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ONCO-FAIR Project: Improving Data Interoperability in Oncology Chemotherapy Treatments for Data Reuse

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Abstract. The ONCO-FAIR project's initial experimentation aims to enhance data interoperability in oncology chemotherapy treatments, adhering to the FAIR principles. This study focuses on integrating the HL7 FHIR standard to address interoperability challenges within chemotherapy data exchange. Collaborating with healthcare institutions in Rennes, the research team assessed the limitations of current standards such as PN13, mCODE, and OSIRIS, leading to the customization of twelve FHIR resources complemented by two chemotherapy-specific extensions. The methodological approach follows the Integrating the Healthcare Enterprise (IHE) framework, organizing the process into four key stages to ensure the effectiveness and relevance of health data reuse for research. This framework facilitated the identification of chemotherapy-specific needs, the evaluation of existing standards, and data modeling through a FHIR implementation guide. The article underscores the importance of upstream interoperability for aligning chemotherapy software with clinical data warehouse infrastructure, showcasing the proposed solution's capability to overcome interoperability barriers and promote data reuse in line with FAIR principles. Furthermore, it discusses future directions, including extending this approach to other oncology data categories and enhancing downstream interoperability with health data sharing platforms.

Keywords. Data Interoperability, Oncology, HL7 FHIR Standard, Big Data

1. Introduction

The integration of big data, particularly from real-life sources in cancer research, is transforming the landscape with its potential to reduce costs, foster patient-centered studies, and expedite medical discoveries. However, the efficacy of pivotal technical infrastructure like Clinical Data Warehouses (CDW) and Health Data Sharing Platforms (CDSP), is currently limited by significant interoperability barriers. These barriers obstruct the efficient collection and secure exchange of data, highlighting the urgent need for a comprehensive interoperability framework that encompass data primary and secondary use and aligns data with the FAIR principles of Open Science, making data Findable, Accessible, Interoperable, and Reusable. However, the development of such a framework demands a meticulous approach in choosing standards and specifications

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tailored to the use case of secondary data reuse. We demonstrated this process through an experiment with chemotherapy data, utilizing the HL7 FHIR standard for feeding data into a CDW.

2. Material and Methods

2.1. Material

Study Focus and Collaborative Framework: This investigation concentrates on the domain of oncology, specifically targeting chemotherapy. It involves collaboration with two main healthcare facilities of Rennes city: the Academic University Hospital and the Cancer Center of Rennes. The data of interest are those related to the prescription and administration of chemotherapy, aimed at enriching the data warehouses of each hospital, which utilize the eHOP technology.

Data Standardization Practices: Initial acquisition of chemotherapy prescription data is conducted via source applications at the collaborating institutions, adhering to the French PN13 standard. Managed by Interop'Santé, the PN13 standard provides a comprehensive structure for the representation of pharmacy data, detailing prescription processes and medication administration [1].

Exploration of Healthcare Data Standards: In seeking the optimal standard for integrating oncology data into our CDW, we evaluated various standards, including the Fast Healthcare Interoperability Resources (FHIR) standard by HL7. FHIR stands out for its broad approach to the electronic exchange of healthcare information, designed to improve interoperability between healthcare systems and streamline data sharing. Utilizing standard web technologies like HTTP, XML, and JSON, FHIR enables accessible healthcare data via APIs that adhere to specific resource models [2]. The study also reviews oncology-focused standards such as mCODE (Minimal Common Oncology Data Elements) by the American Oncology Association [3], and the OSIRIS model, developed by inter-integrated cancer research sites [5]. mCODE seeks to standardize oncology information collection and is based on the "US CORE" guide [4], which establishes the fundamental elements for the American healthcare system. OSIRIS aims to establish an interoperable data model for oncology, integrating clinical and genomic data with clinicians and researchers' expertise to promote interoperability.

Implementation and Guidance: The application of FHIR and other standards is supported by Implementation Guides (IGs), providing specific instructions for their deployment in healthcare contexts. The creation of these IGs can use XML, JSON, or FHIR Shorthand (FSH), with SUSHI (SUSHI Unshortens ShortHand Inputs) converting these definitions into practical FHIR artifacts, thus enhancing our CDW's data integration capabilities [6].

2.2. Methods

Our approach was inspired by the methodology of the French Digital Health Agency which is structured in four key stages, aimed at ensuring the effectiveness and relevance of health data reuse for research.

Defining use cases based on research data reuse objectives: This stage involved interviews with hospital clinicians, pharmacists, and CDW data engineers with specific technical and research needs. Clinician-researchers need to be able to cross-reference different data sources to meet the needs of clinical research, epidemiology or health surveillance. We have therefore drawn up detailed scenarios and use cases, including *Querying chemotherapy data from a hospital information system for a feasibility study* or *Extraction of chemotherapy data from a CDW for a multicenter study*. The data engineers need to collect fine grained data about drug prescription and administration, but also the clinical context described in the chemotherapy protocol. Thus, the *Feeding of a clinical data warehouse with chemotherapy data* use case has been developed. This use case, at first sight focused on the technical aspects of integrating data into the CDW, is in fact rooted in the research context. It revolves around the need to align with the needs of clinicians, who define the data essential to their studies and research. This process enables the precise selection of information to be incorporated into the CDW.

Study of norms and standards: To ensure optimum interoperability, we assessed existing norms and standards, both national and international. This research was based on an in-depth literature review. The aim of this analysis was to measure the coverage of standards in the relevant domain, based on several criteria. We examined the maturity and adoption of standards, considering stability and degree of community acceptance as key indicators of reliability. The visibility of standards was also assessed, considering their geographical scope, and finally, the responsiveness of standards was studied to determine their ability to evolve in line with new user needs.

Drawing up functional and technical specifications: We used the resources provided by the preliminary study to ensure that all functionalities were correctly defined and technically feasible, while complying with interoperability standards and regulatory requirements. Functional specifications define use cases, data flows and interactions between the various system components, and technical specifications include system architecture, technological choices (programming languages, databases, etc.), APIs, as well as the communication and security protocols to be adopted.

Modeling via a FHIR IG: The final stage of our methodology involved modeling our approach through the production of an implementation guide. This guide includes a selection of FHIR resources adapted to our context, customized profiles and extensions for accurate modeling of chemotherapy data, and clear guidelines for their implementation and use, thus ensuring efficient implementation and compliance with interoperability requirements.

3. Results

The study we conducted on standards and norms (see Table 1) indicates that the PN13 standard does not sufficiently express all the information required for our use case. Specifically, PN13 lacks the capability to represent key information influencing

chemotherapy prescriptions or administration, as collected in chemotherapy protocols. Such information includes pulse, blood pressure measurements, the use of devices like refrigerated helmets, or the localization of treatment. Moreover, PN13 cannot accurately represent complex prescriptions, such as an intravenous injection involving multiple medications in the same solution.

Table 1. Comparison of standards according to research project evaluation criteria

Criteria studied for our research project	Standards' responses to the criteria studied			
	PN13	mCODE	OSIRIS	FHIR R5
<i>Ability to represent specific vital measures</i>	-	++	++	+++
<i>Coverage of associated medical devices</i>	-	-	+	+++
<i>Treatment location</i>	-	++	++	+++
<i>Representation of complex prescriptions</i>	+	+	-	+++
<i>Flexibility and scalability</i>	+	-	+	+++
<i>System Implementation in real world</i>	+++	?	--	++
<i>Scope</i>	France	USA	France	International

Both mCODE and OSIRIS face challenges in capturing the full scope of chemotherapy prescription and administration data. The terminologies within mCODE, such as RXNORM and CPT (Current Procedural Terminology), are not entirely compatible with French standards like UCD (Unité Commune de Dispensation) or CCAM (Classification Commune des Actes Médicaux). This discrepancy hinders the seamless adaptation of mCODE, unless a major mapping effort is made between these terminologies, with no guarantee of semantic consistency. Finally, OSIRIS is also undergoing development, and did not fully address the chemotherapy topic. As FHIR offers appropriate resources for efficient management of this information, we profiled twelve FHIR resources to meet the specific requirements of our use case. The cardinalities of the resource's attributes were modified to conform to the needs of our French context, and two extensions to precisely represent chemotherapy-specific data were created because the attributes present in the original FHIR resources were not suitable for representing this information. The resulting implementation guide can be viewed here: <https://github.com/ONCOFAIR/FHIR-ImplementationGuide-Article>.

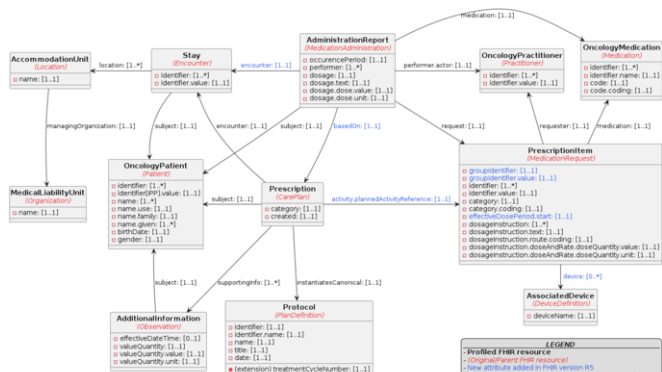


Figure 1. UML class diagram representing the FHIR R5 use case for prescribing and administering chemotherapy medication, with native (original) FHIR resources in red italics and their derived (profiled) FHIR resources in bold black. Attributes in blue are those added in version R5 of FHIR.

Considering the limitations identified with existing standards, we modeled twelve distinct FHIR resources. The UML class diagram in Figure 1 captures the essence of this model. It showcases the customization of FHIR R5 resources, which include *CarePlan*, *Protocol*, *MedicationRequest*, *MedicationAdministration*, *Patient*, *Observation*, *Practitioner*, *Encounter*, *Location*, *Organization*, *Medication*, and *DeviceDefinition*. Our custom extensions, integrated into this model, are instrumental in conveying essential protocol details, specifically the treatment cycle number and the corresponding day. This precision modeling enables a granular and FAIR-compliant representation of complex prescription schemas, which typically involve multi-medications infusions and the incorporation of ancillary devices, thus surpassing the capabilities of the PN13, OSIRIS and mCODE standards.

4. Discussion and Conclusions

In this work, adherence to IHE methodology facilitated the development of an optimized interoperability framework dedicated to chemotherapy data, consistent with FAIR principles to data reuse scenarios. Emphasis was placed on upstream interoperability between chemotherapy software and CDW infrastructure. The research identified limitations within standards such as PN13, mCODE, and OSIRIS, particularly in their capacity to encapsulate the multifaceted nature of chemotherapy data for reuse. Consequently, twelve FHIR resources were tailored and augmented with two novel extensions to enable precise depiction of complex chemotherapy prescriptions. Our work has some limitation: it was based on data and expertise of two hospital and was by design limited to French health care context with the potential need for adaptation to ensure broader application. The selection of FHIR R5 over R4 was a strategic choice, informed by the enhanced functionality of R5 for complex chemotherapy protocols, aligning with the ePI project under the Vulcan FHIR Accelerator for standardizing drug information globally [7]. Future directives are to extend this approach to other cancer data categories and foster downstream interoperability between CDW and CDSP infrastructures, with anticipated collaborative expansion with software vendors to advance comprehensive interoperability in concert with the FAIR tenets of Open Science.

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