Original Paper

Fast Healthcare Interoperability Resources and Observational Medical Outcomes Partnership Integration for Health Data Interoperability in Belgium: Mixed Methods Study

Najat Lechhab[1,2], MEng; Najib Al Idrissi[1,3], MD, PhD

[1]MedPerOne Laboratory, School of Medicine, Mohammed VI University of Sciences and Health (UM6SS), Casablanca, Morocco
[2]Department of Computational Medicine and Neuropsychiatry, Faculty of Medicine, University of Mons, Mons, Belgium
[3]Mohammed VI Center for Research and Innovation, Rabat, Morocco

Corresponding Author:

Najat Lechhab, MEng
MedPerOne Laboratory, School of Medicine
Mohammed VI University of Sciences and Health (UM6SS)
Boulevard Mohammed Taieb Naciri, Commune Hay Hassani, BP 82403 Casa Oum Rabii
Casablanca 20000
Morocco
Phone: +212 616 848 030
Email: nlechhab@um6ss.ma

Abstract

Background: Managing health information is one of the greatest challenges in modern health care. In Belgium, decentralization and fragmentation further complicate interoperability. Primary data, collected through electronic health records, and secondary data, used for research and policy, require distinct approaches. Fast Healthcare Interoperability Resources (FHIR) enables real-time clinical data exchange, while the Observational Medical Outcomes Partnership (OMOP) model standardizes heterogeneous datasets for large-scale analysis.

Objective: The goal of this study was to assess the strengths, weaknesses, and feasibility of using FHIR and OMOP together in the context of Belgian health care to identify barriers and opportunities for their combined use.

Methods: To answer the research questions, a mixed methods approach was used (using both qualitative and quantitative methods). This included an analysis of FHIR and OMOP technical documentation and technical literature as well as semistructured interviews with 8 research experts drawn from 3 professional backgrounds, including health data governance, clinical practice, and biomedical research.

Results: Findings show that primary data use is facilitated by FHIR by improved electronic health record interoperability, public health surveillance, and clinical decision support. However, adoption is hindered by constant updates, economic constraints, and fragmented regulation. OMOP demonstrates great potential for secondary data, facilitating harmonized epidemiological studies, pharmacovigilance, and global collaboration. Integration with legacy systems, high costs, and low granularity are major obstacles. Experts identified clinicians as essential for ensuring data quality and highlighted their importance in preventing administrative burden and encouraging uptake by training and designing user-friendly tools.

Conclusions: FHIR and OMOP complement one another in addressing disparate but connected sides of the reuse of health information. Both together can enhance interoperability, streamline clinical workflows, and expand the ability to perform research. Achieving this requires targeted investment, regulatory alignment, and clinician engagement, placing Belgium at the forefront of digital health innovation in Europe.

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Keywords: health data management; health information; interoperability; Fast Healthcare Interoperability Resources; FHIR; Observational Medical Outcomes Partnership; OMOP; electronic health records

Introduction

Background

Health data management is one of the greatest challenges in modern health care and is mainly due to interoperability challenges that inhibit the optimal and equitable use of data. Interoperability is the ability of systems to exchange, interpret, and make use of data correctly; yet, primary and secondary uses of health data pose different demands on the data. The primary use of health data is direct patient care, supported by electronic health records (EHRs), which facilitate continuity of care, foster collaboration among health care providers, and provide timely and reliable access to information. Secondary uses, including clinical research, public health, and policy making, take clinical data and create a format for analysis at the population level. This creates difficulties for those involved in developing, standardizing, and reusing health data.

Certain standards have been created to assist in resolving these challenges. Health Level Seven International's (HL7's) Fast Healthcare Interoperability Resources (FHIR) is used as a leading interoperability standard because of its flexibility and capability to facilitate real-time data exchange; however, FHIR does not adequately cover the requirements of secondary data use; therefore, other models need to complement FHIR. One such model is the Observational Medical Outcomes Partnership (OMOP), which defines a standardized format for health data that is intended for research and large-scale analysis. Together, FHIR and OMOP provide complementary yet distinct approaches to managing health data for both clinical and analytic purposes.

Belgium's complex and decentralized health care system has been shaped by numerous concurrent, albeit not necessarily interoperable, databases and digital tools in relation to both the primary and secondary use of data. In this paper, we will investigate how the combined use of FHIR as a means of sharing primary data, coupled with OMOP as a means of sharing secondary data, can strengthen both data management and interoperability in Belgium. This study uses a mixed methods approach, using both technical document analysis of FHIR and OMOP and human interviews with experts in the e-health sector in Belgium to identify features, opportunities, and challenges associated with the implementation of the 2 models in Belgium and to propose recommendations for successful implementation.

Presentation on FHIR and OMOP

FHIR

Definition and General Framework

FHIR is a standard, created by HL7, for the exchange of health information between systems. FHIR was built on internet standards using web technologies such as the RESTful (Representational State Transfer) architecture, which allows for flexibility and integration with existing health information technology systems. FHIR specifies a structured way to organize health information into discrete elements (resources), such as patient information, observational information, and medication information, and allows for easy exchange of this information between disparate health systems using standard HTTP-based methods (GET, POST, PUT, and DELETE) [1,2].

The primary advantage of FHIR is its use of modular and standardized information structures, meaning that, while each resource is a stand-alone entity, each resource can be linked to one another. This creates a framework for making complex clinical data available while remaining simple in nature. For example, the "Patient" resource may have links to the "Condition" and "Medication" resources and provide a complete view of all clinical data relevant to that specific patient. Because FHIR follows the international standard for providing consistent formats and terminology across all health care systems, it facilitates interoperability [3,4].

CareSets are a Belgian implementation construct built upon FHIR and are not part of the international FHIR standard itself. They refer to groups of logical FHIR resources organized around a specific clinical process or workflow. In Belgium, CareSets have been developed to arrange sets of data to support specific medical situations, including vaccination guidelines, hospital discharge, and chronic disease management. For instance, a Vaccination CareSet groups related FHIR resources such as "Immunization," "Patient," and "Observation" into a coherent structure. This organization simplifies data management and promotes care coordination through the standardized representation of all activities related to a given process [5,6].

Primary Use in Health Care Systems

The main goal of FHIR is to enhance the management of electronic medical records (EMRs) by providing tools for communicating directly with clinical systems. The following examples illustrate the main ways in which FHIR supports health care delivery.

There are several types of tools that FHIR supports throughout the health care system:

- Integration of EMRs: FHIR is a technology that allows all hospitals, clinics, and other types of health care facilities to share EMR data of a patient without duplicating any of the patient's EMR data or many of the systems' functions. For example, a patient's EMR can be collected by their current health care provider once the patient has transferred to another health care provider, making the process of obtaining that patient's entire EMR, including a list of prior diagnoses and the treatment plan, very easy, which reduces the need for unnecessary and potentially harmful tests while enabling a more effective transition between health care providers. There are currently several pilot programs in Belgium using FHIR to improve how health care systems are integrated (eg, Réseau Santé Wallon and Abrumet in Brussels) [7, 8].
- Clinical decision support: The use of FHIR allows vendors to create common data model (CDM) tools for health care professionals to obtain current and accurate information during decision-making processes

related to their patients receiving care. Some of these tools enable alerts related to potential drug interactions, allowing providers to more appropriately prescribe and/or administer pharmaceutical products. CDM tools based on FHIR will also provide evidence-based therapy recommendations as well as advise providers of abnormal results from laboratory testing [9,10].

- Mobile and web applications: The use of modern web technologies in combination with FHIR makes it possible for software developers to build intuitive applications that can be used by both health care providers and patients. These applications enable patients to have control over their health data, schedule appointments, and quickly access their health history. On the provider side, FHIR-enabled mobile apps reduce the time and effort required to access patient records at the point of care [11,12].
- Interoperability in public health: The FHIR specification enables the centralized collection and real-time analysis of public health information. For example, during public health emergencies such as pandemics or disease outbreaks, FHIR facilitates the rapid computation of key metrics, such as infection rates and vaccine coverage, and the reporting of these measurements to government health agencies. The availability of such information allows public health professionals to make timely decisions based on the data and to use it to target and allocate resources to reduce risk [13,14].
- Workflows implemented through CareSet: A CareSet contains all the care activities related to a particular patient, grouped together in structured collections of FHIR resources. For example, a care set of a patient being discharged from a hospital, which could include a discharge summary, a care plan, and a medication request. Organizing the patient's information this way allows clinicians and caregivers to easily find all relevant information about the patient in one location, helping them transition smoothly between various health care environments [6,15,16].

In Belgium, during the implementation of the FHIR standard, there were ongoing pilots and the use of the CareSet model, which allowed for better coordination of care as patients transitioned out of hospitals. This approach aimed to provide all involved providers with timely and standardized access to patient data across care settings.

In Belgium, the adoption and use of the FHIR standard are developing, and the level of implementation is regional and institution-specific. While some systems have already begun to leverage FHIR, others are still evaluating FHIR use cases.

Multiple projects have been launched to help bring Belgium into alignment with European standards and to further the use of FHIR to support cooperation among EU member states when delivering health care across borders, such as MyHealth@EU, a European initiative that will make it possible for member states to exchange their citizens' health data across borders [17,18].

Strengths of FHIR

FHIR offers several key advantages that enhance interoperability, streamline health data exchange, and support the efficient integration of health care information systems. Its major strengths are outlined as follows:

1. FHIR is itself an HL7 standard, which ensures its compatibility with numerous health care systems and facilitates data exchange between them, thereby reducing interoperability barriers [19].
2. The modular resource structure of FHIR allows for many different types of data to be used in many different types of use cases (eg, patient records and clinical trials) and can be altered as health care continues to change [20].
3. Because FHIR is built using common web technologies, there are fewer technical barriers for developers and health care organizations when implementing it. A user-friendly interface enables faster and less expensive integration with existing systems [21].
4. By using RESTful principles, FHIR allows for real-time sharing of data necessary for timely medical decisions, such as emergencies or surgeries [22].
5. FHIR is currently being adopted globally by many of the largest health care systems and organizations to improve their data management capabilities. This establishes a global standard that enables international collaboration in the provision of health care [16,23].

Limitations in the Belgian Context

Belgium's health care system has several strengths that can help make FHIR work for us. However, there are still some challenges that must be overcome to implement FHIR in Belgium:

1. Fragmentation of health care data**:** The health care system in Belgium is highly decentralized and, therefore, fragmented across many different providers and regions. This makes it difficult to develop a single FHIR-based infrastructure that will work for all [7].
2. Privacy issues: The sharing of sensitive patient information raises numerous concerns with regard to compliance with the General Data Protection Regulation (GDPR) and any other privacy laws. As a result, ensuring secure data exchange and storage must continue to be a top priority [9].
3. Resource limitations: Smaller health care providers may not have the financial or technical resources to adopt and sustain FHIR-based systems. As a result, there are inequities in access to modern ways of managing data [8].
4. Adoption of standards: While, globally, FHIR is gaining momentum among many organizations for using FHIR-based systems, a number of Belgium-based stakeholders might still rely upon using legacy standards such as HL7 v2 or Clinical Document Architecture, which creates gaps where they cannot interoperate with each other and, therefore, this slows down widespread implementation across Belgium [10].

5. Knowledge and skillsets: The successful use of FHIR will be directly related to the skills and knowledge of individuals who implement and use FHIR-based systems to their fullest potential. A shortage of these individuals would likely impede the adoption of FHIR-based solutions [12].

By addressing these areas of limitations, Belgium can maximize FHIR's potential to achieve greater improved interoperability of health data and improved health care outcomes for Belgian patients.

OMOP

Definition and General Framework of OMOP

The OMOP initiative provides a common framework for collecting and storing health care or medical-scientific data that may come from multiple different sources. The main purpose of the OMOP model is to provide a framework for systematically using datasets that are generated by the health care system in research and epidemiology as well as pharmacoepidemiology. A key component of the OMOP model is the CDM, which has been designed as a relational data structure organized into standardized tables, so that they are able to capture the most common and central elements of health care and medical-scientific information, without claiming to be exhaustive.

The CDM is designed to allow for the creation of a standardized and integrated data model that bridges the gaps between heterogeneous and dispersed databases to permit multicenter studies and facilitate international collaboration. The CDM includes 5 domains:

- The person domain contains demographic information (eg, age and gender) and pseudonymous identifying information for patients.
- The medical condition domain contains information about medical conditions and diagnoses.
- The medication domain contains information about how medications have been prescribed, their dosages, and medication histories.
- The clinical results domain contains information about laboratory tests and biological samples, as well as the behaviors and clinical observations that occurred during the study.

The CDM, adopted in Belgium, is designed to help health care providers in Belgium link local source datasets to EU-level data standards such as European Health Data and Evidence Network (EHDEN) and European Medicines Agency regulations. This will help all health care providers fulfill their evolving requirements as well as comply with the GDPR [23,24].

Secondary Use in Health Care Systems

OMOP represents an innovative solution for exploiting health care data for secondary purposes, maximizing its potential for large-scale analyses and strategic studies. The following examples illustrate its application in Belgium:

- National epidemiological studies: OMOP is a central lever for epidemiological studies in Belgium. For example, Sciensano, the national public health institute, uses the model to monitor chronic diseases such as diabetes and cardiovascular disease. Thanks to OMOP's ability to integrate and harmonize data from a variety of sources, Sciensano can identify regional disparities and monitor epidemiological trends over the long term. This information makes it possible to design more targeted public health interventions tailored to the specific needs of Belgian populations [25].

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- Pharmacovigilance: One of the most notable uses of OMOP is in the field of pharmacovigilance. The Federal Agency for Medicines and Health Products uses the model to quickly identify the side effects of medicines, including those that are rare or serious. For example, OMOP facilitates the analysis of cohorts of patients exposed to recent treatments, making it possible to adjust prescription recommendations and improve patient safety [26].

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- European multicenter research: Thanks to OMOP, Belgian researchers are actively involved in collaborative European projects such as Observational Health Data Sciences and Informatics (OHDSI) and EHDEN. These initiatives make it possible to compare medical practices and clinical results between different countries using standardized data. For example, a recent multicenter study assessed the efficacy of COVID-19 vaccines across several European databases, including those standardized via OMOP [27].

Key Strengths

OMOP offers significant advantages, including the following:

- Rigorous standardization of data: OMOP ensures that Belgian data are aligned with international standards such as SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms) for diagnostics, LOINC (Logical Observation Identifiers Names and Codes) for laboratory data, and Anatomical Therapeutic Chemical for drugs. This standardization not only facilitates multicenter comparisons but also the integration of Belgian data into strategic international studies [28].

- Compatibility with advanced analytical tools

Data standardized in OMOP can be analyzed using tools such as ATLAS, which offer advanced functionalities for data visualization, cohort creation, and predictive analysis. This compatibility with cutting-edge technologies strengthens the ability of Belgian researchers to produce relevant and exploitable results [29,30].

- Facilitating European interoperability: OMOP positions Belgium as a key player in European initiatives to harmonize health care systems. By facilitating cross-border collaboration, OMOP enables a better understanding of common challenges in public health and contributes to the development of coordinated policies at the European level [31].

Weak Points

OMOP has a number of built-in limitations as a data model, despite the following merits:

- Reliance on data quality: The analytical use of OMOP lies in the quality of its source data. The data from Belgian hospitals have many instances of coding errors and incomplete datasets, which result in the analyses generated from them having a lower level of reliability; as such, they will require a large amount of data preparation before they can be consolidated.

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- Lack of granularity: OMOP contains some of the most common and perhaps all of the essential pieces of clinical information, but it does not pretend to be exhaustive. Thus, advanced or specialized research may be difficult because certain very specific elements of clinical data are unavailable in a standardized format.

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Implementation Challenges

Other areas of concern regarding the adoption of OMOP in Belgium include the following:

- Costs and technical complexity: Implementing OMOP requires substantial financial investment in technical infrastructure and personnel training, which many smaller institutions might struggle to sustain, leading to disparities in implementation across the institutions [30].

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- Fragmentation of regional systems: The Belgian health care system is organized along 3 regions (Wallonia, Flanders, and Brussels) and each region has its own information systems; therefore, it becomes difficult to incorporate data into a common data structure such as OMOP, which necessitates a large amount of coordination effort to complete [32].

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- Compliance with the GDPR: GDPR contains strict requirements on how to collect, anonymize, and then share personal information. Therefore, adherence to this regulation imposes an additional cost on implementing OMOP [33].

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Methods

Documentary Sources

In this section, the key technical references used to review the FHIR and OMOP models are identified. The primary references used to define FHIR are the official HL7 FHIR standard documentation [11], the HL7 Belgium FHIR implementations guide [1], and the Belgian eHealth platform FHIR medication implementation guide [3]. The primary references for OMOP are the original OHDSI publications [23,28], EHDEN network documentation [25], and the Belgian e-health action plan 2022 to 2024 [24]. Each of the references selected has either a direct or indirect relationship to Belgium and provides authoritative sources by which both models can be defined, both theoretically and practically [23].

Description of the Technical Documents Used for FHIR and OMOP

The analysis draws upon a broad range of sources, from technical guides and official specifications to scientific publications and project commentary, providing a glimpse into the inner workings and daily applications of FHIR and OMOP.

FHIR sources are primarily drawn from HL7 International, the leading organization in health information standards. Of particular relevance are the FHIR R4 specification and its subsequent updates, along with implementation tools, such as Firely (Firely BV) and HAPI-FHIR (University Health Network) that support practical deployment. OMOP sources are primarily provided by the OHDSI community, including extensive documentation of the CDM and examples from European initiatives such as EHDEN. These documentary

sources are further supported by peer-reviewed scientific literature and relevant conference proceedings.

These materials define the structural logic of both models: tables in OMOP and resources in FHIR. They highlight integration principles, including extract, transform, load processes for OMOP and APIs for FHIR. Comparative studies are valuable because they evaluate the performance, scalability, and compatibility of both models. Concrete use cases, such as hospital data-sharing programs and multicenter research platforms, support the analysis [34].

Justification for the Choice of These Sources

The documents selected meet rigorous criteria that guarantee the quality and relevance of the information used. First and foremost, their credibility and reliability are key factors. Specifications, such as those published by HL7 for FHIR or by OHDSI for OMOP, provide accurate and comprehensive data and have become essential references in their respective fields.

Second, publications and reports from actual projects, such as those developed as part of EHDEN or pilot initiatives in Belgium, provide a particularly valuable practical perspective. These examples make it possible to assess the extent to which these standards can be applied in specific contexts, particularly within European health care systems. Finally, these sources are perfectly aligned with the objectives of the study. The implementation guides and practical examples analyzed help to illustrate how the FHIR and OMOP models address the complex challenges associated with the interoperability and integration of health data. This approach ensures the comprehensive coverage of both theoretical and practical aspects while providing a robust analysis that is applicable to health care systems such as those used in Belgium.

Interviews With Experts

To understand the opportunities and challenges in adopting FHIR and OMOP standards in Belgium, semistructured interviews were conducted with 8 experts drawn from 3 professional backgrounds: clinical practice (4 clinicians from ZAS, CSCT, and Helora), health data governance (2 governance professionals from RIZIV-INAMI [Rijksinstituut voor ziekte-en invaliditeitsverzekering—National Institute for Health and Disability Insurance]), and biomedical research (2 researchers from Université de Hasselt). A formal questionnaire was designed on 3 topics: interoperability, adoption challenges, and practical use cases. Interoperability probed experts' perceptions regarding deficits in health care IT systems and how FHIR and OMOP address them. Adoption challenges covered technical, organizational, and regulatory problems, while use cases evidenced tangible benefits (eg, improved clinical outcomes and value for money).

Questions were phrased to elicit rich, qualitative feedback, eg, including expert opinions about the interoperability issues in the Belgian system, barriers to using FHIR or OMOP, and examples of potential practice improvement opportunities. Experts were selected with care based on their knowledge of IT, clinical practice, and health care governance to provide varied perspectives on technical integration, workflow impact, and regulatory and financial considerations. Each participant is an experienced professional in their respective field, and they all have substantial practical work experience within the Belgian health care system. Before conducting the interviews, the researchers confirmed that all the participants had at least some familiarity with FHIR and OMOP; therefore, the participants' responses were grounded in evidence and their own experience rather than only theoretical assumptions.

Given Belgium's fragmented and multilingual health care system, local knowledge was critical. Semistructured interviews lasting between 45 and 90 minutes allowed a focus on the most significant themes while ensuring confidentiality and transparency.

Data were analyzed manually using thematic analysis, given the limited sample of 8 experts. Interview responses were read carefully and coded by the lead researcher to identify recurring patterns across the 3 topics of interoperability, adoption challenges, and practical use cases. Codes were then grouped into broader themes through comparison across responses. Findings were reviewed and discussed with the coauthor to ensure the consistency of interpretation. The thematic findings were also cross-validated against the documentary sources analyzed in the preceding section. The full interview guide is available in Multimedia Appendix 1.

Ethical Considerations

Formal ethical approval from an institutional review board or ethics committee was not required for this research. The study is noninterventional in nature and is based on semistructured interviews with professionals whose expertise is relevant to the field under study. No patient or sensitive personal data were collected. Participants were selected on the basis of their professional experience, and no vulnerable populations were involved. In accordance with Moroccan Law number 28-13 on the Protection of Persons Participating in Biomedical Research, noninterventional and observational research studies are explicitly exempt from the provisions of this law and do not require ethics committee approval [35].

Informed consent was obtained from all participants via email correspondence before the interviews commenced. All participants were contacted by email to confirm their willingness to participate and their agreement to have their responses used for research and publication purposes. Written records of this consent are retained by the corresponding author and are available upon request. Participant names have been removed from the paper to protect their privacy.

All data collected during the interviews were handled in strict confidence. Responses were anonymized during the thematic analysis process and no personally identifiable information appeared in the paper. Data were stored securely and were accessed only by the research team.

No financial compensation or any other form of incentive was provided to participants for their involvement in this study.

Results

Overview of Expert Interview Findings

The interviews, using a thematic analysis, reported that data integration and a lack of standardized practices were the highest ranked areas of concern around interoperability. Budget constraints were the most commonly reported impediments to the adoption of FHIR and OMOP, followed very closely by resistance to change. In terms of practical use cases, experts primarily see a country-wide longitudinal follow-up of patients with chronic diseases as a tangible use case for both FHIR and OMOP.

Summary of Feedback on FHIR

The experts shared some enlightening perspectives on the strengths and limitations of FHIR for primary data management.

All of the participants in this study agreed that FHIR's adaptability and scalability make it an ideal fit for health care IT ecosystems, and highlighted that FHIR's modular approach provides hospitals with the ability to build on top of existing hospital information systems and to be compatible with other systems worldwide. The participants were adamant that whatever methods are used to implement an application will depend on the specific workflows in Belgium.

Experts identified many challenges that will hinder the adoption of FHIR in Belgium. Initially, the lack of a coherent national framework, with variations between regions, was identified as one of the first obstacles put forth by experts as it is difficult to conduct standardization activities in the absence of a national framework. Experts also cited technical and operational constraints specifically regarding the rapid release of FHIR version updates, which require institutions to continually invest in system reconfiguration and personnel training. These requirements were perceived to be a major burden on smaller health care organizations that lack the technical expertise to do so. Finally, experts noted that financial constraints and limited budgets create significant challenges for many hospitals adopting FHIR, as they may not be able to afford the expenditures necessary to implement FHIR, such as upgrading infrastructure or licensing proprietary tools.

In order to maximize the benefits of the FHIR standard, it was suggested that experts identify use cases specific to Belgium. Cancer registries have been identified as potential beneficiaries of the standardized and simplified processes involved in data aggregation. Experts also highlighted rare diseases as an area where FHIR could offer a great opportunity to create a solid foundation of support through appropriate data harmonization for diagnosing individuals and following up on their conditions. Additionally, it was mentioned that FHIR would allow for effective interhospital cooperation among institutions to address this important issue within Belgium's regionally-operated health care system.

Summary of Feedback on OMOP

Experts had mixed excitement and concern regarding the use of OMOP for secondary data in research. All agreed that OMOP was a strong tool for creating standardized digital records from a range of disparate datasets for large-scale research projects and multicentered studies within Belgium. Experts noted that OMOP established a standardized data structure across all institutions, providing a common basis of reference for standardized comparative analysis and analysis at a national level. However, experts also pointed to the weaknesses of OMOP, particularly in relation to gathering clinical details at a granular level of precision. All feel that this could pose a significant impediment to studies requiring very finely leveled data for their analyses.

The integration of OMOP, experts agreed, is limited by practical barriers experienced by Belgium's health institutions. One expert said that many hospitals still use legacy data exchange standards that make the implementation of OMOP much more complicated. They also said that the fragmented Belgian health system makes OMOP implementation difficult because each institution uses its own approach, thereby rendering overall interoperability and implementation of the concept effectively impossible. A lack of national frameworks was cited as a significant impediment to realizing the full capabilities of OMOP.

Moving forward, experts were keen to highlight how much of this will require all of us to work collaboratively. Furthermore, they believe that providing educational training programs can help develop an understanding of OMOP and its advantages among health care professionals as well as equipping them with the necessary tools to overcome any obstacles they face with OMOP. In addition, developing collaboration among hospitals to share best practices through resource sharing will be critical in supporting the implementation process of OMOP. To provide tangible assistance for wider use and broader implementation of OMOP in Belgium's health care system, financial incentives and targeted pilot projects were also proposed.

FHIR vs OMOP Comparison

Experts carried out an evaluation of FHIR and OMOP models through comparative analysis during the interviews and outlined each model's strengths and limitations regarding health care data accessibility in Belgium. While the primary reason for developing each of these models is unique, both the FHIR and OMOP models offer different capabilities for supporting the interoperability and management of health care data in Belgium (Tables 1 and 2).

Table 1. Benefits of Fast Healthcare Interoperability Resources (FHIR) and Observational Medical Outcomes Partnership (OMOP) implementation.

Benefit	Description	Source
Improved interoperability and data exchange	FHIR enables real-time data exchange between clinical systems, facilitating communication between hospitals and other health care institutions.	Expert interviews
Primary data management	FHIR provides a robust standard for structuring primary data in electronic health records, making it easier to capture and exchange information.	Expert interviews
Standardization of secondary data	OMOP offers a standardized framework for transforming disparate clinical data, supporting research and comparative analyses.	Expert interviews
Improving research and epidemiology	OMOP enables efficient aggregation of data from multiple institutions, ensuring consistency and quality for research and epidemiological studies.	Expert interviews
Specific use cases	FHIR can standardize and simplify data aggregation for cancer registries and rare disease management. Interhospital collaboration is also improved by FHIR.	Expert interviews
Complementarity between FHIR and OMOP	FHIR facilitates real-time clinical data exchange, while OMOP enables in-depth analysis for research purposes, making the 2 models complementary.	Expert interviews
Potential for transforming the health care system	The joint adoption of FHIR and OMOP can improve quality of care, process efficiency, and decision-making in Belgium.	Expert interviews

Table 2. Criticalities of Fast Healthcare Interoperability Resources (FHIR) and Observational Medical Outcomes Partnership (OMOP) implementation.

Criticality	Description	Source
Regulatory obstacles	The lack of a coherent national framework and the fragmentation of regional regulations complicate standardization efforts.	Expert interviews
Financial limitations	The costs of integrating FHIR and OMOP, including infrastructure upgrades and licenses, may exceed available budgets, particularly for hospitals with limited IT resources.	Expert interviews
Complexity of integration with existing systems	Many hospitals still use earlier data exchange standards, which complicates OMOP integration. The heterogeneity of systems in Belgium is a major obstacle to interoperability.	Expert interviews
Lack of granularity in OMOP	OMOP can lack precision in capturing specific clinical details, which may limit advanced research.	Expert interviews
Need for technical expertise	Smaller health care institutions often lack the technical expertise needed to deploy and maintain FHIR- and OMOP-based solutions.	Expert interviews
Need for training and awareness	Health care professionals need training on the benefits of FHIR and OMOP to ensure data quality and minimize administrative burden.	Expert interviews
Technical and operational constraints	Rapid updates to FHIR require considerable effort to reconfigure systems and retrain staff. The diversity of systems in Belgium and limited technical expertise are additional obstacles.	Expert interviews

According to expert definitions, FHIR is a reference standard for primary data management due to its flexibility and modular design. Experts argue that the adoption of FHIR on a global scale is one of the most significant elements supporting interoperability between systems. They believe that it would be a good fit for use in existing ecosystems such as hospital information systems in Belgium with regard to its integration capabilities. Experts pointed out the need to revise existing data exchange practices to meet both national and international connectivity requirements. Experts also cited a number of challenges associated with implementing FHIR in practice, including the pace of version releases, technological/financial limitations, and the need for Belgian workflow adaptations.

OMOP was considered by experts as being the best oriented for secondary data management and analysis in terms of research. They say it gives you an equal base or standardized way to get a consistent way to change different types of clinical data into an equal product that can be compared with one another or used for comparative studies and epidemiology. The experts highlighted how OMOP has impacted several types of projects, such as rare disease studies and cancer registries. However, the experts also indicated that it is still very difficult to integrate OMOP into existing systems due to technical difficulties and the need for professionals to implement and support it.

Although FHIR and OMOP had different goals, experts agreed that they were complementary. FHIR was viewed as supporting real-time exchange of clinical information; meanwhile, OMOP provided a mechanism for extensive analysis of data and for the addition of data for research. Experts indicated that implementing both systems would meet immediate interoperability requirements as well as support evidence-based decision-making.

The successful realization of this complementary potential will require a coordinated approach that takes into account the needs of all interest groups. Three key priorities to be addressed are developing IT infrastructure, developing health care professionals' capabilities, and developing harmonized regulatory frameworks. The experts indicated that a highly collaborative approach, which would support the full intersection of FHIR and OMOP, would enable a more integrated and efficient health system in Belgium.

Impact on the Belgian Health Care System

The amalgamation of FHIR and OMOP is perceived by experts to offer fundamental benefits for modernizing health data management in Belgium. In particular, the FHIR standard enables primary clinical data (including EMRs) to be

structured, using a flexible, modular framework to facilitate real-time collection and secure transmission of health data from hospitals, health care providers, and various other entities involved in the provision of health services. Therefore, experts acknowledged that sharing standard prescriptions or laboratory results through an FHIR-based approach will provide a more reliable method for sharing these types of information.

The experts said that when FHIR is used with OMOP they support each other. Both OMOP and FHIR improve the way we can study people by making it easier to understand how similar they are to one another and how different they are in other ways. FHIR provides ways to collect and organize data, while OMOP creates a method to standardize or harmonize data and to analyze data on a large scale. The experts believe that, because of the ways in which FHIR and OMOP fit together, they may assist in the development of national cohort studies, collaborative European projects, and evidence-based decision-making.

The experts stressed that clinicians play a very important part in producing high-quality data for both the FHIR and OMOP systems. Accurate and uniform data entry is of utmost importance to both frameworks. Manual data entry tends to be error-prone and presents an administrative burden to clinicians when recording the same information multiple times. To reduce the frequency of these events and improve data quality in general, the experts recommended developing user-friendly data entry tools, using automated data capture systems, and creating targeted training programs.

According to experts, both model implementations go beyond simply technical reasons and involve redesigning clinical processes and workflows.

They suggested that the integration and interoperability of FHIR and OMOP could improve the Belgian health care system by strengthening the quality of care, research results, and operational efficiency while also preparing it for future innovation [36].

Discussion

Principal Findings

This study analyzed the strengths and weaknesses of both FHIR and OMOP within the context of the Belgian health care system. This was done mainly through documentary analysis (including the analysis of existing documents) and interviews with experts in the field. The main findings of the study are that FHIR is an ideal fit for the exchange of primary data due to its modular, interoperable architecture, while OMOP offers a solid foundation/platform for standardization of secondary data and large-scale research. However, each model has a number of barriers that will prevent implementation in Belgium. These include fragmentation of the regulatory environment across 3 regions, limited financial resources, and the need for further active engagement by clinicians. The subsequent sections will elaborate on how these results will impact Belgian digital health policies.

Analysis of Critical Results

This study's results demonstrate the complementary uses of FHIR and OMOP within the Belgian health care system. Expert interviews validate the theoretical advantages as outlined in the literature; however, there are other considerations in the application of these models to Belgium. Specifically, Belgium has fragmented governance across 3 regions that speak different languages and follow different administrative processes, which creates an overarching barrier to implementing either model. The most urgent priority is to bridge the technical gap between FHIR and OMOP with customized extract, transform, load processes and shared infrastructure. However, their complementary nature presents an opportunity for a fully integrated and ready-to-use Belgian health data ecosystem in the future.

The Role of Clinicians in Data Systems

EHR systems rely on clinicians to enter data and assure its quality. Clinicians' administrative workload has been consistently highlighted as one of the major barriers to entering data into EHR systems. This administrative burden reduces their engagement in the data entry process, thus reducing the reliability of the data, regardless of whether it is FHIR-structured or OMOP-standardized. Solutions need to be implemented that provide clinicians with the tools and resources to help them effectively capture and enter data into the EHR systems. Examples include automated data capture tools and intuitive data entry systems that help to minimize the burden on clinical workflows. Additionally, training programs educating clinicians on the tangible benefits of using FHIR and OMOP in clinical practice will go a long way toward securing clinician engagement in data entry and ultimately ensuring high-quality data over time.

Challenges Specific to the Belgian Context

This research identifies additional systemic barriers unique to Belgium by suggesting that the fragmentation of health care systems is not just due to different regulatory and organizational models. There are 3 separate health systems, with each having unique governance structures, which result in fragmentation beyond technical standards such as FHIR or OMOP and compliance with the GDPR, making it increasingly difficult to appropriately govern data anonymization, sharing, and reporting. Coordinated policy-based responses must be implemented at both regional and federal levels to address these issues, based on harmonizing technical standards, making targeted investments in digital health systems, and supporting regional implementation through public-private partnerships at scale.

Opportunities for the Future

The Belgian digital health ecosystem presents opportunities despite these challenges. As collaboration grows between research and technology, hospitals and research institutions indicate that there is a positive trend for interoperability. The combined adoption of FHIR and OMOP could accelerate the development of e-health initiatives in Belgium, particularly

in areas such as precision medicine and chronic disease management.

If the FHIR-OMOP model achieves its intended success in Belgium, the model could be replicated by other European Union countries that face the same issues of fragmentation as Belgium, helping to establish Belgium as a standard for national health data interoperability.

Limitations

This study has some limitations that must be taken into account. The first limitation is that the sample size of 8 experts is small and hence affects the generalizability of the findings of this qualitative expert consultation study. With a larger and more diverse sample of stakeholders comprising patients, policymakers, and system vendors, more comprehensive insights could have been gained into the barriers and opportunities associated with the use of FHIR and OMOP in Belgium.

The second limitation of the study lies within the geographical limitation of the study to Belgian health care context. Due to the specific nature of Belgian health care settings, the results may not be applicable in the health care settings in other countries, which have their own characteristics.

The third limitation of the research is that the interviews were conducted at one time. Considering the rapidly developing nature of digital health standards and technologies, some results may no longer be relevant, since the interviews were conducted.

Although measures were taken to ensure consistency in interpretation between the 2 authors, the results were primarily analyzed by the lead researcher, which may lead to subjectivity in the interpretation of the data.

Architecture Proposal for the Hub/Meta Hub System in Belgium

This section outlines where health data can be exchanged within a proposed architecture for Belgium that uses FHIR and OMOP as the core building blocks.

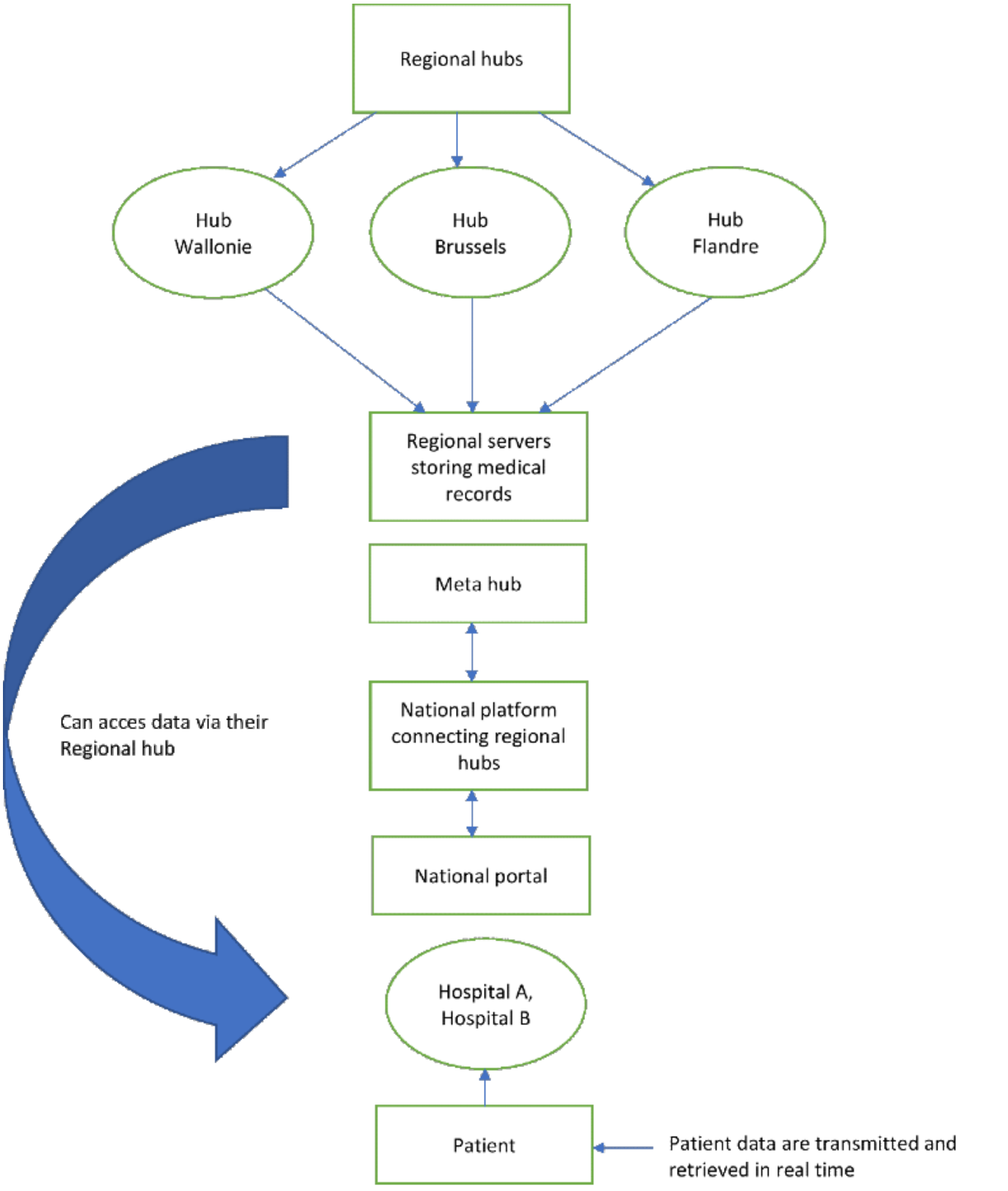
The infrastructure consists of 3 regional hubs in Belgium: Wallonia, Brussels, and Flanders. These regional hubs will function as data repositories for patients and will store individual medical records at the regional level. Within each hub, the real-time exchange of clinical data will occur using FHIR to enable hospitals and clinics to communicate standardized medical records, such as prescriptions, lab results, and EHRs.

Each of these regional hubs will connect via a centralized platform, known as the Meta Hub, which will act as a regional-to-national hub to enable interoperability and improve communication between regions. The Meta Hub uses FHIR-based interfaces that allow medical data to be shared across different regional hubs, thereby allowing for national integration of medical data. In addition, OMOP will be applied at the Meta Hub to standardize the clinical data from the regional repositories, allowing for these data to be transformed and harmonized into datasets suitable for secondary analyses, such as epidemiological research, pharmacovigilance, or national cohort studies.

Health care workers in Belgium can connect to a secure national digital patient portal by using the Meta Hub. The Meta Hub allows health care providers to easily access and obtain patient records in real time using modular (ie, FHIR) technology and a common language (ie, OMOP).

Using FHIR to define and provide an interface for national and regional access to clinical data allows for efficient electronic communication between health care professionals and hospitals. Storing patient clinical information as OMOP data within the Meta Hub provides valuable tools for epidemiological research and provides information to the public health community to monitor trends in population health. The combination of the Meta Hub and OMOP will continue to facilitate the development of research and analysis tools for Belgian health care, as shown in Figure 1.

Figure 1. Architecture of the system hub/meta hub in Belgium. Hubs: regional networks storing patient data; meta hub: national platform for interconnection; national portal: secure access interface for health care professionals; hospitals: local structures accessing data in real time.



Conclusion

This analysis highlights the immense potential of the FHIR and OMOP models to transform health care data management in Belgium. By building on their respective strengths, these technological frameworks can transform current health care systems into interoperable, dynamic, and efficiency-driven ecosystems. FHIR, by structuring the primary data of EHRs in a flexible and standardized way, meets the immediate needs for integration and communication between stakeholders. At the same time, OMOP offers a powerful platform for analyzing secondary data, enabling complex information to be exploited for clinical research, health care policy, and the evaluation of medical practices.

However, this transformation depends on the active involvement of clinicians. Their role goes beyond simply collecting data; they are the guarantors of its quality, relevance, and interpretation. For their contribution to be valued, it is imperative to provide them with user-friendly tools that are integrated into their existing workflows and to invest in training programs that reinforce their digital skills. This synergy between technology and clinical expertise is essential to maximize the benefits of the FHIR and OMOP models while minimizing the administrative burden. At a strategic level, Belgian decision-makers have a key role to play. The successful integration of these frameworks requires a systematic approach, supported by clear policies and adequate funding. Cross-sector collaboration, combined with strong governance, could accelerate this transition. For example, a simplified but rigorous regulatory framework should be established to harmonize efforts between the various players while respecting local specificities. The approach could begin with pilot projects in pioneering institutions, accompanied by feedback to adjust future deployments.

Adopting the FHIR and OMOP models also represents a unique opportunity to strengthen Belgium's competitiveness in the field of digital health. By positioning the country as a leader in interoperability and data management, it would be possible to attract more investment, encourage innovation, and lay the foundations for a resilient and sustainable health care system.

In the future, several lines of research could be explored. First, it would be valuable to assess how the FHIR and OMOP models can be combined to address complex use cases, such as precision medicine or chronic disease management. Second, a comparative study of international initiatives could provide valuable lessons for improving local practices. Finally, adapting these models to other health care systems could reinforce their universality and offer prospects for cross-border collaboration.

In conclusion, FHIR and OMOP are not simply technological tools; they embody a vision of a health care system in which information circulates fluidly and securely and is exploited for the benefit of all. Their integration in Belgium could not only improve the quality of care but also serve as a model for other nations. At the intersection of innovation and collaboration, these frameworks offer a unique opportunity to reinvent the way we approach the challenges of modern health care.

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Data Availability

The data that support the findings of this study consist of qualitative interview responses collected from expert professionals. In accordance with the informed consent provided by participants, the raw interview data are not publicly available in order to protect participant confidentiality. The thematic findings derived from the data are presented in full in the manuscript. Researchers wishing to access the data may submit a reasonable request to the corresponding author.

Authors' Contributions

Conceptualization: NL, NAI
Formal analysis: NL
Investigation: NL
Methodology: NL
Supervision: NAI
Validation: NAI
Writing – original draft: NL
Writing – review and editing: NL, NAI

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview guide used for expert semistructured interviews.
[DOCX File (Microsoft Word File), 15 KB-Multimedia Appendix 1]

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Abbreviations

ATC: Anatomical Therapeutic Chemical
CDM: common data model
EHDEN: European Health Data and Evidence Network
EHR: electronic health record
EMR: electronic medical record
FHIR: Fast Healthcare Interoperability Resources
GDPR: General Data Protection Regulation
HL7: Health Level Seven International
LOINC: Logical Observation Identifiers Names and Codes
OHDSI: Observational Health Data Sciences and Informatics
OMOP: Observational Medical Outcomes Partnership
RESTful: Representational State Transfer
RIZIV-INAMI: Rijksinstituut voor ziekte- en invaliditeitsverzekering—National Institute for Health and Disability Insurance
SNOMED CT: Systematized Nomenclature of Medicine Clinical Terms

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