability among different health information systems; the complexity of data collection and attribution processes; and inconsistencies in taxonomy that may lead to bias and to the so-called "garbage-in, garbage-out" problem. Significant methodological challenges also arise, such as controlling for confounding variables, selection bias, and information bias, which require advanced analytical methodologies to be mitigated [37]. Ethical and privacy concerns are equally prominent. The management of sensitive data, the need for effective anonymization or pseudonymization, data sharing across institutions, and the requirement of informed consent for secondary use of health data are critical aspects that must be carefully considered to ensure both integrity and public trust in RWD-based research [36,38,39].

We observe a growing awareness and acceptance of RWE among various stakeholders [32]. Regulatory agencies such as the FDA (United States) and the EMA (Europe), as well as bodies like NICE (United Kingdom), are developing frameworks and guidelines for the efficient use of RWE, recognizing its complementary role to RCTs [15,32,36]. Initiatives such as the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) and networks like the Data Analytics and Real-World Interrogation Network (DARWIN EU) are being established to facilitate large-scale data harmonization and analysis, enabling the implementation of distributed network studies [39,40].

In the end, we can say that the growing consolidation of RWD and RWE into health research reflects an evolution in evidence development methodologies. By complementing RCTs with insights from real-world settings, these approaches have the potential to accelerate innovation, inform regulatory and policy decisions, and support more personalized and equitable healthcare. Considering this, data visualization emerges as a supportive yet vital role, helping to transform complex, heterogeneous datasets into accessible and interpretable insights that can be shared across researchers, clinicians, regulators, and patients. The challenge ahead lies in ensuring that methodological rigor, ethical safeguards, and data quality keep pace with this momentum, while also adopting visualization strategies that promote transparency, enhance trust, and strengthen the practical use of RWE in clinical and policy decision-making.

3.1.3 Digital Visualization Tools in Clinical Practice

Clinical dashboards significantly impact the daily lives of healthcare professionals and managers, improving efficiency, quality of care, decision-making, and job satisfaction [41,42].

For professionals providing direct care, clinical dashboards transform how they access and use patient information, supporting decision-making and enhancing the quality of care [41,43]. They provide a summary of clinical data and patient outcome trends, offering timely evidence-based recommendations to assist in treatment choices and care strategy management. Dashboards enable all the stakeholders to monitor wound status, facilitating knowledge transfer [12,43,44]. The use of digital tools can significantly reduce the time spent on data collection, as well as the complexity and cognitive effort associated with this process, this efficiency translates into a faster completion of clinical tasks [41,42]. In the context of home care, such optimization helps relieve nurses of a substantial workload related to data collection and reporting. The integration of dashboards and dynamic visualization systems promotes enhanced situational awareness and more precise decision-making. These systems enable the immediate highlighting of relevant changes in the patient's clinical status that require intervention [42]. Digital solutions enable the implementation of personalized treatment plans by allowing the visualization of specific risk factors and the generation of individualized recommendations. For patients with chronic wounds, this approach facilitates the reception of clinical care and guidance, with real-time monitoring and decisions based on objective data [45].

Technology can strengthen communication among members of care teams. However, it is important to recognize that some professionals may continue to prefer traditional methods for the exchange of sensitive information (Chen et al. 2025). The digitalization of care contributes to greater adherence to evidence-based safety guidelines and clinical practice standards. By facilitating access to updated protocols, it fosters safer practice aligned with the most recent recommendations. Moreover, the improvement in the presentation of clinical information has the potential to increase professionals’ satisfaction. A clearer and more intuitive visualization of clinical data can reduce frustration and enhance confidence in decision-making (Khairat et al. 2018).

For managers, clinical dashboards are a valuable tool, providing a global overview that supports supervision and strategic planning. These systems facilitate performance analysis and the identification of opportunities for improving the quality of care. Furthermore, they allow for continuous monitoring and evaluation of health programs, contributing to more informed and results-oriented management decisions [41,46]. Clinical dashboards can be aligned with institutional strategic objectives, supporting management decision-making [45]. Additionally, they provide relevant information for the efficient allocation of resources, ensuring that these are directed to areas of greatest need and impact [41,46]. Managers can use dashboards to monitor incident information at both organizational and unit levels, falls indicator are one example of doing it. These tools enable the identification of units with higher incident rates compared to others, as well as the detection of specific risk factors within each unit [44].

The effectiveness of dashboards reaches its maximum potential when their development continuously involves stakeholders, including healthcare professionals, managers, patients, and caregivers. This participatory process ensures that the resulting solutions adequately respond to the specific needs and constraints of each group [42,44]. These facilitate the integration of multiple sources of information, such as EHRs, administrative data, and socioeconomic indicators, with the goal to generally use real-time or near real-time data for decision support and monitoring. The adoption of semantic standards, such as Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT), is fundamental to ensure a truly interoperable data exchange, being particularly relevant in contexts like wound care [44,46,47].

The implementation of clinical dashboards also faces some obstacles. Some of the main ones are problems related to hardware, limitations in visualization options and the need for adequate user training. The fact that there is a high existing workload and limited human resources should also be considered, as they may hinder regular access to these tools. [41]. Furthermore, overly complex visual functionalities, such as spider or radar charts, revealed low acceptability among nurses, who considered them difficult to interpret [41]. Interoperability challenges also persist, as well as constant changes in underlying data systems, which need to be overcome to ensure the sustainability of the solution [44]. Finally, with potential impact on the quality of care, is the variation in data interpretation, which depends on each user's experience and familiarity [41].

In general, clinical dashboards represent a powerful tool for strengthening healthcare. They contribute to operational efficiency and support more informed decisions, simultaneously benefiting both professionals involved in direct care provision and managers responsible for service oversight [41,42].

3.1.4 Challenges and Methodological Gaps in Wound Research

Frequently described as a “silent epidemic”, chronic and complex wounds create a substantial burden on patients and health systems. The problem unfolds slowly, often outside acute-care settings, so it attracts little public or policy attention. Underreporting, inconsistent diagnostic criteria, and fragmented care pathways obscure the true incidence [48].

Evidence regarding the use of RWD in wound care indicates a positive impact on the continuous use of a Digital Wound Treatment Solution. Results revealed a reduction in the average healing time, particularly for highly prevalent and complex wound types such as diabetic foot ulcers and pressure injuries. Furthermore, an improvement in wound area reduction was observed, even in wounds that had not completely healed but showed progress [49]

Wound research suffers from limited focus and is hampered by significant methodological and funding challenges. Financial resources are often insufficient relative to the burden of disease, and studies lack standardization. Furthermore, clinical trials frequently rely on small samples with short follow-up periods, leading to inconsistent outcomes across studies. The field is also marked by an underutilization of patient-reported measures and the underrepresentation of high-risk groups in research [48].

These weaknesses slow validation and diagnostics, delay head-to-head comparisons of therapies, and restrict the evidence base for clinical guidelines. Enhancing wound research through shared data from EHR, setting core outcomes, leveraging RWD to produce robust RWE that informs reimbursement, guideline development, and bedside decision-making, would enable targeted, cost-effective strategies that reduce variation and improve patient outcomes.

There are other less obvious factors that may go unnoticed but should be considered when capturing an image of clinical records related to wounds. These include patient participation in treatment, full autonomy in treatment, and patient preference for 5–7 day dressings [50,51](Moore and Coggins, 2021; Ryan and Post, 2022). This highlights the need for more comprehensive data models that can capture these and other less granular but equally pertinent pieces of information, which hold significant potential in how we interpret data and institute treatment.

3.2 State Of the Art

3.2.1 Open Standards for Clinical Data Modelling

In this project, we considered two main approaches for the architecture of the clinical wound data model: openEHR and HL7 Fast Healthcare Interoperability Resources (FHIR). Both are open standards widely discussed in recent literature, but they serve different, albeit complementary, purposes.

OpenEHR is an open standard designed for the persistent, longitudinal storage of health data. Its architecture is built on a dual-level model, which separates the stable technical reference model from the flexible clinical knowledge models, known as archetypes [52]. This separation allows the system to adapt to evolving clinical knowledge without requiring structural changes to the underlying database. Consequently, openEHR provides a "future-proof" solution that overcomes the limitations of traditional clinical records, which often create data silos that are difficult to reuse [53]. The model promotes the extensibility and reuse of clinical content, ensuring a patient-centric focus where data retains its context and meaning over time. These major benefits, summarized in Table 2, help explain why openEHR has gained international traction, with several national systems choosing it as their base clinical information model [53,54].

HL7 FHIR was designed primarily as a data exchange standard. It provides a RESTful API with a set of predefined resources for clinical and administrative operations (e.g., patient registration, prescriptions, scheduling). This orientation makes FHIR excellent for rapid communication between heterogeneous systems, promoting continuity of care across different entities. However, by design, FHIR's fixed catalogue of resources, while ideal for transactional interoperability, was not intended to persist all clinical details with the same semantic depth and flexibility as openEHR. This distinction is acknowledged by the international technical community, and both standards organizations are actively collaborating to enhance synergy and interoperability between their ecosystems [55].

Therefore, the choice between these standards depends on the primary goal. While FHIR excels as a format for exchanging data between applications, openEHR serves as a robust format for representing and storing that data with rich clinical detail. Against this background, and because the central objective of this work is to build a semantically rich, persistent, and scalable foundation for a wound data model, openEHR was selected as the most suitable standard for this project.

Table 2: Detailing the advantages of adopting openEHR, focusing on how its architecture preserves clinical meaning, protects data longevity, and leverages expert-driven archetypes for reliable reuse.

BENEFITS	DESCRIPTION
Semantic Interoperability	Ensures that the clinical meaning of data is preserved and unambiguously understood across different systems. It uses reusable, internationally shared archetypes, allowing for consistent interpretations and eliminating ambiguities (e.g., "granulation tissue" will always have the same meaning). This makes health information machine-actionable and aligned with the FAIR principles (Findable, Accessible, Interoperable, and Reusable).

Data Flexibility and Longevity	The two-level architecture (a stable reference model + evolving clinical models) makes the system resistant to obsolescence. Collected data remains valid for decades, even if clinical protocols or models (archetypes) change. New scales or clinical concepts can be added without the need to migrate or refactor the historical database, providing unique agility to keep pace with medical advancements.
Clinical Governance and Knowledge Reuse	Clinical models (archetypes) are developed and validated by communities of experts in repositories like the Clinical Knowledge Manager (CKM). This ensures a high degree of consensus, quality, and standardization. Reusing these validated "knowledge blocks" accelerates development, increases semantic robustness, and ensures the reliability and comparability of the collected clinical data.

These benefits are particularly relevant for wound data modelling, as semantic interoperability supports multicentre studies by ensuring that wound-related concepts are consistently understood across systems. Data flexibility and longevity enable the traceability of healing trajectories over extended periods without compromising historical records. Clinical governance fosters the reuse of validated archetypes, which can be tailored to wound care while maintaining comparability with broader datasets. On this basis, we adopted openEHR as the clinical data modelling methodology for the wound project, aiming to build a database that is both clinically detailed and computationally tractable. Only a semantic and extensible data structure can keep pace with the ongoing evolution of health information systems, particularly with the growing role of artificial intelligence in interpreting clinical data. This approach guarantee reliability and generates actionable knowledge for both research purposes and our dashboard objective.

The openEHR Reference Model classifies Entry archetypes into five primary categories, each corresponding to a distinct type of clinical information (Table 3). The model developed in this study focuses on three of these classes: OBSERVATION, EVALUATION, and INSTRUCTION.

Table 3: The openEHR framework for Entry archetypes, distinguishing five complementary categories; among them, OBSERVATION, EVALUATION, and INSTRUCTION were central to the wound project's data model.

ARCHETYPE CATEGORY	DESCRIPTION	EXAMPLES
OBSERVATION	Used to record clinical facts and measurements that are observed or gathered at a specific point in time or over a period.	Body Weight, Laboratory Test Result
EVALUATION	Used to record clinical interpretations, judgments, and conclusions made by a healthcare professional based on one or more observations.	Problem/Diagnosis, Adverse Reaction Risk, Family History
INSTRUCTION	Specify an action to be performed in the future. They represent orders, requests, and intentions for care.	Medication Order, Service Request, Care Plan

ACTION	Used to record the execution of an instruction or another clinical action that has occurred. They document what was done.	Medication Administration, Procedure, Service Delivery
ADMIN_ENTRY	Used to record administrative and non-clinical information that is part of the health record.	Admission, Discharge Summary, Consent

Within the openEHR ecosystem, the Archetype Definition Language (ADL) functions as the formal specification for modelling clinical knowledge, being the language used to create archetypes, as a computable definition of clinical concepts. The primary role of an ADL is to guarantee that clinical data maintains a consistent structure and unambiguous clinical meaning, allowing for consistent reuse and to be understood, with its full context, by any system compliant with openEHR specifications.

ADL is designed to bridge the gap between clinical experts and technical implementation. Its syntax is both human-readable and machine-processable, which is fundamental to the collaborative governance model of openEHR. This feature enables clinicians to directly validate and refine data models so that they better reflect clinical practice. At the same time, its formal grammar allows software systems to parse these models to generate user interfaces, construct database schemas, and validate incoming data against specified constraints, such as value ranges and terminology bindings. In this way, ADL ensures the separation of clinical knowledge from software implementation, safeguarding data integrity and longevity.

For our project, this separation is particularly important, as it enables structured wound data to be reused for research and for visualization in dashboards, where clarity, consistency, and reliability are critical. To operationalize, we employed the openEHR Archetype Designer tool, this is a web application for clinical modelling through a visual and intuitive interface. This tool is the result of development by the openEHR community and the company Better, maintaining the Open-Source philosophy. Through the Archetype Designer, it is possible to create and edit openEHR archetypes and templates, in ADL formats and generate Operational Templates (OPT) as well as other computable artifacts. With Archetype Designer, it was possible to combine multiple archetypes into a specific template created from scratch, in line with our main objective: to model a representative set of data that impacts decision-making in wound treatment; as for the archetypes, only those validated or in validation by the international Clinical Knowledge Manager (CKM) repository were used, and restrictions were then adjusted and elements customized according to the needs of the wound use case (Modelling Tools ; Garde and Ocean Health Systems ; Archetype Designer).

EHRbase represents another essential component within the openEHR ecosystem. It is an Open-Source clinical repository fully compliant with openEHR specifications, designed to serve as a backend platform for storing, querying, and managing EHRs through a REST API. In contrast to modelling tools like Archetype Designer, which focus on the creation of archetypes and templates, EHRbase provides the infrastructure necessary to operationalize these models in real-world scenarios. Ensuring that clinical data are structured according to openEHR archetypes can be securely persisted, efficiently retrieved, and consistently shared consistently across applications. EHRbase also stands out as one of the most mature and widely adopted Open-Source implementations of the openEHR standard currently available, standing alongside only a few alternatives, which highlights both its robustness and its acceptance within the technical and scientific community [56]. By adopting this repository, we secured the standards-compliant environment capable of supporting interoperability, scalability, and secondary uses of data, including analytics and visualization.

3.2.2 Open-Source and Open Science in Health Informatics

The choice to implement Open-Source tools in this project aligns with the principles of modern science, which aims to be rigorous and collaborative. We intend to contextualize the Open-Source paradigm with the Open Science ecosystem and health informatics. We begin by defining what constitutes Open-Source Software (OSS), transcending the simplistic notion of free software. The Open-Source philosophy rests on three essential pillars that distinguish it from the proprietary software model. (i) the freedom for anyone to use, study, modify, and contribute to the software, rather than it being exclusively controlled and maintained by a single company or a closed group. (ii) the source code must be publicly and easily accessible to all, allowing for complete inspection and auditing. (iii) to protect the software from manipulation and ensure its quality, there must be a transparent, peer-review-based decision-making process for accepting contributions, involving both developers and end-users [57,58].

The philosophy of Open-Source is not an isolated phenomenon; it is the manifestation, within the domain of software, of the foundational principles of Open Science, which aims to make the entire scientific process from the conception and data collection to analysis and publication public, auditable, and accessible, ensuring the free availability and reuse of scientific knowledge [59,60]. The adoption of an Open-Source model is naturally aligned with our pursuit of best scientific practices.

Open-Source software becomes essential in health informatics due to its inherent benefits in flexibility, cost, and collaboration. In the context of electronic health record (EHR) systems, Open-Source solutions allow institutions to tailor and improve the software to meet specific clinical needs, as the source code is freely available and modifiable, this adaptability is particularly valuable in domains like wound care, where unique documentation and analysis requirements could remain unmet when relying on uniform proprietary EHR solutions. Removing licensing constraints decreases expenses and simultaneously fosters the broader adoption and durability of technology in various settings, including resource-constrained environments [61]. Another critical justification for an Open-Source focus is the enhancement of interoperability and avoidance of vendor lock-in. Open standards, such as openEHR [54] or Apache Superset, exemplify how Open-Source paradigms lead to improved data portability and longevity; both provide a vendor-neutral, common data structure for health IT systems, which has led to its growing preference over proprietary formats in some health systems.

Fundamentally, Open-Source standards ensure that data remains accessible and reusable even as technologies evolve. This interoperability is essential for our point of view, which seeks to integrate wound care data from diverse sources and enable its secondary use in analytics. Open-Source approaches also align with principles of data sovereignty and security, which are paramount in healthcare. By opting for Open-Source, we retain the ability to deploy systems on-premises or in controlled cloud environments, thereby keeping sensitive patient data under local governance rather than relying on third-party vendors. This control helps address concerns around data protection, confidentiality, and ownership that often arise with health IT implementations [61]. Given the central role of software models in shaping health informatics, it is important to contrast their underlying principles and implications. To provide a structured overview of the divergent logics underlying Open-Source and proprietary software models, Table 4 presents a comparative framework that highlights how each paradigm shapes technical, organizational, and scientific practices within the field [54,58,61–64].

Table 4: Contrasting the Open-Source and proprietary paradigms by outlining their implications for clinical and research contexts, with attention to acquisition cost, auditability, adaptability, and vendor dependency

Dimension	Open-Source Model	Proprietary Model
Acquisition Cost	Generally null or low, without license fees. Investment focuses on implementation, customization, and support.	High initial cost of license acquisition. Represents a significant barrier, especially for research and low-resource contexts.
Transparency and Auditability	Publicly accessible source code, allowing full auditing by any interested party. Facilitates security verification and scientific validation.	The code is a "black box" controlled by the vendor. External validation is limited or impossible, depending on trust in the vendor.
Flexibility and Customization	High capacity to modify and adapt the software to specific needs (e.g., niche clinical protocols) without depending on the vendor.	Customization is limited and depends entirely on the vendor's will and roadmap, often implying additional costs and long waiting times.
Interoperability	Inherently promotes the adoption and development of open standards, facilitating data exchange between systems from different vendors.	May use standards, but often with proprietary extensions that create "vendor lock-in", making data migration and integration with other systems difficult.
Innovation	Innovation is distributed and accelerated by a global community of contributors. Continuous peer review leads to rapid improvement and more robust products.	Innovation is centralized and limited to the capacity of a single company. The development cycle can be slower and less reactive to community needs.
Support and Maintenance	Support is diversified, including user communities and a competitive market of companies offering commercial services.	Support is exclusive to the vendor, creating total dependence and often expensive maintenance contracts.
Long-Term Sustainability	Software and data viability does not depend on the survival of a single company. The code can be maintained and developed by any entity, ensuring the longevity of the investment.	The future of the software and access to data are intrinsically linked to the vendor's fate. Product discontinuation or company bankruptcy can result in loss of investment and data.

The adoption of an Open-Source approach directly facilitates the implementation of reproducible research. By adopting this approach, our project commits to producing a data model described in a static document. The result will be a dynamic, and reproducible research artifact, transforming the data model from just a description into an active and verifiable component. The concept of reproducibility refers to the capacity to achieve the exact results of a study (including figures, tables, and statistical values) using the original data and code. Achieving this level of reproducibility is the first step towards ensuring the reliability of a study. If a study is reproducible, any analytical problems can be more easily identified and corrected by the community [65].

One of the strongest arguments for Open-Source is its ability to accelerate innovation and scientific discovery. By making the source code available, we enable other researchers and developers to reuse and build upon existing work, avoiding duplication of effort and the costly process of starting a new one [63,66]. In the context of our project, this means that the wound treatment data model we develop can serve as a foundation for future extensions, adaptations, or integration into clinical decision support systems. This collaborative process, where multiple stakeholders can identify flaws, suggest improvements, and contribute code, results in a final product of higher quality, more robust, and more reliable than would be possible to achieve in a proprietary environment [63]. For research projects, especially those conducted by early-career researchers with limited resources, access to these communities of practice and the support they offer is an invaluable asset, providing access to knowledge, tools, and opportunities for international collaboration [58] .

The technical agility afforded by Open-Source is fundamental in a domain as specialized and constantly evolving as wound care. Healthcare systems and clinical protocols have specific requirements that are rarely fully met by proprietary solutions. The ability to freely modify and customize the source code allows us to precisely adapt the data model to the clinical and research needs of wound care, ensuring that data collection is semantically rich and clinically relevant. An Open-Source approach can even be seen as a necessary, though not sufficient, condition for achieving true semantic interoperability of health data. Proprietary systems, even when claiming adherence to standards, can create data silos through opaque implementations or non-standardized extensions, hindering information sharing and locking in customer data [54,67].

A credible and robust scientific justification must acknowledge and proactively address the potential drawbacks and risks associated with the chosen approach. We identify the main risks of Open-Source software related to governance and security. The indiscriminate use of Open-Source Software (OSS) can lead to uncertain quality, for example, by using software developed under different quality control processes. Despite the inherent benefits, we cannot automatically assume that all Open-Source software is secure and reliable without prior evaluation. It is imperative to assess and quantify the associated security risks [68,69]. Another rapidly expanding risk category involves software supply chain attacks. In these scenarios, attackers do not directly exploit an existing vulnerability but rather compromise the distribution or maintenance process of an Open-Source project to inject malicious code. Various tactics have been observed: for instance, compromising a legitimate package through an account with permissions in the official repository to inject a backdoor into a new version, or publishing malicious packages with names identical to recognized projects (typo squatting) resulting in the misguidance of unalert users. In addition to technical risks, the use of Open-Source involves legal risks related to licensing. Each OSS component is made available under a specific license (GPL, MIT, Apache, etc.), whose terms impose obligations and restrictions on users. Failing to comply with these conditions can result in copyright infringement, loss of intellectual property, or litigation. Finally, we must consider the risks arising from the variable quality and maturity of Open-Source projects. Not all open software strictly follows development best practices. There are highly professional projects, with a broad user base and exemplary testing and review practices; but many others are small or immature efforts, without comprehensive testing, adequate documentation, peer review, or regular versioning practices. The use of a component of unknown or questionable quality can introduce functional errors, instability, performance issues, or new vulnerabilities, in addition to hindering integration into the final system.

3.2.3 Visualization

Effective data visualization is fundamental in wound management, as it allows useful information to be extracted from a large volume of data. It was with this in mind that we selected Apache Superset as the Business Intelligence (BI) tool to be used. Typically, these tools are designed with connections that enable data exchange, offering a global view of the data and facilitating interpretation for decision-making [70].

There are several tools on the market in this same scope as shown in Table 5 [70,71], differing in terms of user interface, market position (commercial or Open-Source), and dataset access and dataset access and storage policy.

Table 5: Comparison of commercial and Open-Source Business Inteligence tools, outlining their main strengths and drawbacks.

BI TOOL	TYPE	STRENGTHS	DRAWBACKS
Tableau	Comercial	Known for its intuitive interface and variety of advanced visualizations.	It is proprietary and requires licensing; its free version (Tableau Public) mandates that data/dashboards be public, making it unsuitable for use with confidential data.
Microsoft Power BI	Comercial	Offers native integration with the Microsoft ecosystem and enterprise-level robustness.	It incurs subscription/license costs and is dependent on the Microsoft environment.
Grafana and Kibana	Open-Source	Widely used for monitoring time series, system metrics, and logs. They are free and scalable.	Focused on streaming data (e.g., server metrics) and may require more configuration to accommodate relational clinical data. Recent studies show the use of these Elasticsearch-based tools (e.g., Kibana, Siren) with BI for biomedical data, though their performance varies with data complexity and volume.
Metabase	Open-Source	A more simplified Open-Source BI tool with easy installation and a user-friendly interface. It handles basic queries quickly.	Offers fewer advanced customization and scalability features compared to solutions like Superset.
R Shiny	Open-Source	A highly flexible framework for building custom dashboards via programming in R. It allows full control over visualizations.	Requires considerable programming knowledge and code maintenance. Additionally, complex Shiny applications can face performance challenges with large datasets, and public deployment involves dedicated infrastructure or paid hosting services.
Apache Superset	Open-Source	Free and Open-Source, with a wide variety of visualization options. It is highly customizable and does not require programming knowledge for basic use, only SQL knowledge.	The learning curve can be steep. Permission management can be complex and has limited options for linking multiple tables. Real-time support is limited, but there is a large supportive community.

Superset is a mature Open-Source BI solution managed by the Apache Foundation, standing out as a viable alternative to the proprietary tools mentioned. This decision aligns with our strategy of prioritizing Open-Source technologies, avoiding licensing costs and promoting greater flexibility and transparency.

From a functional and technical standpoint, it aligns with the philosophy of this project, easily integrating with standardized clinical data repositories, demonstrating the ability to connect to databases and generate interactive visualizations agilely [72]. Superset offers ease of use and customization capabilities, the web interface with drag-and-drop functionality and interactive filters makes usability more accessible for simpler graphics. At the same time, for more sophisticated analyses, Superset provides an integrated SQL Lab, where more experienced users can write custom SQL queries. This combination of intuitive visual exploration with advanced query options was an important differentiator compared to purely "no-code" alternatives or, in contrast, options that require full coding. Another advantage is the data autonomy and security provided by a self-hosted Open-Source solution. Unlike proprietary cloud tools, Superset can be deployed in our own server environment, ensuring that sensitive patient data remains under our control. This approach is particularly relevant concerning security and scalability, allowing healthcare institutions to adopt a BI solution without exposing clinical data on third-party platforms. With Superset, we can publish dashboards internally (or in a controlled environment) without compliance concerns or improper information sharing, meeting ethical and legal requirements. Furthermore, being Open-Source may mean there are fewer licensing barriers for future collaboration or reuse of the tool by other institutions in our domain, a natural alignment with open science and interoperability principles [71]. An example of Apache Superset's use in large-scale scenarios, highlighting its robustness, is the co-developed platform for WHO, *EpiGraphHub*, with the Superset-enabled virtualization core demonstrating the ability to scale in distributed infrastructures and provide simultaneous access to multiple users [73]. In clinical research contexts, Superset has also been shown to allow interactive visualization of complex patterns in health data, helping researchers gain insights and generate new hypotheses from large databases [70].

Although we perceived occasional limitations of Apache Superset, we believe that they do not compromise the project's objectives. A potential disadvantage of generic BI tools is the lack of some specialized statistical visualizations or native advanced analyses (e.g., ROC curves, specific quality controls), which would require supplementation by external scripts [70]. However, this aspect was not critical in visualizing wound data, which mainly involves descriptive clinical indicators (lesion prevalence, healing times, classification distributions) well addressed by Superset's standard charts.

Materials and Methods

4. Materials and Methods

This study follows a sequential and iterative methodology, comprising interdependent phases of structural data modelling, semantic mapping, and functional validation. The approach is designed to first establish a semantically rich clinical data model for wound care and then to demonstrate its practical utility for both data collection at the point of care and secondary data analysis. The entire process relies on established open-source technologies and community-driven standards. Each of these phases is described in detail in the following subsections.

4.1 Structural Data Modelling

The development of the information model begins with the definition of the clinical requirements for a comprehensive wound assessment record, which is informed by a review of clinical guidelines and consultation with domain experts. Based on these requirements, the international openEHR Clinical Knowledge Manager (CKM) repository is searched to identify and select existing, validated archetypes corresponding to the required data elements. Priority is given to archetypes with a status of "Published" or "Team Review" to ensure a high degree of clinical consensus and technical stability. The core information model is then authored using the Archetype Designer tool, which provides an integrated environment to assemble the selected archetypes into a coherent clinical document structure, specifically an openEHR COMPOSITION. The tool's graphical and tree-based visualizations facilitate the verification of the model's hierarchical structure and logical integrity as it is being built, ensuring the organization into sections corresponds to the clinical workflow.

Technical conformance of the resulting template is validated using an instance of EHRbase. The final template is exported from Archetype Designer as a standard Operational Template (OPT) file and deployed to the EHRbase server, which confirms its syntactical correctness and compliance with the openEHR specifications. A sample COMPOSITION instance is generated by populating the template with synthetic, yet clinically plausible, data. This COMPOSITION, representing a complete clinical document, is submitted to the repository via the EHRbase REST API. The successful persistence and indexing of this record confirm that the data model is a functionally executable artifact, ready for implementation and for data querying via the Archetype Query Language (AQL).

4.2 Semantic Mapping

For the semantic mapping of the data points included in the previous step, a hybrid strategy is employed, which begins by leveraging the existing terminology bindings within the pre-validated archetypes selected from the CKM. This foundation is then complemented with a manual mapping process for concepts specific to the wound care domain or those not covered by existing bindings, with SNOMEDCT as the primary target vocabulary. The official SNOMED CT Browser is used to explore the terminology hierarchy and identify the most appropriate concepts, while the Observational Health Data Science and Informatics (OHDSI) Athena platform is used to cross-validate concept codes, ensuring alignment with vocabularies used in large-scale observational research.

4.3 Data Visualization

The final phase is dedicated to validating the dual-purpose utility of the data model by demonstrating that the structured data can be transformed into actionable insights. This is achieved through the development of an interactive dashboard using Apache Superset. The synthetically generated data, structured according to the developed model, serves as the data source. The development of visualizations for key clinical and management indicators serves as the functional test, confirming that the data model can effectively support analytics for quality monitoring and decision support.

Results

5. Results

5.1 Structural Data Model

Using Archetype Designer, we imported the relevant archetypes from CKM (e.g. identification, date of birth and scales). This web-based tool facilitated the visualization and verification of the model's structure as we built it and provided a graphical and tree representation of all template fields / archetypes, allowing for visual validation on whether the organization into sections and the data hierarchy correspond to the actual clinical workflow.

From a technical standpoint, the Wound-DM was implemented as an openEHR COMPOSITION of the "Encounter" type, a structure that represents a complete clinical document related to a wound assessment consultation. This COMPOSITION organizes information into logical SECTION archetypes, which function as thematic containers, analogous to sections in a clinical form. Each SECTION contains the specific ENTRY archetypes required to record the detailed clinical data for that domain; a hierarchical structure visualized in Figure 1.

The general structure of the Wound-DM template can be described as follows:

i. *Patient Bio & Demographic Data:* This section groups identifiers and basic demographic information. It is implemented using archetypes to capture data points such as personal details (name, date of birth), gender, height, and weight.

ii. *Medical History:* General clinical section using EVALUATION archetypes to record relevant diagnoses and health problems. Here we insert instances of archetypes such as problem_diagnosis to document the medical history and other comorbidities that influence healing and medication_summary to list patient regular medication. Additionally, we use an OBSERVATION archetype laboratory_test_results to add information due to test results that potentially influences the treatment and evolution of the wounds. However, it is important to note that this section not part of our curated data model, we just add to receive values from other EHR to aggregate in the end dashboard.

iii. Scales: This section is dedicated to OBSERVATIONS of standardized scales. Specifically, we have included the Braden Scale OBSERVATION.braden_scalev1 to assess the risk of pressure ulcers, and a malnutrition screening tool OBSERVATION.malnutrition_screening_tool. For pain, we had to use a validated archetype from the Edmonton scale OBSERVATION.esas_r.v1, selecting only the pain-related aspects from it. These scales provide objective numerical scores that summarize multiple risk factors into single values. The decision to include standard scales aligns with the modeling practices, as coded observations are preferable to narrative descriptions from a knowledge extraction perspective.

iv. *Wound Evaluation:* This is the core section of Wound-DM, where all characteristics of the wound itself are structured and documented. We developed a composite archetype of the EVALUATION type, from wound_exam.v0, a reviewed Draft from CKM, to gather the various attributes necessary for a complete characterization of the wound at the time of observation. In this wound evaluation archetype, we included fields for: lesion dimensions, types of tissues present in the wound bed, percentage or predominance of each tissue type, wound coloration, presence and quantity of exudate, odor, and characteristics of the surrounding skin. By structuring the wound examination in this manner, we increase the variables available for analysis, as each attribute can be treated as an independent variable. It is important to note that this wound_exam archetype was designed to be extensible: for example, it contains slots where additional CLUSTER archetypes can be inserted for specific details (wound pH, microbiological culture, wound imaging, among others) should the project evolve in that direction. In terms of the openEHR model, an EVALUATION was suitable here as it represents a comprehensive clinical assessment of the current state of the wound, similar to a focused physical examination summary, rather than simply an isolated observation.

v. *Medical Devices | Dressings:* This section is intended to record therapeutic actions performed and future guidelines. To this end, we utilize two complementary types of Entry archetypes: an INSTRUCTION INSTRUCTION.therapeutic_item_order.v1 to prescribe the treatment carried out during the consultation, in example application of a silver hydrofiber dressing; and a CLUSTER.device.v1 to actual select coded prescribed care plan and add a time stamp to the beginning and ending of use.

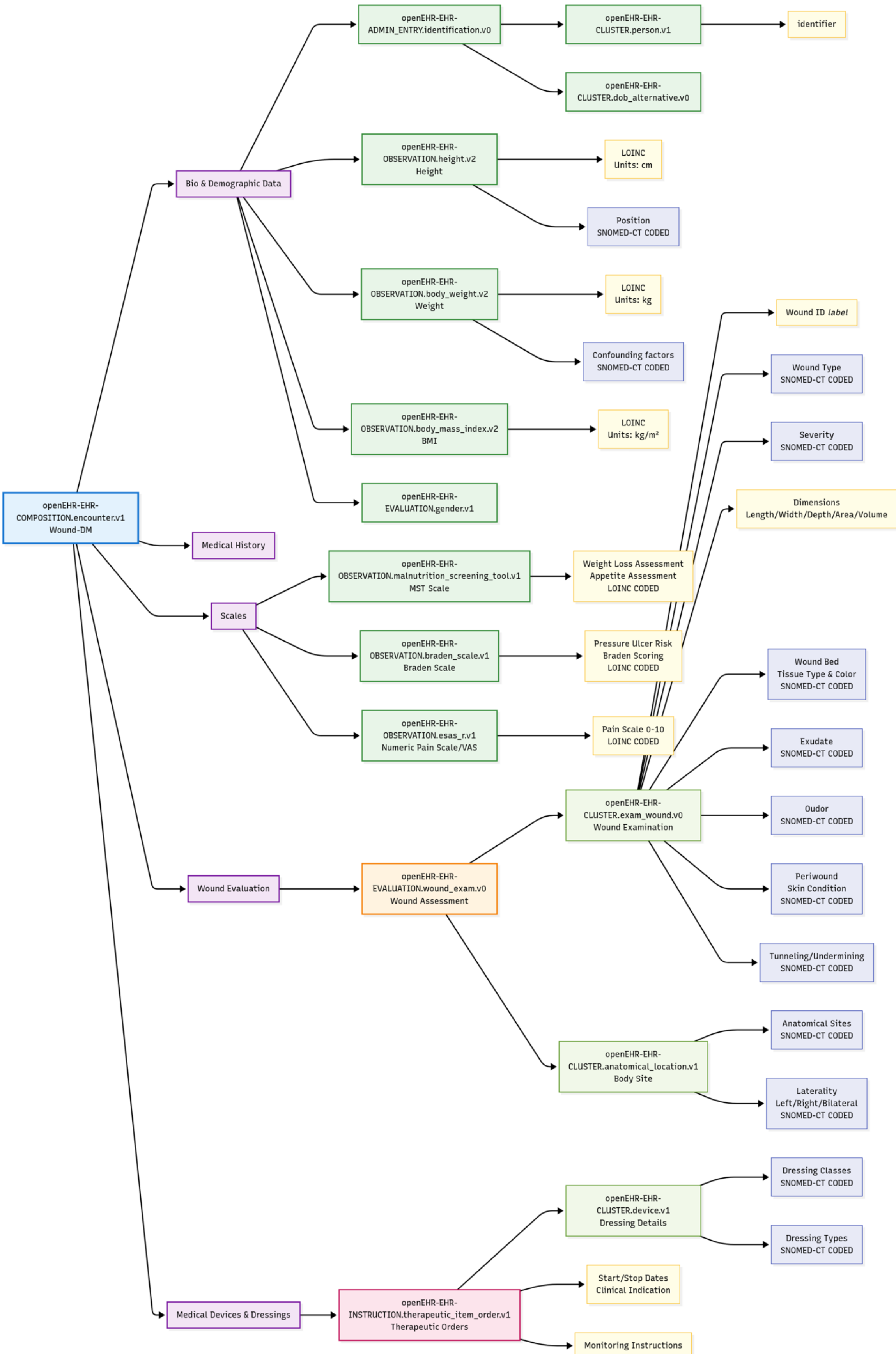


Figure 1: Structure of the Wound-DM template implemented as an openEHR COMPOSITION of "Encounter" type. Organized into sections, each containing specific Entry archetypes mapped to standardized terminologies (SNOMED CT and LOINC) to ensure semantic interoperability.

5.2 Semantic Layer and Terminology Binding

To ensure semantic interoperability, a hybrid mapping strategy was employed, combining pre-validated terminology bindings from the selected archetypes with targeted, manual curation. This process was conducted within the Archetype Designer tool, where local terms were explicitly linked to external Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) concepts, as shown in Figure 2. Key data points within the model were bound to concepts from the SNOMED CT, with all mappings cross-validated using the SNOMED CT Browser and the OHDSI Athena platform.

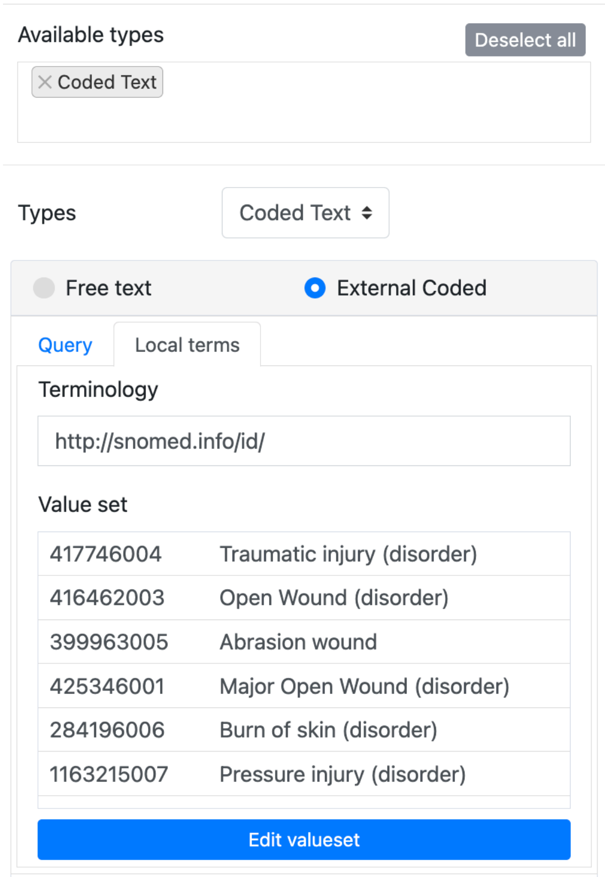


Figure 2: Screenshot during the formulation of constraints through the mapping of local terms to SNOMED CT terminology, integrating standardized clinical concepts into the wound data model using the Archetype Designer.

A multi-step process was used to create value sets for specific clinical domains. The mapping of anatomical locations, for example, began by defining the primary anatomical super-regions where wounds most frequently occur (e.g., trunk, upper and lower limbs). This was achieved using a SNOMED CT Expression Constraint Query (Listing 1) to select high-level concepts from the Body Structure hierarchy.

```
(
((< 91723000 | Body Structure|) AND
(< 52530000 |Body region structure (body structure)|) AND
(< 38866009 |Entire body part (body structure)|)
) OR
((< 70104002 |Upper body part structure)|) OR
(< 22943007 |Trunk structure|) OR
(< 53120007 | Upper Limb Structure|) OR
(< 70104002 | Lower Limb Structure|)
 )
```

Listing 1: SNOMED CT Expression Constraint Query used to define the primary anatomical super-regions (upper limb, lower limb, trunk) most frequently associated with wounds. This query provided the basis for selecting relevant body parts throw filters for the final wound location value set.

The resulting concept set was then used as a filter to guide the manual selection of more granular, clinically relevant body parts for inclusion in the final value set, as illustrated in Figures 3A and 3B.

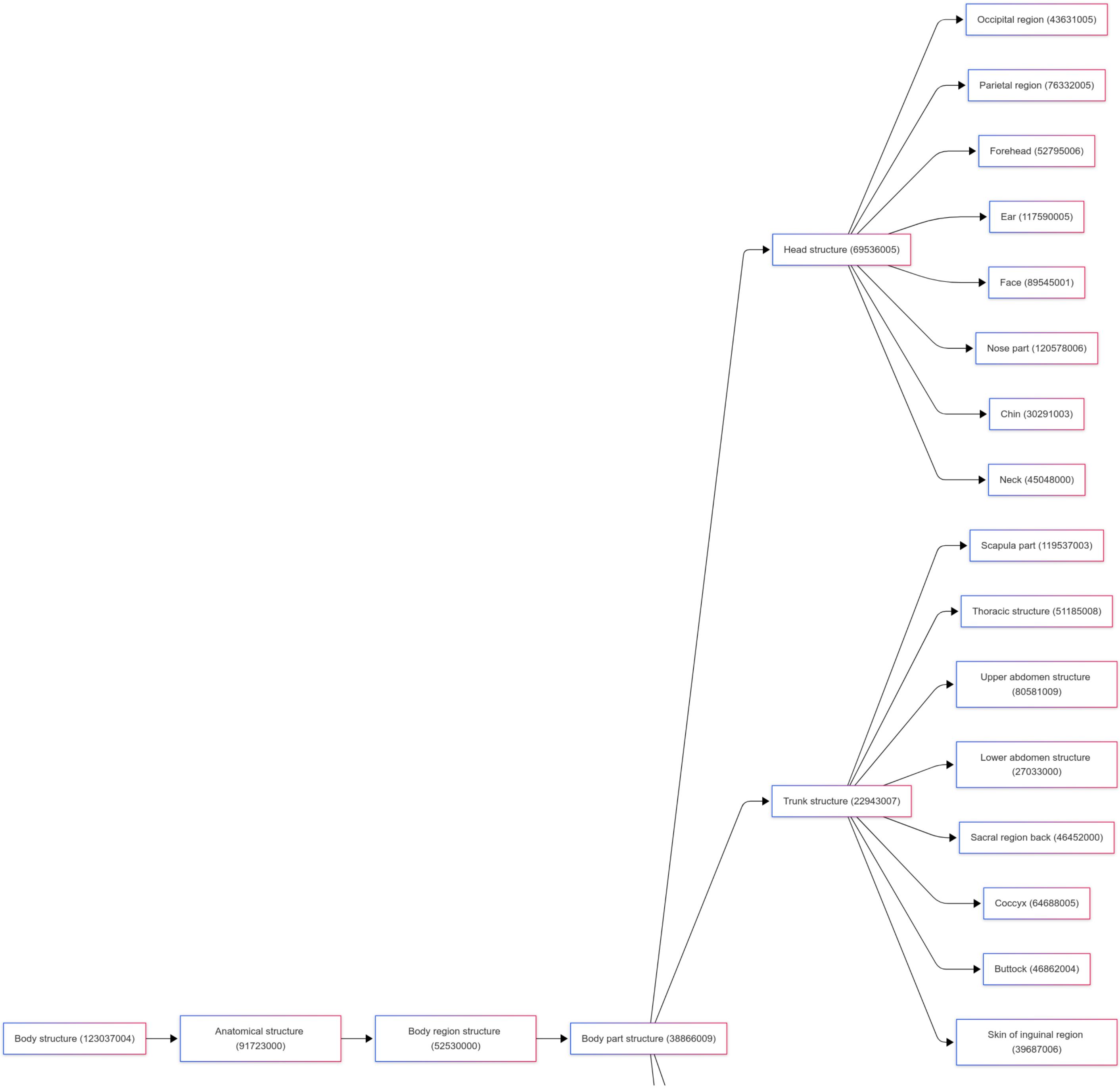


Figure 3A: Hierarchical representation of anatomical body regions after filtered and seleted from the SNOMED CT Body Structure hierarchy. [A- Head and Trunck Structures]

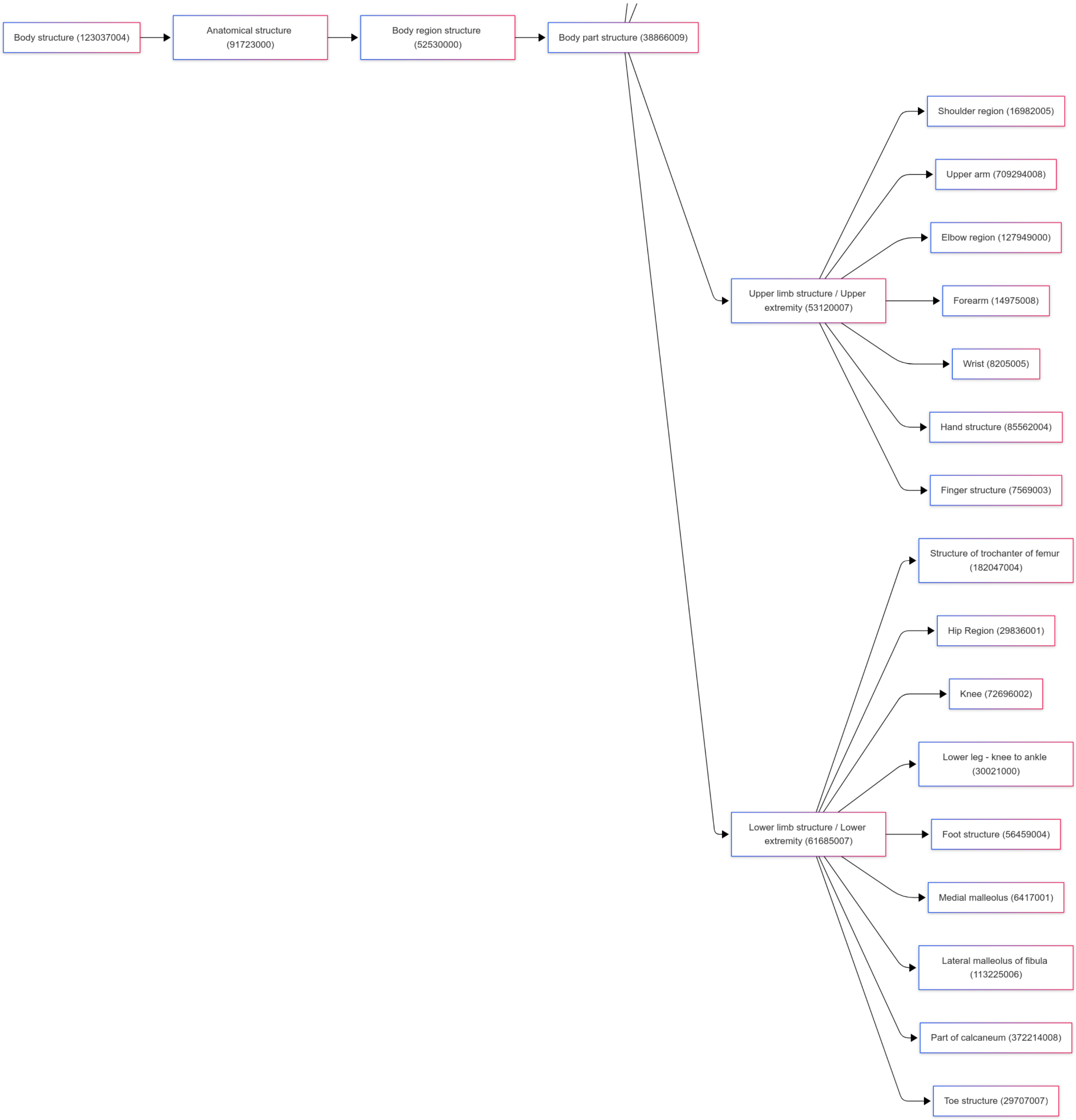


Figure 3B: Hierarchical representation of anatomical body regions after filtered and selected from the SNOMED CT Body Structure hierarchy. [B- Upper Limb and Lower Limb Structures]

This systematic approach was applied across other domains, such as wound tissue types, exudate characteristics, and dressing materials, ensuring that the resulting data is terminologically consistent and computationally reliable. Wound-DM incorporates clinical findings, procedures and materials. This systematic approach was applied across all relevant clinical domains. Observable wound characteristics (e.g., slough, granulation, odour) were coded using the SNOMED CT *Clinical finding* hierarchy to answer the question, "what is wrong with it?". Similarly, materials used in care, such as specific dressings, were coded using appropriate SNOMED CT concepts to answer, "what was done to it?". Standardizing both findings and materials in this way ensures that the data is not only semantically rich but also prepared for advanced secondary uses, such as facilitating migration to the OMOP Common Data Model domains (e.g., Condition, Procedure, Device).

However, this hierarchical approach occasionally presented challenges. The wound typology provides a concrete example (Figure 4), where multiple branches of the hierarchies diverged in ways that were not always clinically intuitive for the purpose of this data model. In such cases, a more manual approach was required, often supported by visual inspection of the hierarchical branches, to appropriately select and organize the relevant concepts.

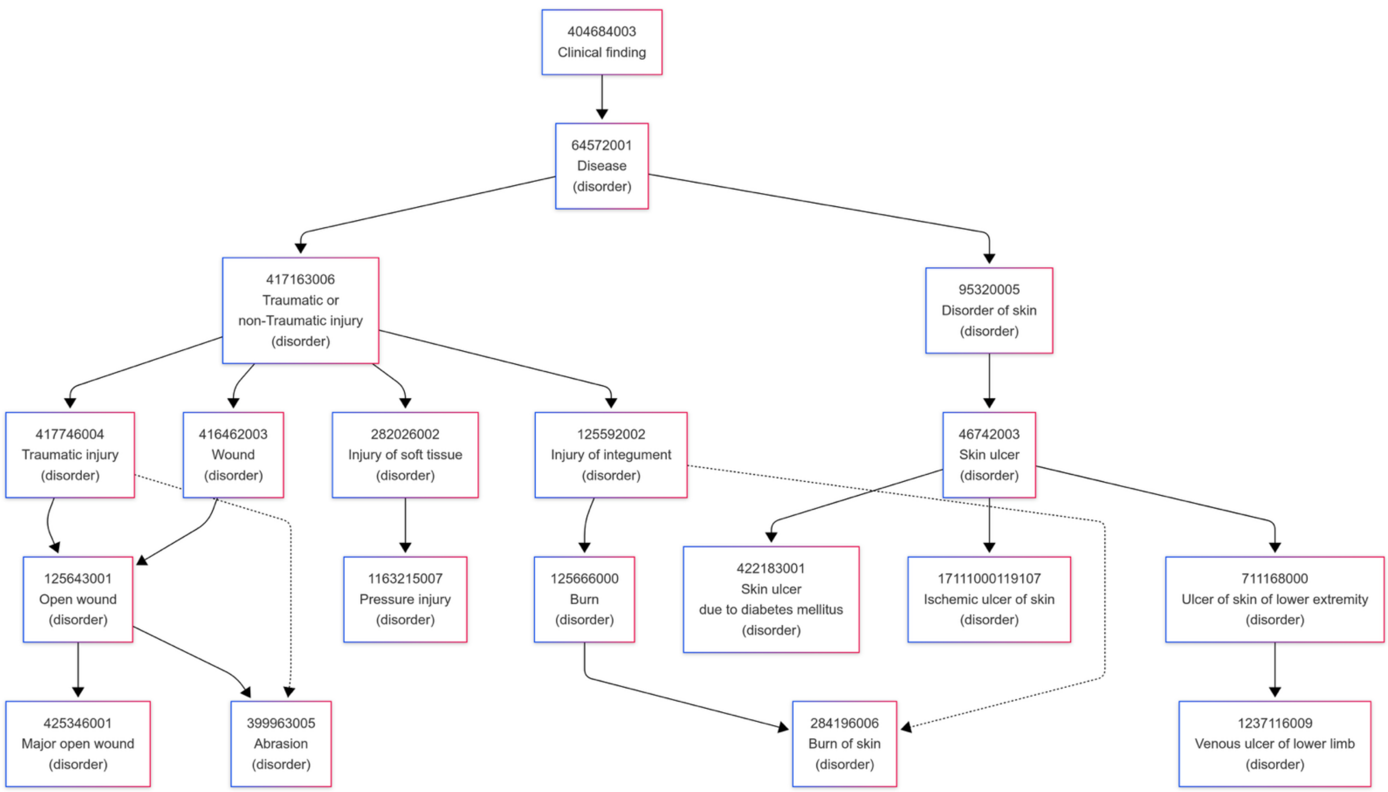


Figure 4: An illustration of the divergent hierarchical branches for wound typologies within SNOMED CT, highlighting the need for manual curation to maintain clinical coherence for a specific purpose.

5.3 Technical Implementation and Validation

After the terminology bindings described previously were technically implemented within the Archetype Designer tool, the resulting rules and value sets were embedded directly into the model's Operational Template (OPT), ensuring the standardized terminology is an integral part of its definition. Listing 2 shows an excerpt of the OPT's XML structure, illustrating how a human-readable term is formally linked to its SNOMED CT identifier.

```
<!—Excerpt: more codes could be included-->

<term_definitions code="http://snomed.info/id/::417746004">
   <items id="text">Traumatic injury (disorder)</items>
</term_definitions>
<term_definitions code="http://snomed.info/id/::416462003">
   <items id="text">Open Wound (disorder)</items>
</term_definitions>
<term_definitions code="http://snomed.info/id/::399963005">
   <items id="text">Abrasion wound</items>
</term_definitions>
<term_definitions code="http://snomed.info/id/::425346001">
   <items id="text">Major Open Wound (disorder)</items>
</term_definitions>
<term_definitions code="http://snomed.info/id/::284196006">
   <items id="text">Burn of skin (disorder)</items>
</term_definitions>
<term_definitions code="http://snomed.info/id/::1163215007">
   <items id="text">Pressure injury (disorder)</items>
</term_definitions>
<term_definitions code="http://snomed.info/id/::422183001">
   <items id="text">Skin ulcer due to diabetes mellitus (disorder)</items>
</term_definitions>
<term_definitions code="http://snomed.info/id/::17111000119107">
   <items id="text">Ischemic ulcer of skin (disorder)</items>
</term_definitions>
<term_definitions code="http://snomed.info/id/::1237116009">
   <items id="text">Venous ulcer of lower limb (disorder)</items>
</term_definitions>

<!--Excerpt: more codes could be included-->
```

Listing 2: Excerpt of the XML representation of the value set, with human-readable descriptions for each concept. The <term_definitions> tags define a set of terms, and each term is linked to a SNOMED CT code via the code attribute (e.g., code="http://snomed.info/id/::417746004"). The human-readable text, such as "Traumatic injury (disorder)", is nested within the <items> tags.

The final OPT was then deployed to an instance of EHRbase, an open-source clinical data repository (CDR), to validate its technical conformance. The successful deployment confirmed the template was syntactically correct and compatible with the openEHR reference model.

To confirm operational readiness, a sample COMPOSITION was populated with synthetic data and submitted to the EHRbase repository. The successful persistence and subsequent retrieval of this data via the Archetype Query Language (AQL) validated that the model is a fully executable artifact, ready for both data capture and secondary use. Listing 3 shows an excerpt of the persisted JSON COMPOSITION, the final, computable data instance.

```
{
 //<!--Excerpt: more codes could be included-->

  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/type|code": "284196006",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/type|terminology": "http://snomed.info/id/",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/type|value": "Burn of skin (disorder)",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/severity|terminology": "http://snomed.info/id/",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/severity|code": "6541008 ",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/severity|value": "FSecond degree burn injury
(morphologic abnormality)",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/anatomical_location/laterality|terminology":
"http://snomed.info/id/",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/anatomical_location/laterality|code": "7771000",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/anatomical_location/laterality|value": "Left",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/body_site|code": "7569003 ",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/body_site|value": "Finger structure (body
structure)",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/body_site|terminology": "http://snomed.info/id/",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/shape|code": "42700002",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/shape|value": "Round shape (qualifier value)",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/shape|terminology": "http://snomed.info/id/",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/edge_type|code": "271807003",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/edge_type|value": "Eruption of skin (disorder)",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/edge_type|terminology": "http://snomed.info/id/",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/edge_attachment|terminology":
"http://snomed.info/id/",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/edge_attachment|code": "449748001",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/edge_attachment|value": "Wound edges attached
(finding)",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/wound_bed_tissue:0/tissue_type|terminology":
"http://snomed.info/id/",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/wound_bed_tissue:0/tissue_type|code": "449746002",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/wound_bed_tissue:0/tissue_type|value": "Wound
slough (finding)",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/wound_bed_tissue:0/proportion|denominator": 100,
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/wound_bed_tissue:0/proportion": 0.5,
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/wound_bed_tissue:0/proportion|numerator": 50,
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/wound_bed_tissue:0/proportion|type": 3,
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/exudate_appearance|code": "447112000",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/exudate_appearance|value": "Serous discharge from
wound (finding)",
  "wound-dm.v1/wound_evaluation/wound_exam/examination_of_a_wound:0/exudate_appearance|terminology":
"http://snomed.info/id/",
  "wound-dm.v1/medical_devices_dressings/therapeutic_item_order/order:0/dressing:0/type|code": "334582005",
  "wound-dm.v1/medical_devices_dressings/therapeutic_item_order/order:0/dressing:0/type|terminology":
"http://snomed.info/id/",
  "wound-dm.v1/medical_devices_dressings/therapeutic_item_order/order:0/dressing:0/type|value": "Hydrocolloid dressing
(physical object)"

  //<!--Excerpt: more codes could be included-->
  }
```


Listing 3: Excerpt of the JSON output, a COMPOSITION of the Wound-DM model, linking archetype paths to standardized SNOMED CT codes, illustrating how clinical data are codified for computable actions and reuse.

5.4 Data Visualization: The Wound Management Dashboard

The dual-purpose utility of the Wound-DM model was validated by developing an interactive dashboard in Apache Superset. This final step demonstrates the model's capacity to translate structured clinical data into actionable insights for both clinical and managerial decision-making.

5.4.1 An Interactive Dashboard for Clinical and Managerial Insights

The developed dashboard results in two panes, *Clinical* and *Management*, designed to provide segmented and strategic visualizations tailored to different user profiles needs.

To enable this work, the dataset for this validation was expanded from the core 53 wound-specific data points to a consolidated set of 107 variables. This was achieved by integrating the Wound-DM model with contextual data from the "Medical History" section, simulating data from ancillary sources like the main EHR or laboratory systems. These data points were populated through a synthetic data generation python script (Annex 2), ensuring consistency for testing and visualization purposes.

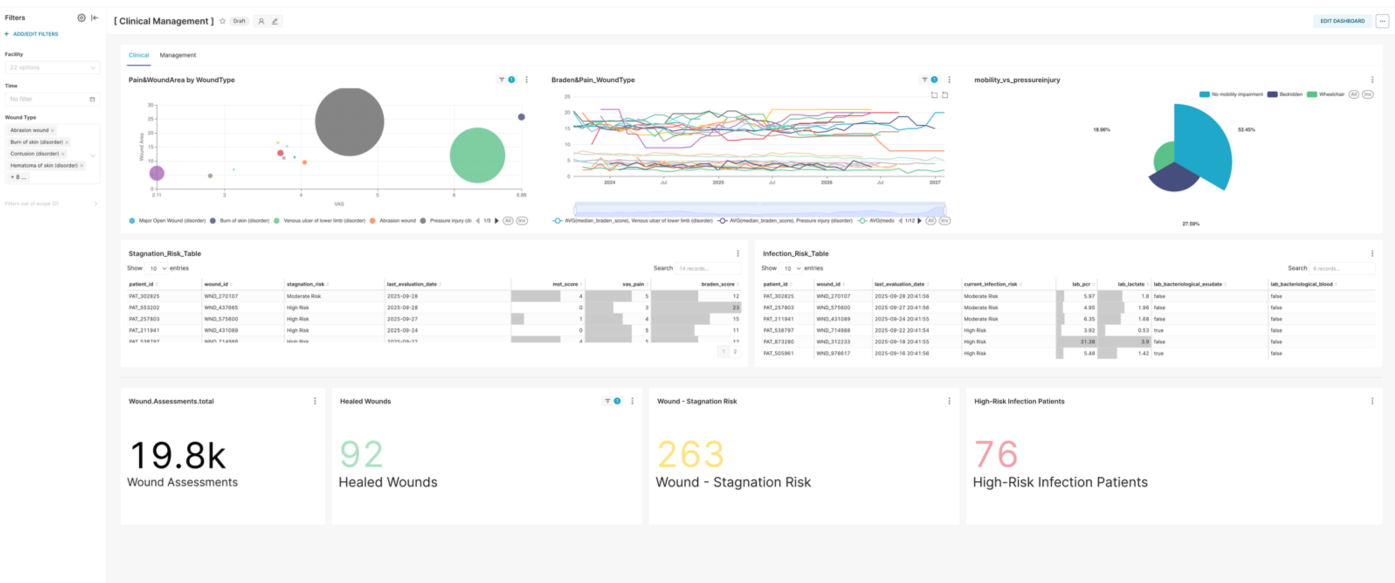


Figure 5: Screenshot of clinical dashboard, designed to provide actionable insights for decision-making in wound care. This view integrates key performance indicators such as total Wound Assessments, Healed Wounds, and patients at High-Risk for Infection or Stagnation. These metrics are complemented by dynamic visualizations that track wound area evolution, analyse wound type distribution by population segments, monitor healing progression, and identify at-risk patients through detailed tables.

The design of the dashboard was guided by key clinical and administrative questions, such as tracking wound prevalence over time, identifying high-risk patient cohorts, and evaluating the effectiveness of specific interventions. Each visual element was developed to provide actionable insights derived from these questions, creating a dynamic tool for monitoring quality and optimizing care, as shown in Figure 5.

5.4.2 Key Visualizations for Decision Support

The following visualizations are presented as concrete results from the implemented dashboard. They are grouped into three distinct analytical themes to demonstrate the system's capacity to support decision-making across operational, clinical, and preventative care domains. Each component translates the structured data from the Wound-DM model into actionable insights.

Part 1: Service-Level Metrics and Risk Stratification

The dashboard translates the abstract data model into actionable information by presenting key visualizations designed to track trends, detect risks, and inform decision-making. The primary components are the Key Performance Indicators (KPIs), which provide an at-a-glance overview of the service's status.

The main dashboard view highlights four critical KPIs that serve as the service's pulse (Figure 6). The "Wound Assessments metric" quantifies the operational workload and clinical activity, providing an evidence-based foundation for resource management. In parallel, the "Healed Wounds KPI" serves as the primary clinical outcome metric, measuring the success of the care program and providing a crucial benchmark for quality. Completing this high-level view are the proactive risk indicators: "Wound - Stagnation Risk" and "High-Risk Infection Patients". These metrics are designed to shift the care paradigm from reactive to preventative by flagging patients who require immediate clinical attention, allowing for early and targeted interventions.

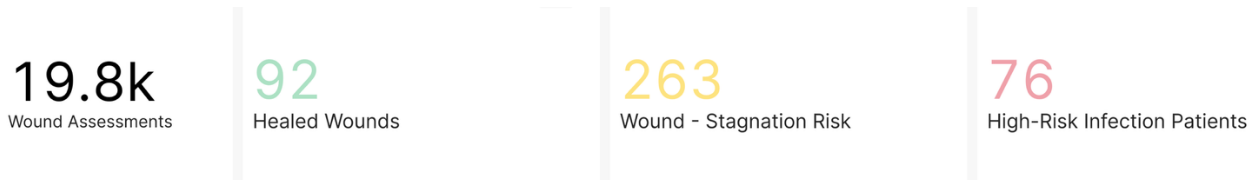
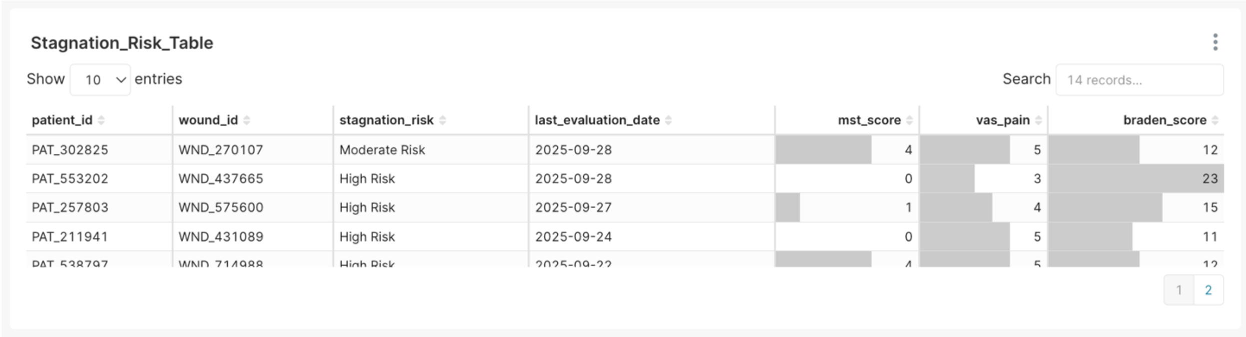


Figure 6: Screenshot of the Big Number visualization for the total number of wound assessments performed, representing the workload and operational volume of the service. This is part of both Clinical and Management Dashboard.

Beyond the high-level summary, the dashboard provides drill-down capabilities for both risk indicators. The Stagnation Risk KPI links to a dynamic table (Figure 7) that lists the individual patients whose healing is predicted to be stalled. Similarly, the High-Risk Infection Patients KPI links to its corresponding risk table (Figure 8). Both components provide actionable, patient-level data, including the contributing clinical scores and risk factors, enabling clinicians to immediately review high-priority cases and adjust care plans accordingly.



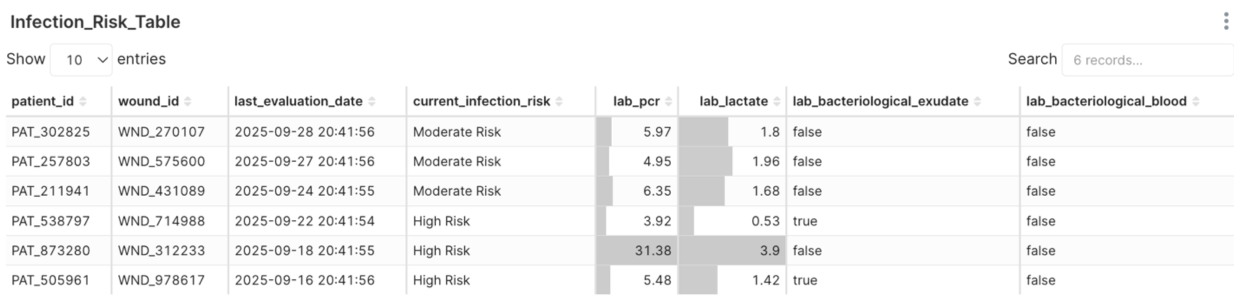
Stagnation_Risk_Table

Show 10 entries Search 14 records...

patient_id	wound_id	stagnation_risk	last_evaluation_date	mst_score	vas_pain	braden_score
PAT_302825	WND_270107	Moderate Risk	2025-09-28	4	5	12
PAT_553202	WND_437665	High Risk	2025-09-28	0	3	23
PAT_257803	WND_575600	High Risk	2025-09-27	1	4	15
PAT_211941	WND_431089	High Risk	2025-09-24	0	5	11
PAT_538797	WND_714988	High Risk	2025-09-22	4	5	12

1 2

Figure 7: Screenshot of the Stagnation Risk Table, which provides a patient-level drill-down from the Key Performance Indicators to support targeted interventions for non-healing wounds. This interactive element is part of both Clinical and Management Dashboard.



Infection_Risk_Table

Show 10 entries Search 6 records...

patient_id	wound_id	last_evaluation_date	current_infection_risk	lab_pcr	lab_lactate	lab_bacteriological_exudate	lab_bacteriological_blood
PAT_302825	WND_270107	2025-09-28 20:41:56	Moderate Risk	5.97	1.8	false	false
PAT_257803	WND_575600	2025-09-27 20:41:56	Moderate Risk	4.95	1.96	false	false
PAT_211941	WND_431089	2025-09-24 20:41:55	Moderate Risk	6.35	1.68	false	false
PAT_538797	WND_714988	2025-09-22 20:41:54	High Risk	3.92	0.53	true	false
PAT_873280	WND_312233	2025-09-18 20:41:55	High Risk	31.38	3.9	false	false
PAT_505961	WND_978617	2025-09-16 20:41:56	High Risk	5.48	1.42	true	false

Figure 8: Screenshot of the Infection Risk Table, which provides a patient-level drill-down from the Key Performance Indicators, highlighting individuals at high risk for infection to enable preventative care. This interactive element is part of both Clinical and Management Dashboard.

Finally, the strategic value of these components is summarized in a conceptual framework (Table 6). This framework explicitly maps the dashboard's visualizations to specific clinical and managerial challenges, detailing the rationale for each metric and the operational strategies it enables.

Table 6: A conceptual framework illustrating how dashboard components translate data into actionable strategies. The table maps specific clinical challenges, such as resource management and infection control, to their corresponding Key Performance Indicators, explaining the rationale for each metric and outlining the operational strategies they enable.

CHALLENGE	DASHBOARD COMPONENT *WHAT IT SHOWS*	FOUNDATION *WHY IT MATTERS*	OPERATIONAL STRATEGIES *WHAT TO DO*
Operational Volume and Resources Management	KPI Card / Big Number *Number of wound assessments over time*	Indicates service demand, resource pressure, and potential trends in caseload	– Use the volume to plan staff scheduling and distribution; – Anticipate consumables demand; – Correlate activity peaks with institutional capacity.
Clinical Efficacy Measurement and Outcomes	KPI Card / Big Number *Number of healed wounds over time*	Demonstrates effectiveness and quality of care; Serves as a justification for investments in wound care programs.	– Key quality indicator; – Benchmark across services; – Identification associated factors to healing rates for replication.

Early detection of non-healing wounds	KPI Card / Big Number *Number of wounds currently classified as being at risk of stagnation* Dynamic Table (Figure 7)	Early detection of non-healing wounds prevents clinical deterioration and reduces costs.	– Review flagged patients in multidisciplinary meetings; – Adjust care and therapeutics plans; – Prioritize advanced or adjuvant therapies.
Infection Prevention and Control	KPI Card / Big Number *Number of patients identified as being at risk of wound infection*	Early recognition of infection risk reduces complications, avoids unnecessary hospitalizations, and supports rational use of antimicrobials and advanced dressings.	– Implement infection surveillance protocols for flagged patients; – prioritize microbiological cultures and specific testing; – Reinforcement of prophylactic interventions such as antimicrobial dressings or systemic adjustments; – Review care and therapeutic plans for high-risk cases in multidisciplinary meetings.

Part 2: Multivariate Analysis of Wound Characteristics

This section demonstrates the dashboard's capacity for more complex clinical analysis, exploring the relationships between multiple wound characteristics to support care prioritization and resource allocation.

The bubble chart in Figure 9 provides a multivariate view of the wound population. Each bubble represents a distinct wound type, plotting the median patient-reported pain (VAS score on the x-axis) against the median wound area (y-axis). The size of each bubble corresponds to the total number of patients with that wound type, representing its prevalence in the cohort. The strategic application of this visualization is detailed in the conceptual framework in Table 7.

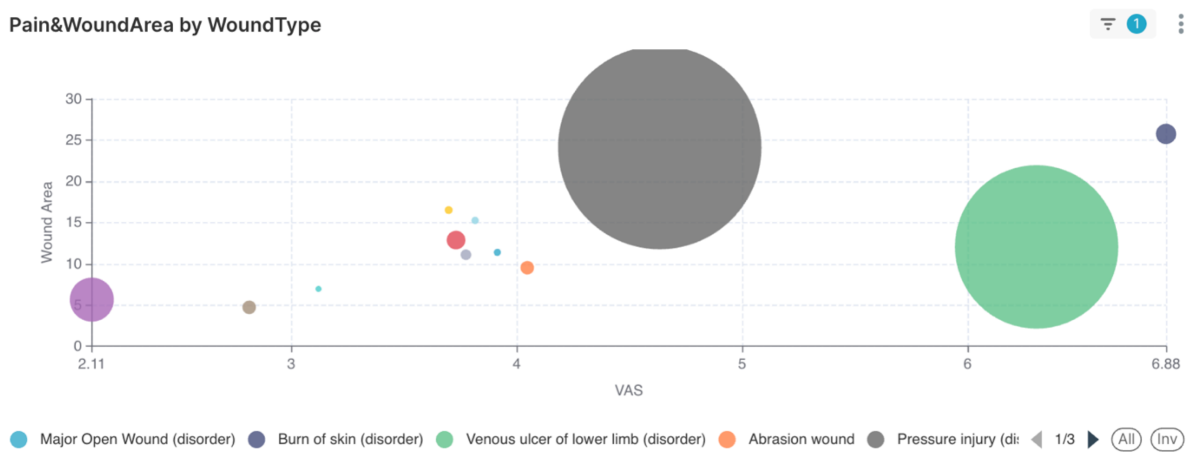


Figure 9: Screenshot of multivariate bubble chart correlating median VAS pain scores (x-axis), median wound area (y-axis), and patient volume (bubble size), stratified by wound type. This visualization allows for the simultaneous assessment of pain severity, wound extension, and prevalence, highlighting clinically significant patterns to support care prioritization, being part of the Clinical Dashboard.

Table 7: A conceptual framework for pain and wound area management using multivariate analysis. This table details how the bubble chart visualization addresses this clinical challenge by simultaneously assessing pain, wound area, and patient prevalence, explaining the rationale for this approach and outlining the targeted operational strategies it enables.

CHALLENGE	DASHBOARD COMPONENT *WHAT IT SHOWS*	FOUNDATION *WHY IT MATTERS*	OPERATIONAL STRATEGIES *WHAT TO DO*
Pain and Wound area management	Bubble Chart Entity: Wound Type Term X axis: Median VAS pain Y axis: Median Wound Bubble size: Total Patients *Median pain and wound area by wound type, with bubble size reflecting the number of patients.*	Enables clinicians and managers to identify wound types with higher pain and larger areas, which may require specialized interventions or resources.	– Targeted pain management protocols for wound types with high VAS scores – Prioritize monitoring and follow-up for wound types with increasing area trends; – Refer selected cases for advanced interventions (e.g., plastic surgery) when size and pain are disproportionally high.

Part 3: Quality Indicators for Preventative Care

This section demonstrates how the dashboard can be used to monitor the quality and safety of care, specifically in the prevention of pressure injuries. Because pressure injury incidence is a key nursing-sensitive quality indicator, quantifying its distribution provides a direct measure of the effectiveness of preventative protocols.

The pie chart in Figure 9 segments patients with existing pressure injuries by their mobility status (e.g., bedridden, wheelchair-bound, no impairment). The analysis of this distribution is crucial for effective risk management. A high percentage of injuries among bedridden or wheelchair-bound patients may indicate a gap in the consistent execution of prevention strategies for known high-risk groups. Conversely, a significant proportion of injuries among patients with no mobility impairment would highlight an overlooked risk, signalling the need to expand and tailor preventative protocols to a broader population.

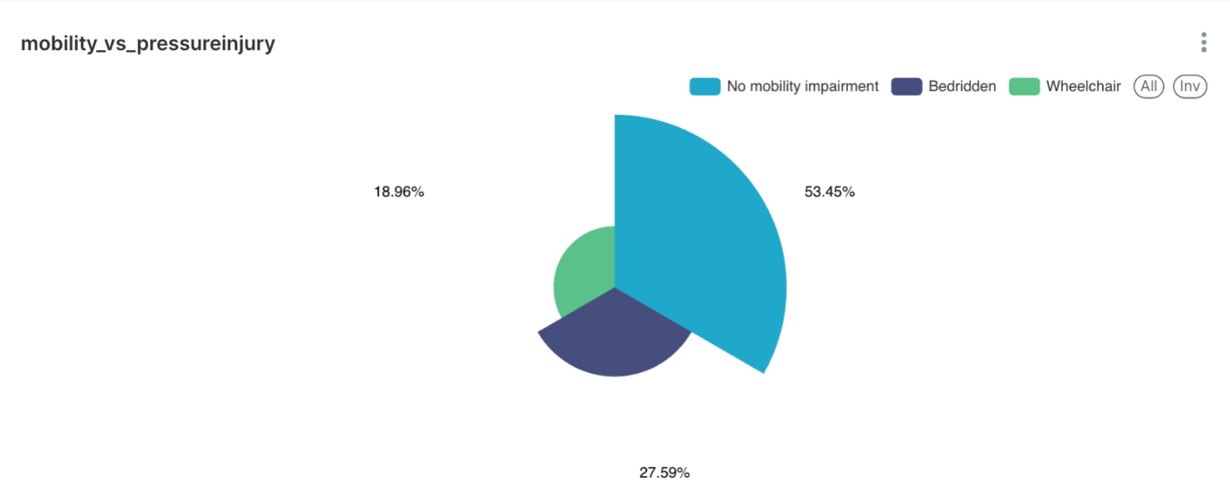


Figure 10: Screenshot of pie chart with a breakdown of patients with pressure injuries by mobility status, serving as an indicator for the quality of preventive care, being part of the Clinical Dashboard.

Quantifying the distribution of pressure injuries across mobility statuses, the dashboard transforms a well-known clinical association into a measurable quality indicator, directly informing targeted interventions and institutional performance monitoring as suggested in the Table 8 in a conceptual framework for prevention and management of pressure injuries.

Table 8: A conceptual framework for pressure injury prevention and management centred on patient mobility analysis. The table details how the pie chart visualization assesses the distribution of pressure injuries across different mobility groups.

Challenge	Dashboard Component *What it shows*	Foundation *Why it matters*	Operational Strategies *What To Do*
Prevention and management of Pressure Injuries	Mobility Group Risk and Pressure Injury Pie Chart Dimensions: Mobility Status Metric: Patients in Mobility Group Filter: Wound Type == Pressure Injury *Proportion of pressure injuries across mobility groups (bedridden, wheelchair, no mobility impairment)*	Identifies whether preventive care is adequately targeted to high-risk populations, while also detecting overlooked risks in lower-risk groups.	– Reinforce adherence to prevention protocols (e.g., repositioning, pressure-relief surfaces) in bedridden and wheelchair-bound patients; – Expand risk assessment and preventive interventions to mobile patients, incorporating factors such as nutrition, comorbidities, and skin integrity; – Use distribution trends as a quality metric to monitor compliance with institutional guidelines.

Discussion

6. Discussion

This work set to design and validate a scalable wound data model that supports both the structured persistence of clinical records and their secondary reuse through real-time visualization and analysis. We explored and selected openEHR archetypes to construct a wound template capable of standardized and semantically consistent data collection. Building upon this basis, we implemented an interactive dashboard in Apache Superset, provided with filters and dynamic interaction, to facilitate decision-making and continuous monitoring of outcomes in wound care in two different panes *"Clinical"* and *"Management"*. In the coming discussion, we reflect on the results for health informatics and clinical practice.

The ideation and development process that led to the current version of Wound-DM was shaped by key questions aimed at enhancing the understanding and structural representation of data in chronic wound assessments. Foundational queries such as "What data should be recorded in a chronic wound assessment?", "How should this data be structurally represented?", and "What contextual factors influence wound treatment?" guided our approach.

Designed on clinical guidelines, expert experience, and insights from the literature, we identified and categorized essential information domains. These included demographic and biological patient data, wound typologies, tissue classification, and anatomical references, all of which are crucial for a comprehensive assessment. Given the scope of this project, we made the deliberate choice to narrow the focus specifically to chronic wounds, excluding broader domains such as detailed medical history, in order to achieve a more accurate and clinically relevant data model.

Each information domain was mapped to existing validated openEHR artifacts, which grounds the model in internationally vetted, reusable clinical concepts. This process revealed several challenges, prompting the evaluation and eventual development of new archetypes or specializations. To ensure the completeness and accuracy of the recorded data, we adapted a specific archetype for wound assessment. This archetype was selected from the Clinical Knowledge Manager (CKM) as the others, but with the particularity of being an open draft version, still under development and validation. Its structure allows the inclusion of sub-archetypes, maintaining the flexibility needed to incorporate more granular clinical details as validated sub archetypes, assuring the overall quality. The template construction then involves aggregating these archetypes, organizing them hierarchically, following this basic structure: a Composition archetype as a starting point, containing Section archetypes, which in turn contain Observational and Data Entry archetypes, Clusters, Instructions and Evaluation archetypes as needed to express the assessment (Figure

2 represents the structural design with the selected archetypes). During this stage, we also focus on specializing certain elements of the archetypes to adapt them to our objective. We remove fields not pertinent to the context, define default values, and make some fields mandatory or optional as appropriate.

This modular organization of Wound-DM aims to reflect the logical flow of a wound assessment and treatment consultation, facilitating data entry by healthcare professionals. Each section of the template corresponds to a cognitive grouping of information: first patient data, then health history, scales, followed by wound assessment and treatment, mirroring clinical reasoning. Furthermore, each document section can be computationally processed independently; if necessary, we can acquire information from only specific selections, such as "Laboratory Exams" data, and feed the model for the dashboard with this selection from a source other than immediate patient observation. We can also use it in the opposite direction, extracting only a specific selection or several for a particular dataset, allowing a different scope in wound treatment research. In terms of implementation, when exporting this template to the openEHR CDR, each filled instance of Wound-DM becomes an indexed composition, consultable via AQL queries as a whole or by filtering specific sections/archetypes. The Wound-DM.v1 template, designed and implemented in this project, becomes a computationally actionable clinical knowledge artifact. To support semantic precision and interoperability within the Wound-DM architecture, we adopted SNOMED CT and LOINC as the primary reference terminologies. These terminologies were incorporated into the openEHR-based model by linking relevant archetype elements to standardized codes, following the guidance and capabilities offered by the openEHR framework.

SNOMED CT is widely recognized as the most comprehensive and scientifically validated multidisciplinary clinical terminology. Its extensive coverage of concepts related to diagnoses, clinical findings, procedures, and body structures makes it particularly well-suited for modelling the wound care domain. LOINC, by contrast, specializes in the standardization of clinical measurements and laboratory observations, playing a complementary role in encoding the parameters and units of wound assessments.

The openEHR standard explicitly encourages the integration of external terminologies such as SNOMED CT and LOINC within archetypes. This approach enables clinical content to be captured in a semantically consistent and interoperable way, facilitating both the exchange of structured information and its secondary reuse. Recent collaborations between openEHR and SNOMED International have further emphasized the importance of harmonizing clinical information models with international terminology standards.

The decision to use SNOMED CT as the core terminology for was driven by its broad international adoption, comprehensive concept coverage, and its status as the preferred standard vocabulary in the OMOP CDM for clinical conditions. Aligning our openEHR model with SNOMED CT ensures that wound-related data are both semantically robust and compatible with downstream data transformation processes, particularly for secondary uses such as clinical analytics and research in the OHDSI network. LOINC was integrated as a complementary terminology to encode quantitative and qualitative observations, particularly in archetypes related to wound measurement (e.g., *wound length*, *wound depth*) and physiological scoring. This combination allows for precise, structured recording of both the eliciting question and its clinical interpretation, enhancing data quality and facilitating interoperability across systems (Figure 2 reflets the terminologies with the yellow and blue boxes representing LOINC and SNOMED CT terminologies respectively). Many openEHR archetypes already support LOINC mappings natively, making it a natural fit for integration into the Wound-DM template. When we incorporate both terminologies, we established a semantically precise and interoperable model capable of supporting high-quality data capture, real-time visualization, and suitable with analytic packages.

Despite its advantages, the integration of SNOMED CT into the Wound-DM model presented challenges. Mapping the clinical concepts of wound care to SNOMED CT codes was not always straightforward, particularly those related to wound types and anatomical locations. Specialized domains such as wound assessment and treatment often lack direct one-to-one correspondences in standardized terminologies, particularly when dealing with granular clinical nuances. In several cases, the existing SNOMED CT codes were either too broad or insufficiently specific, making it difficult to preserve the full clinical meaning of the source data. When exact matches could not be identified, we encountered situations where only higher-level, less detailed codes were available, introducing a risk of semantic dilution. To mitigate these limitations, we considered for future work strategies as i) post-coordinating terms, allowing structured compositions of simpler codes, achieving more specificity; ii) proposing new concepts when not existing. However, each of these approaches requires specialist input, validation, and rigorous modelling to ensure semantic accuracy and maintain clinical validity, ensuring that intended clinical meaning is fully preserved. These challenges reflect a broader issue in semantic interoperability: even the most comprehensive terminologies may struggle to represent complex, domain-specific knowledge without loss of detail, requiring tailored solutions and manual refinement.

A challenging aspect of the terminology mapping process was the classification of wound types within the SNOMED CT hierarchy. While SNOMED CT offers broad coverage of clinical conditions, its hierarchical structure often leads to dispersed representations of related concepts. This issue was especially evident in the context of chronic wounds.

A concrete example lies in the distinction between the terms "Pressure Ulcer" and "Pressure Injury" (Figure3). Although "Pressure Injury" has gained acceptance as a more accurate and clinically appropriate term, its placement within SNOMED CT's hierarchy does not align with related conditions such as "Skin Ulcer" for example. This lack of alignment complicates the creation of a cohesive and logical categorization framework, as clinically similar entities are scattered across different hierarchical branches. We addressed this by combining the hierarchical exploration capabilities of the SNOMED CT Browser with the more immediate hierarchical visualizations provided by OHDSI's ATHENA. This ensured that our selected concepts were both clinically precise and technically compliant with the OMOP CDM vocabularies. This example exemplifies that relying only on hierarchical logic can lead to semantically incoherent or incomplete models. The need for manual, expert-driven validation was very important. This finding underscores that the development of specialized data models requires clinical domain expertise and a practical tool-assisted approach where interdisciplinary collaboration is used to navigate and resolve the discrepancies between formal terminologies and the complex semantics of real-world clinical data.

The design and development of the wound data visualization layer were guided by two complementary and yet distinct user perspectives: clinical practice and healthcare management. Recognizing the importance of addressing both, the implemented dashboard was structured into two dedicated panes, "Clinical" and "Management", to deliver targeted, role-specific insights derived from the same underlying data model.

From the clinical standpoint, the goal was to empower healthcare professionals with timely, relevant information to support early risk detection, prioritization of interventions, and continuous monitoring of patient outcomes. The dashboard serves as a console for wound care, enabling clinicians to track healing trajectories, tissue types, and other key indicators. It also helps identify deviations from expected recovery paths, supporting proactive decision-making and improving both patient care and clinical workflow efficiency.

The management view was designed to provide a broader organizational perspective. It presents macro-level insights into the performance of wound care services, including KPIs such as the volume of wound assessments, healing rates, and stagnation risks. By visualizing these metrics over time and across care units, the dashboard supports resource planning, inventory management, and quality benchmarking, contributing to improved service coordination and operational effectiveness.

A great example of how visualization enhances understanding can be seen in the integration of pain scores with wound size and type. While clinical documentation often emphasizes healing status or infection control, pain remains a critical dimension of the patient experience that is frequently underrepresented in aggregate-level views. By combining pain intensity, wound area, and classification, the dashboard reveals population-level patterns. For instance, certain wound types such as venous ulcers or burns may be associated with higher pain levels relative to their size, in contrast to pressure ulcers. These patterns inform clinical priorities and guide interventions that account for both physiological outcomes and patient quality of life.

Additionally, the dashboard functions as a readable and actionable layer built on top of the Wound-DM semantic model. It bridges the gap between structured data collection and real-time clinical reasoning, while also supporting secondary data use for RWD and RWE analyses. This dual-perspective approach exemplifies how semantically structured data, when rendered effectively, can support evidence-informed care and data-driven management.

Conclusion

7. Conclusion

This work introduces a conceptual and methodological framework for wound care that integrates primary and secondary data use through a single, dual-purpose information model. It demonstrates how RWD can be captured and reused for analysis, quality monitoring, and research.

Our data model is grounded in the OpenEHR standard to create persistent and longitudinal records, ensuring semantic interoperability through a context-rich data architecture, where standardized bindings establish that clinical meaning is preserved. Additionally, a modular curated archetype, facilitates both data entry and computable capacity. This approach ensures a reliable data model that leverages data visualization and ultimately reveals the true value of RWD.

This framework integrates with modern business intelligence tools, enabling EHRs to function as an intuitive and actionable resource, improving clinical decision-making and positively impacting KPIs such as patient outcomes and strategic management.

The resulting framework is scalable and transferable. By separating content models from implementation details, it can be extended with additional clinical concepts, adapted to heterogeneous information systems, and integrated with ancillary data sources without compromising semantic integrity. In practical terms, it supports data-driven decision-making at both patient and service levels, enabling earlier detection of adverse trends, clearer tracking of outcomes, and more efficient allocation of resources.

The work demonstrates a viable pathway to unlock the value of RWD in wound care through a standards-aligned, robust, and data-driven model that ties primary capture and secondary use.

Future Work

8. Future Work

This work establishes a foundational data model and visualization framework that enables several trajectories for future research and development. A natural extension involves the refinement and expansion of the clinical model itself. Future efforts could focus on broadening its semantic coverage to include specific wound aetiologies, authoring a unified wound archetype for submission to the international CKM, and integrating advanced media capture with essential metadata to create a repository of standardized visual documentation for longitudinal analysis.

To enable the reuse of this data at scale, a critical avenue for future work is its technical integration with broader health data ecosystems. This would involve developing ETL (Extract, Transform, Load) pipelines to map the detailed openEHR data into a standardized format suitable for large-scale analytics. Mapping to a common data model, such as the OMOP Common Data Model, is a key strategy for enabling multi-site analytics and federated research networks. The portability of any such ETL process would need to be assessed across different EHR systems and clinical contexts to ensure broad applicability.

The ultimate trajectory for this work involves its translation into clinical practice through pilot deployments in contrasting care settings to evaluate operational fit and clinical impact. The high-quality, structured data captured during such a deployment would, in turn, serve as the ideal foundation for developing and validating predictive models. This final step would aim to create models for the early identification of infection risk or healing stagnation, transforming the dashboard from a descriptive tool into a predictive one and enhancing its value for clinical decision support.

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Annexes

10. Annexes

10.1 IJUP 2025

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Background & Aim: The rapid expansion of digital health is changing healthcare, integrating clinical research and everyday practice. Real World Data (RWD) from Electronic Health Records (EHRs) is crucial for generating Real World Evidence (RWE) that informs clinical decision-making, improves treatment pathways and supports regulatory processes. Effective data management and visualisation improve care quality improving outcomes. Chronic wounds, requires continuous monitoring and intervention. Tradional wounds assessment, remains inefficient and subjective. This study aims to develop and validate a scalable, data model for wound management, where data and visualization tools transform clinical outcomes and research. **Methods:** Standardized frameworks like Observational Medical Outcomes Partnership - Common Data Model (OMOP-CDM) and openEHR ensure interoperability, data quality and reproducibility. EHRbase supports openEHR standards. Wound management data points are identified to create specific wound management templates using OpenEHR archetypes, these form the basis for a data model in PostgreSQL. Data transformation processes are performed to prepare data for analysis and visualization. Lypto and SQLAlchemy are employed in the Extract, Transform, Load processes to facilitate data harmonization with the OMOP-CDM. This allows the integration of distinct sets of clinical characteristics -phenotypes, which can ultimately support automated, precise identification of patient conditions and outcomes. **Results:** Data visualization enhances this model. Integrating RWD with Apache Superset, delivers a wide dashboard for health practitioners to assess wound progression, trends, and make informed interventions based on real-time data, improving accessibility to data insights and phenotypes, supporting clinical awareness and decision-making. **Conclusions:** This study integrates standardized data models with real-world wound care data to enhance clinical information and foster better decision-making in wound care.

Keywords: OMOP-CDM; Data-Visualization; Wound-Management; RWD; EHRs

Sample Annex 1

Exploring Data Models: *Use Of Real-World Data and OMOP Standards for the Development of a Wound Management Dashboard*

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Introduction

The rapid expansion of **digital health** technologies has significantly **reshaped healthcare** delivery and **research**. Real World Data (RWD) from Electronic Health Records (EHRs) has emerged as a cornerstone in bridging the gap between clinical trials and everyday medical practice. Harnessing RWD to generate Real World Evidence (RWE) has the potential to inform clinical decision-making, improve treatment pathways, and support regulatory processes. This improvement emphasizes the importance of effective **data management** and **visualization** in improving care quality.

In wound management, characterized by chronic, complex conditions that demand continuous monitoring, the integration of **advanced data models** and visualization tools **can transform clinical outcomes**. Accurate wound assessment is essential for effective clinical management and outcome monitoring; however, RWD frequently suffer from incomplete or inaccurate documentation, variable collection methodologies and standards, subjective interpretation, which compromise consistency, efficiency, and the validity of secondary use for research and decision-making. Thus, implementing standardized frameworks, such as the **Observational Medical Outcomes Partnership Common Data Model** (**OMOP-CDM**) and **openEHR**, becomes important to ensure **interoperability**, **data quality**, and **reproducibility** of **research findings**.

Methodology

We use **EHRbase** as a repository which is built to support **openEHR standards**. Relevant data points within the wound management domain are identified to create specific wound management templates using **openEHR archetypes**. These templates serve as the basis for developing a comprehensive **data model** implemented in **PostgreSQL**.

Data transformation processes are then performed to prepare the data for **analysis** and **visualisation**. Tools such as **Lypto** and **SQLAlchemy** are employed in the **Extract**, **Transform**, **Load (ETL)** processes to facilitate **data harmonisation** with the **OMOP-CDM**. This harmonisation allows the incorporation of computable distinct sets of **clinical characteristics**, **phenotypes**, which can ultimately support automated, precise identification of **patient conditions** and **outcomes**.

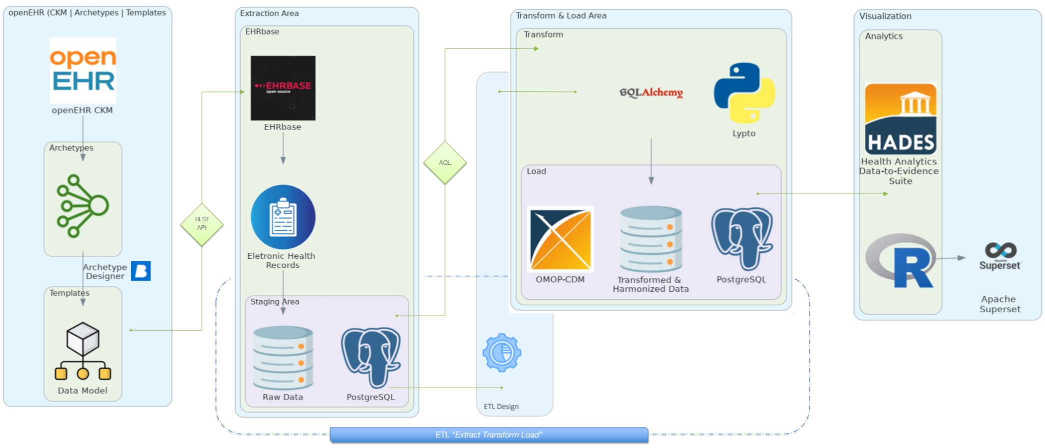
Data visualisation further enhances the practical utility of this model. By integrating RWD with **Apache Superset**, this project delivers a broad **dashboard** that will enable healthcare professionals to quickly assess wound **progression**, identify **trends**, and make informed interventions based on **real-time data**. This will improve **accessibility** to data insights and serves as a platform for **visualising phenotypes** and **endpoints**, supporting **clinical awareness** and **decision-making**.

Aim

In recognition of the growing need for high-quality data structures and real-time analytics in the management of chronic, complex wounds, this study sets forth the following objectives:

- ***Develop*** *and* ***validate*** *a scalable data model for wound management;*
- ***Transform*** *clinical outcomes and advance medical research through the integration of data and visualization tools*
- ***Create*** *a* ***real-time dashboard*** *with customizable filters and interactive drill-down charts that display clinical data over time and support informed decision-making*

Results



Conclusion

This study integrates **standardised data models** with **real-world wound care data** to enhance clinical information and foster **better decision-making in wound care**. Despite these advances, challenges persist around data quality, heterogeneity, and privacy. Attending these through **harmonised** methodologies, **governance** frameworks, and **reproducible** reporting practices will be essential to fully realise the potential of RWD and RWE in chronic wound management.

References

Organização

Apoio

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10.2 Synthetic Data Generator

Although not the focus of this project, we felt the need to develop a Python script to generate synthetic clinical trajectories of wounds that were close to clinical reality. In health research contexts, there is often a scarcity or difficulty in accessing real patient data due to privacy and logistical issues. The generation of synthetic data thus emerges as an alternative to circumvent confidentiality restrictions and allow for simulations close to reality [74,75] and, in our particular case, to populate our data model and create a dataset capable of being represented on the dashboard, simulating wound evolution and treatment journeys.

In terms of structure and plan, we proceeded from the creation of patient profiles to expected outcomes, including demographic attributes and wound assessments.

For each trajectory, the generator creates an initial patient profile with demographic data and comorbidities. Values are sampled randomly, but informed by realistic distributions and clinical literature, such as the higher probability of hypertension in elderly patients and the link between obesity and high body mass index. These relationships reflect the evidence that chronic wounds often affect patients with comorbidities such as *diabetes mellitus*, vascular deficits, hypertension, or chronic kidney disease, which can delay normal healing [76]. By incorporating these risk factors, we ensure that the generated clinical trajectory begins with credible premises.

The script implements explicit clinical correlations to imitate real interdependencies, such as the relationship between diabetes, high HbA1c, and slow wound healing, or advanced age and wound chronicity. Dynamic wound parameters, such as pH and bacteriological results, are generated conditionally on the underlying clinical state. This "medical rules system" lends clinical plausibility to the simulations. Each wound trajectory includes 3 to 150 evaluations, with stochastic time intervals based on real protocols. The system distinguishes between conventional and special therapies, optimizing the frequency of evaluations. Currently, 93% of intervals follow a 3 or 5 day pattern. For Negative Pressure Wound Therapy (NPWT), the preferred intervals are 5 to 7 days. These rules created a simulated average duration with a mode of 5 days, aligning with clinical practice. The script generates realistic schedules for each patient, from the beginning to the end of the case. The end of each synthetic trajectory is determined by a wound outcome, probabilistically defined by patient parameters and wound type. We introduced specific clinical exceptions and made the number of generated evaluations dependent on the outcome: chronic wounds generate more evaluations and can exceed 1 year, and wounds healed early, fewer. This ensures that the simulated duration of each case corresponds to the outcome.

Finally, the synthetic data is organized into a consistent tabular format, generating records with date, status, measurements (dimension, pH, exudate, infection…), interventions, and results. In this way, we were able to model complete clinical wound trajectories that incorporate multiple levels of realism, from the patient's epidemiological profile to laboratory details, within a synthetic data structure. It is important to emphasize that the generated data served only the purpose of finding some balance and realism for testing, and the generator was not the focus of this dissertation.

To deadlines,

and those who (almost) made me miss them

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