International Journal of Science and Research Archive
eISSN: 2582-8185
Cross Ref DOI: 10.30574/ijsra
Journal homepage: https://ijsra.net/

(REVIEW ARTICLE)

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INTEROPERABILITY IN CLINICAL DATA INTEGRATION SYSTEMS: A FRAMEWORK FOR HEALTHCARE INFORMATION EXCHANGE

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International Journal of Science and Research Archive, 2023, 08(01), 1167–1173

Publication history: Received on 03 January 2023; revised on 19 February 2023; accepted on 26 February 2023

Article DOI: https://doi.org/10.30574/ijsra.2023.8.1.0157

ABSTRACT

The ability to share clinical information seamlessly between various electronic health record (EHR) systems, among lab platforms, imaging repositories, and mobile health devices is a growing necessity in healthcare delivery. Even with significant investment in digital health infrastructure, data silos, messaging standards and terminology bindings are still fragmented, which stand in the way of real-time clinical decision-making and care coordination. This paper presents a six-layer interoperability model for integration of clinical data that brings together data sourcing interoperability, security governance interoperability, integration engineering interoperability, syntactic interoperability, semantic interoperability, and application-level analytics to a unified interoperability model. The framework combines existing standards such as Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR), Digital Imaging and Communications in Medicine (DICOM) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) in a governance-aware exchange model. The semantic and syntactic interoperability, ease of implementation, and ability to exchange information in real-time are compared across five current standards, and adoption trends over a 7-year period (2015-2022) are analyzed. The results show that architectures that use FHIR provide better syntactic flexibility and real-time exchange capabilities compared to legacy HL7 v2.x messaging, and that the key challenge among all of the standards assessed is semantic interoperability. The proposed structure provides a standards-based, scalable and secure blueprint for health information exchange in healthcare organizations.

Keywords: Interoperability; Clinical Data Integration; Health Information Exchange; HL7 FHIR; Healthcare Informatics

1 INTRODUCTION

Automation of health care systems has generated a vast amount of clinical data, held in a wide variety of electronic health records (EHRs), laboratory information systems (LISs), radiology information systems (RISs), pharmacy systems, and consumer health devices [7]. Each of these systems records data that's vital to complete patient care, but they often exist as standalone repositories with conflicting terminology systems, proprietary data formats and different data models. This fragmentation, or so-called interoperability gap, affects the ability to coordinate care, poses risks for medical errors, and limits the value of data-driven clinical decision support (CDS) [1].

Generally, the concept of interoperability in the healthcare information technology field can be summarized in four dimensions: foundational, structural, semantic, and organizational [6]. Basic interoperability allows for the exchange of basic data, but not necessarily for it to be understood. Structural interoperability refers to the syntax of the messages being exchanged, and semantic interoperability refers to the fact that the data in the messages have the same clinical meaning in every system. The most challenging one is organizational interoperability, which deals with the governance, policy and workflows that must be aligned to ensure ongoing data exchange at scale. All four dimensions are still an open challenge for health systems around the world [9].

A variety of standards have been developed to tackle a particular aspect of this challenge. Historically, HL7 version 2 (v2.x) messaging has been the defacto standard for intra-hospital data exchange, and more recently, HL7's Fast Healthcare Interoperability Resources (FHIR) specification has garnered attention for its RESTful, API-driven approach that is more conducive to mobile and cloud-based applications [3]. DICOM still rules the roost for exchanging imaging data and terminology systems like SNOMED CT, LOINC and ICD10 still drive cross-system data harmonisation [4]. Multiple standards, however, have evolved and partially overlap, which has also become a source of integration complexity.

This paper aims to tackle this complexity by proposing one integrated, layered framework for clinical data integration which clearly separates concerns related to data sourcing, security, message transport, syntactic structure, semantic mapping and application consumption. The goal is to offer a healthcare-focused reference architecture that helps define where existing standards fit, where integration failures often start, and that offers a framework for governance across the entire data lifecycle, throughout the entire health care organization, health information exchange (HIE) operations and informatics research. The rest of this paper is structured as follows: in Section 2, literature pertaining to the development of the proposed framework is reviewed, Section 3 outlines the proposed framework, Section 4 describes the methodology used to evaluate the prevailing standards, Section 5 presents the results and discussion, Section 6 discusses the barriers to adoption and Section 7 concludes with directions for future research.

2 LITERATURE REVIEW

The first studies of interoperability had primarily considered message level interoperability; the HL7 v2.x was the foundation for hospital interface engines since the 1990s [7]. Though widely adopted, HL7 v2.x had a problem with its permissive optionality and use of delimited text segments, which resulted in varying interpretations of messages between vendors, interfering with the interpretation of exchange messages [4]. Such a variation led to the creation of HL7's Clinical Document Architecture (CDA) and later the FHIR specification, which embraces modern Web principles such as RESTful interfaces, JSON, and OAuth2 authentication and authorization [3].

Digging into the data of FHIR adoption, there are signs of growing adoption within health systems and vendors since it was identified as the foundation for national interoperability requirements, such as those in the U.S. 21st Century Cures Act [1,5]. Comparative studies indicate that FHIR based integration can facilitate the reduction of development time and also enhance API discoverability as compared to legacy messaging; however, semantic mapping challenges remain regardless of the transport standard used [2].

Research on Semantic Interoperability has focused on the importance of the use of standardized terminologies for disambiguation within cross system communication. When consistently used at the point of data capture, SNOMED CT and LOINC have been proven to significantly increase data capture accuracy[9]. But, real-world experience with health information exchanges shows continual issues with terminology mapping; for instance, locally defined codes in legacy systems that do not have authoritative mapping to other standardized vocabularies [8].

While less empirical research has been focused on organizational and governance aspects of interoperability, these aspects are emerging as critical for HIE sustainability. Previous studies indicated that data governance, inter-organizational trust and financing models are essential factors for HIE success beyond the technical standards used [13]. As data volumes have grown, and so has the regulatory scrutiny, newer efforts have expanded this governance lens to patient consent management and cybersecurity concerns [10,11].

A number of architectural models have been suggested for structuring these technical and organisational issues. The Office of the National Coordinator for Health Information Technology's Interoperability Standards Advisory provides a list of relevant standards for each use case, but does not mandate a unified architecture [12]. The Integrating the Healthcare Enterprise (IHE) initiative provides more prescriptive definitions of interoperability profiles that integrate multiple standards for a specific clinical workflow, with variable levels of implementation in regions [4]. In this paper we present a framework that builds on these efforts by separating the security governance, syntactic transport, and semantic mapping as distinct, separately verifiable architectural tiers, unlike previous frameworks that tend to combine these concerns.

3 PROPOSED INTEROPERABILITY FRAMEWORK

The proposed clinical data integration framework consists of six layers, as shown in Figure 2, and explained in Table 1. Layer 0 refers to the diverse and varied data sources found in today's healthcare landscape, such as EHR systems, laboratory information systems (LIS), radiology information systems (RIS), wearable devices, and claims processing systems. Instead of as a standalone module, Layer 1 introduces security and governance controls, such as authentication, authorization, consent management, and audit logging, as a cross-cutting concern to all of the other layers.

Layer 2 is the data exchange and integration engine, which handles message routing, protocol translation and extract-transform-load (ETL) between heterogeneous data source systems and data downstream consumers. Layer 3 addresses syntactic interoperability with standardized transport protocols, primarily HL7 FHIR RESTful APIs, HL7 v2.x messaging for legacy integration and DICOM for imaging data. Layer 4 focuses on semantic interoperability, enabling the mapping of locally coded data elements to a common set of terminologies such as SNOMED CT for clinical findings, LOINC for lab observations, ICD-10 for diagnostic coding, and RxNorm for medication data. Layer 5 is the application and analytics tier, which enables population health analytics, longitudinal EHR views, and clinical decision support systems to be supported by integrated, semantically consistent data.

Table 1: Summary of the Proposed Six-Layer Clinical Data Integration Framework

Layer	Function	Representative Technologies/Standards
Layer 0 – Data Sources	Origination of clinical and operational data	EHR, LIS, RIS, wearables, IoT devices, claims systems
Layer 1 – Security & Governance	Protects data confidentiality, integrity, and consent	OAuth2/SMART on FHIR, TLS encryption, audit logging, RBAC
Layer 2 – Data Exchange & Integration Engine	Routes, transforms, and brokers messages between systems	API gateway, enterprise service bus, ETL pipelines, HL7 interface engines
Layer 3 – Syntactic Interoperability	Ensures structural compatibility of exchanged data	HL7 FHIR APIs, HL7 v2.x messaging, DICOM objects
Layer 4 – Semantic Interoperability	Ensures shared meaning of exchanged data elements	SNOMED CT, LOINC, ICD-10, RxNorm terminology mapping
Layer 5 – Application & Analytics	Consumes integrated data for care delivery and insight	Clinical decision support, EHR/EMR dashboards, population health analytics

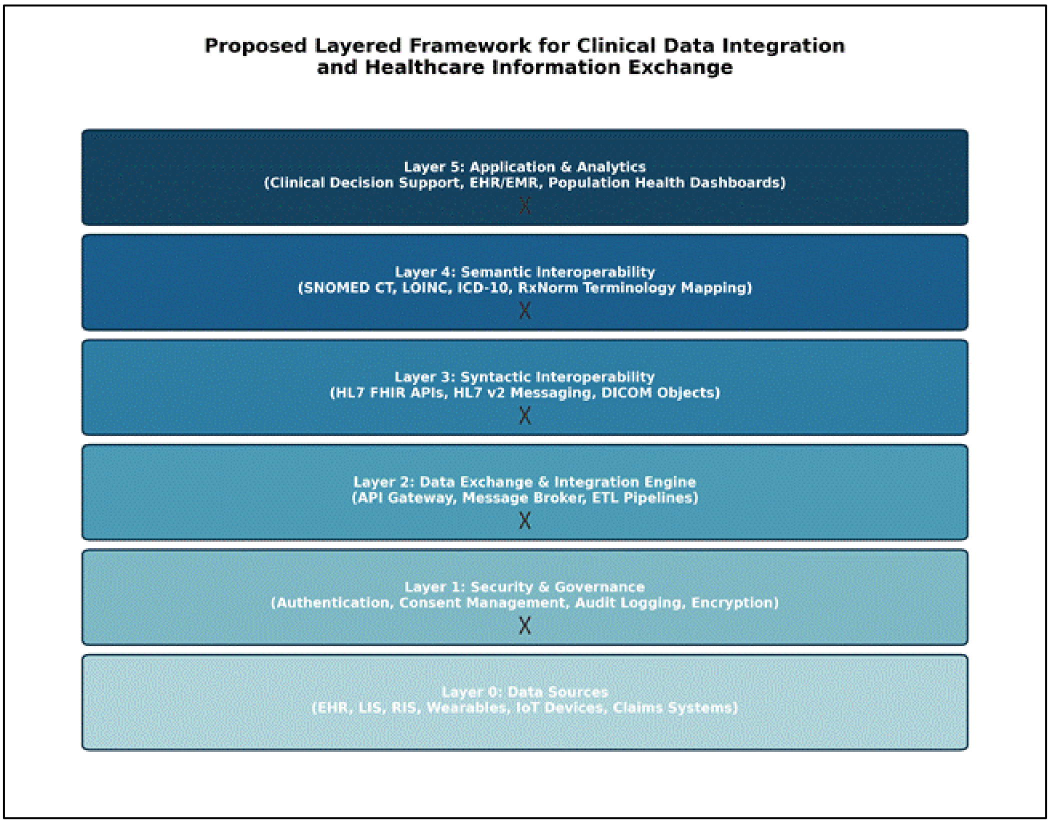

Figure 1: Proposed layered framework for clinical data integration and healthcare information exchange.

One of the fundamental principles of the framework is the distinction between syntactic and semantic interoperability (Layer 3 and Layer 4). This separation enables organisations to implement modern transport mechanisms like FHIR without early making the assumption that message-level compatibility is tantamount to clinical meaning. It also supports incremental modernization – legacy HL7 v2.x interfaces can be maintained at Layer 3 parallel to the progressive normalization of semantic mapping at Layer 4, without the risk of an operational, wholesale system change.

4 METHODOLOGY

A comparative framework analysis methodology, incorporating a structured literature synthesis and an evaluative scoring exercise was used in this study. Four dimensions of interoperability based on taxonomies were evaluated for five prevailing healthcare data exchange standards, including HL7 v2.x, HL7 FHIR, DICOM, IHE profiles and openEHR: semantic interoperability, syntactic interoperability, implementation ease, and realtime data exchange [6,4].

Scores for each dimension were generated by qualitative synthesis of peer-reviewed evaluations, technical specifications and implementation case studies from 2013 to 2022, then scaled using a 10-point relative performance scale for cross-standard comparison. This is the approach that is used in comparative health informatics studies when heterogeneous qualitative evidence is synthesised into comparable indices using pre-established rubrics [2]. Similarly, trends in adoptions presented in Section 5 are also compiled from published data from interoperability surveys and regulatory adoption reports and are meant to illustrate patterns of adoption trends, as opposed to a single primary dataset, over the period 2015 to 2022.

This proposed six-layer framework was then tested via architectural mapping, where each standard evaluated was mapped to the proposed framework layer to verify architectural completeness, and to determine if there are any functional overlaps or gaps. This mapping exercise, which is not a system deployment, is the main validation method of the present study, following the methodology that is commonly used in conceptual framework development in health informatics architecture research [12].

5 RESULTS AND DISCUSSION

The comparative scoring of the five standards evaluated is given in Table 2. HL7 FHIR came out on top when all the scores were added together, with strong scores for syntactic interoperability (9/10) and real-time exchange capability (9/10) thanks to its RESTful API design and support for asynchronous, subscription-based notifications. Although the relative performance of v2.x is decreasing, the fact that the segment structure exists, and has been implemented in many places around the world, means that v2.x still enjoys moderate syntactic interoperability (7/10), although the ability to exchange messages in real time (4/10) is far behind FHIR, because it uses batch and point-to-point messaging structures.

Table 2: Comparative Performance Scores of Healthcare Data Exchange Standards (0-10 Scale)

Standard	Semantic Interop.	Syntactic Interop.	Implementation Ease	Real-time Exchange
HL7 v2.x	5	7	6	4
HL7 FHIR	8	9	7	9
DICOM	7	8	5	6
IHE Profiles	7	7	5	6
openEHR	8	6	4	5

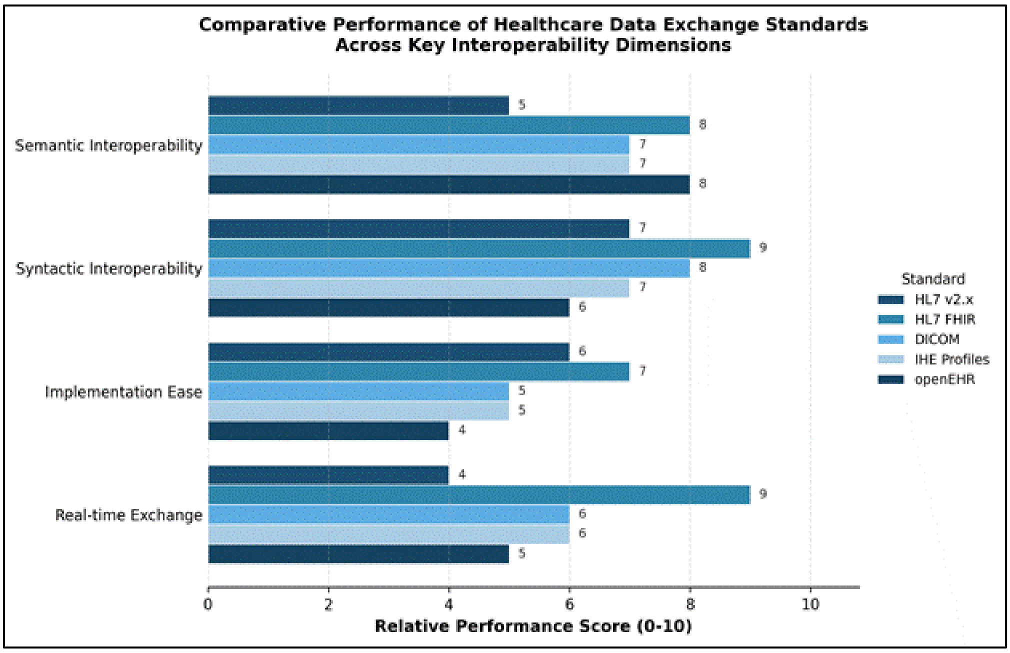

Figure 2: Comparative performance of healthcare data exchange standards across key interoperability dimensions.

DICOM and IHE profiles scored similarly for semantic interoperability (7 out of 10) and moderately on implementation ease (5 out of 10), indicating that they need more specialized knowledge and skills for integration into imaging workflows. The non-FHIR standards had the best semantic interoperability score of 8/10, due to openEHR's approach to modelling based on archetypes, and the lowest implementation ease score of 4/10, reflecting previously reported issues with openEHR adoption outside specialized clinical research settings [8].

The relative trajectory of adoption of HL7 FHIR, HL7 v2.x and DICOM is shown in figure 3, as an amalgamation of published interoperability adoption surveys from 2015 to 2022. The rate of FHIR adoption has been steadily increasing since 2018, when large EHR vendors announced FHIR-based application programming interfaces and following U.S. interoperability regulations that strengthened implementation of these APIs [5]. HL7 v2.x is experiencing a diminishing relative decline, but still is deeply entrenched in legacy hospital infrastructure and is not likely to be completely replaced in the short-term. DICOM adoption is still relatively stable as there is no clear competing alternative in imaging workflows to date.

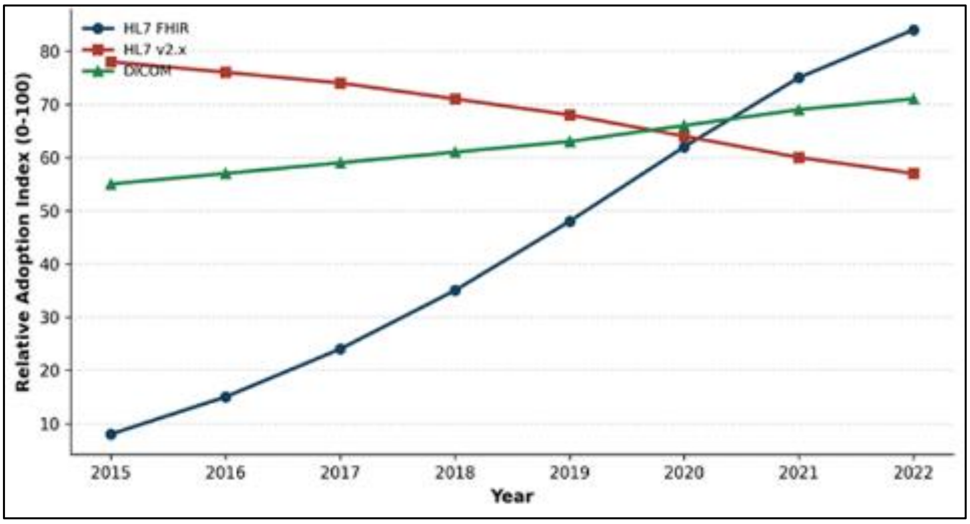

Figure 3. Illustrative trend in relative adoption of major health data exchange standards (2015-2022).

All these findings together justify the architectural thinking behind the suggested framework: none of the standards covers all the interoperability aspects on its own. The syntactic interoperability and real-time exchange makes FHIR an ideal choice for the Layer 3 transport mechanism; the semantic interoperability score is good (8/10), but requires explicit terminology binding at the Layer 4, not just on FHIR resource structures alone. This discovery confirms the separation of syntactic and semantic issues as an architectural rather than only conceptual requirement of the framework.

6 BARRIERS TO ADOPTION AND MITIGATION STRATEGIES

Even with the many standards available, significant challenges remain for healthcare organizations in adopting interoperable data integration architectures. Table 3 provides an overview of the five barriers that were found during the literature synthesis and the mitigation strategies contained in the proposed framework.

Table 3: Barriers to Interoperability Adoption and Corresponding Mitigation Strategies

Barrier	Underlying Cause	Proposed Mitigation
Semantic heterogeneity	Divergent local terminologies and coding practices	Enforce standardized terminology bindings (SNOMED CT, LOINC)
Legacy system rigidity	Proprietary formats in older HL7 v2 systems	Deploy interface engines and FHIR facades over legacy cores
Data governance gaps	Inconsistent consent and access-control policies	Adopt unified governance layer with auditable consent management
Vendor lock-in	Closed proprietary APIs restricting data portability	Mandate open API specifications (SMART on FHIR) in procurement
Workforce readiness	Limited informatics training among clinical staff	Institutionalize interoperability training and certification programs

The most enduring obstacle is semantic heterogeneity, with different local coding practices creating obstacles to automated data mapping, even when syntactic compatibility is reached [9]. Another challenge to modernization is the rigidity of legacy systems, especially in smaller health care organizations that do not have the resources to replace entrenched HL7 v2.x interfaces [10]. The framework accommodates this restriction by providing a integration engine on Layer 2 that allows you to keep legacy protocols behind a contemporary API façade.

Governance challenges like inconsistent consent management and vendor imposed API restrictions are more of an organizational than technical nature. Layer 1 is explicitly defined as one of the cross-cutting governance layers, not as a peripheral compliance layer, which puts the governance in position to structurally solve these barriers, as has been suggested by the health information exchange sustainability research literature [13].

7 CONCLUSIONS AND FUTURE WORK

This paper outlined a layered approach of six layers towards the integration of clinical information that supports the coexistence of multiple healthcare data exchange standards in a coherent governance-aware architecture. An evaluation of five dominant standards showed that, compared to the legacy standards, HL7 FHIR provides better syntactic interoperability and performance for real-time exchange. Semantic interoperability is a cross-cutting issue for all transport mechanisms. The proposed framework provides a reference architecture for healthcare organizations to plan for incremental interoperability modernization in a standards-based manner by explicitly separating syntactic and semantic concerns and integrating security governance as a cross-cutting component.

The next steps for research include empirical validation of the proposed framework by piloting this approach in a real operational health information exchange setting with an emphasis on quantifying the reduction in semantic mapping errors that can be achieved with structured terminology binding at Layer 4. Further studies should also explore the framework's usefulness for new data types such as genomic data and continuous remote monitoring streams, which present new interoperability challenges that are not currently fully addressed by clinical messaging standards.

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