International Journal of Emerging Trends in Computer Science and Information Technology
ISSN: 3050-9246 | https://doi.org/10.63282/3050-9246.IJETCSIT-V4I4P107
Eureka Vision Publication | Volume 4, Issue 4, 60-65, 2023

Original Article

Clinical Information Model with FHIR Interoperability Standard

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Abstract: *The healthcare industry faces increasing challenges in managing and integrating vast volumes of electronic health data distributed across disparate systems. Historically, the HL7 v2 standard addressed many interoperability concerns, but evolving requirements and system complexities have highlighted its limitations. HL7 standards aimed to facilitate seamless data exchange through well-defined protocols, collaborative input from stakeholders, and international standardization. However, with diverse communication protocols and a fragmented ecosystem of Electronic Medical Records (EMRs), consistent integration remains difficult. The emergence of HL7 FHIR (Fast Healthcare Interoperability Resources), designed by Grahame Grieve, offers a modern, flexible, and scalable solution. Leveraging RESTful APIs, OAuth, and SMART on FHIR, FHIR focuses on real-time, standardized access to health data across internal and external systems. Its design reduces vendor lock-in and enables the development of EMR-agnostic applications, addressing many limitations of earlier HL7 versions and traditional integration approaches.*

Keywords: *HL7, HL7 v2, HL7 CDA, HL7 v3, FHIR (Fast Healthcare Interoperability Resources), Interoperability, Electronic Medical Records (EMR), RESTful APIs.*

1. Overview:

The rapidly growing health data stored electronically in desperate systems had a market need to standardize data transmission in a collaborative approach across departments, laboratories, pharmacies, and other external organizations. A few decades HL7 v2 standards were widely used, with multiple features added over time based on evolving requirements. HL7 is abbreviated as Health Level 7, the 7 comes from the 7 layers of ISO Communication Model, which consists of four layers of communication and three layers of function as depicted in the diagram below. HL7 works at the Application Layer. This is the engine that ensures smooth transfer and retrieval of data. In the current healthcare software ecosystem needs HL7 standards, hence the HL7 integration.

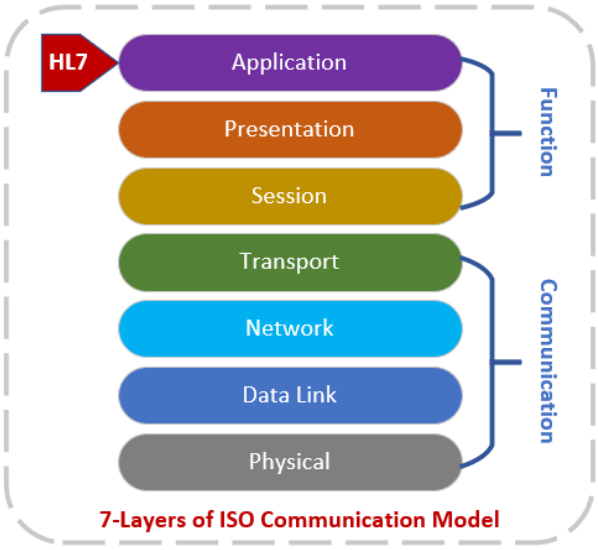

Figure 1. 7-Layers of ISO communication Model

2. HL7 Versions timeline and Interoperability

The below diagram shows the evolution of HL7 versions and their timeline and interoperability.

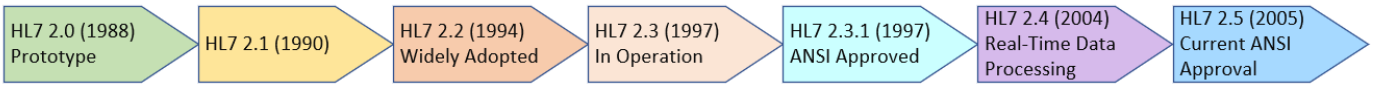

Figure 2. HL7 Versions timeline and Interoperability

The primary objectives of HL7 standards to ensure the Healthcare users can access the data in a standardized manner irrespective of location and time. The following strategies were followed.

- Defining clear standards of healthcare to ensure seamless exchange of information.
- Developing interoperability standards via the HL7 methodology.
- The importance of standardization needs buy-in from all stakeholders e.g. Healthcare professionals, practices, Policy makers etc.
- Domain experts participation in defining the HL7 standards.
- Promote interoperability standards from international institutions and organizations like ANSI and ISO committees.
- Collaborate with hospitals and practices to define real-time requirements.

The Healthcare systems may need to interact with multiple protocols like EDI, HIPAA X12 communications, CDA, DICOM, IHE, HL7 v2 etc. The implementation should be robust scalable, easy to maintain and test, flexible to accommodate varying requirements and compatible with multiple data formats to interact with other existing external application and provider integration.

The below diagram shows an example usage of HL7 and its interaction with other enterprise systems. For an efficient system it's crucial to streamline operation, document data flow, data storage and retrieval, robust and customizable Integration solutions must be selected from existing third-party vendors or custom developed to suit specific needs.

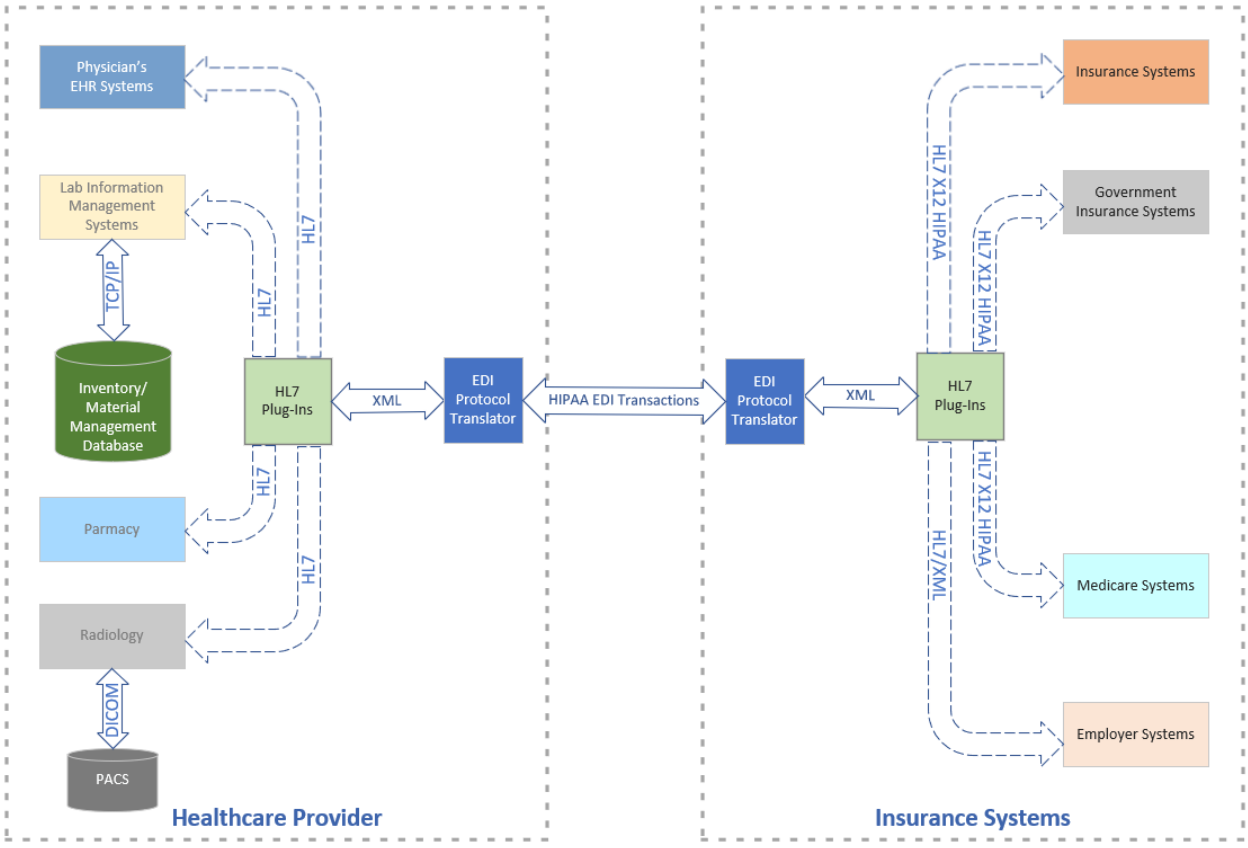

Figure 3. HL7 and its interaction with other enterprise systems

3. FHIR the future of Interoperability:

From the above scenario we can see the many standards in play, The HL7 v2, HL7 CDA is too old and HL7 v3 is too complex and has not been widely implemented. On an average a Hospital in the US has around 75 to 80 systems. With the consolidation of hospitals many systems now have multiple hospitals, but they still need to connect all those systems to one another. Also, we have many external systems like pharmacies, laboratories, home care devices, mobile devices, Genomic sequencing labs, Payer systems etc. The key to interoperability is being able to see all these data in one place for a patient or a population in real-time. The number of data points or facts have increased exponentially, and global initiatives have been advocated for data transparency and push for online data instead of offline data.

With a full spectrum of stable FHIR resources still a work in progress, application developers have struggled to find a consistent way to integrate with the various EMRs. Integrations typically use one of two integration strategies proprietary APIs or direct database calls with each integration requiring deep understanding of the EMR. All major EMR vendors now have proprietary APIs that allow developers to access data from the EMR. These APIs have varying degrees of functionality, the advantages of vendor-supplied API are that it abstracts the implementation details and the developer only need to know how to use them. The EMR vendor manage the functionalities updating the API to work with past, current, and future versions of their software. EMR vendors are finding ways to monetize the APIs. In some cases, for data-intensive applications these charges can be expensive.

Integrating applications by using to the underlying EMR database directly can mitigate the cost and can be performant as well. But this induces a highly coupled system. Moreover, the developers and domain experts need to understand the vendor specific EMRs and its implementation to use the underlying database. The domain knowledge of specific EMRs may usually not apply to other EMR vendors while you use their native functionality. Availability of skillset coupled with reinventing the wheel if you move to another EMR. Moreover, application developers must be constantly aware of the impact of new EMR versions and detail all changes to ensure that upgrades don't break the integration functionality. Some EMR vendors don't even provide access to their databases, so integration isn't even an option.

Once the issues of how to access EMR data from a single pipeline are tackled, the next challenge of creating EMR agnostic applications arises. Imagine finally getting through your first EMR integration only to find out that when you want to sell your application into other EMR markets, the entire integration piece needs to be rewritten because there's no standardization between EMR APIs or databases. Grahame Grieve from Australia architected healthcare's data interoperability when he founded HL7's Fast Healthcare Interoperability Resources (FHIR), the leading healthcare data exchange standard of the future. While HL7 leans toward the protocols that ensure seamless data interoperability within a healthcare organization, FHIR focuses on the protocols that simultaneously ensure data interoperability in and out of the organization - RESTful API, OAuth, WebSocket, SMART on FHIR, and others.

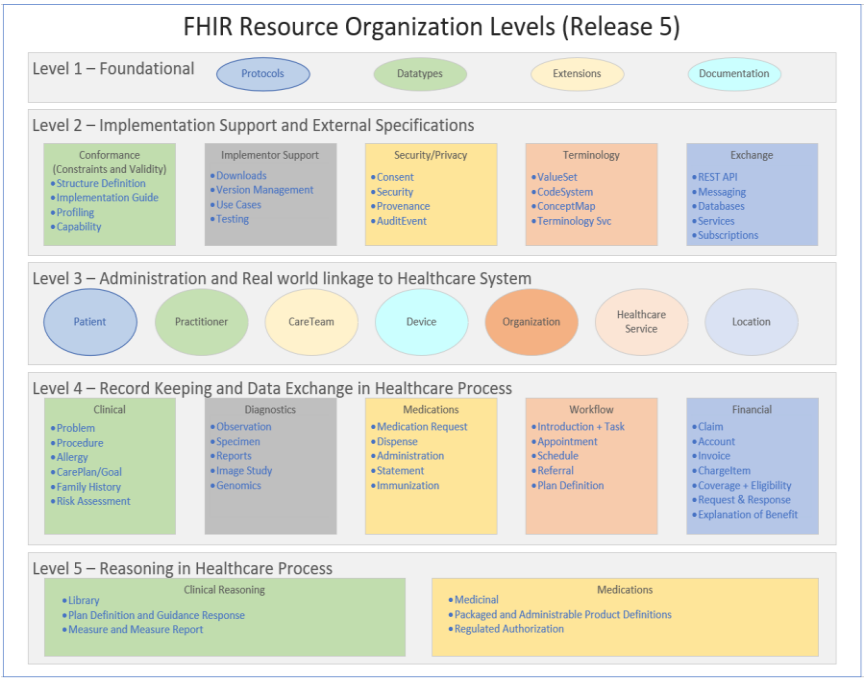

Figure 4. FHIR Resource Organization Levels (Release 5)

4. FHIR Levels referenced from hl7.org

FHIR is a collection of data from patients, providers, payers, and other healthcare entities. This data, referred to as resources, is organized into levels as depicted in the Figure above. Within these levels, resources are further organized into modules to help implementers find their way around the functional areas of the specification. FHIR offers numerous advantages over HL7, including simpler implementation, mobile device compatibility, and improved security measures. These advantages stem from FHIR's modern approach to data exchange, which leverages RESTful APIs, open web technologies, and support for JSON and XML formats. The FHIR data model comprises of around 158 resources as of this writing, profiles built to use-case and defined value sets, FHIR extensions and implementation guides to optimize interoperability, clinical decision support, and patient engagement. FHIR is strongly typed to ensure data fidelity. It consists of Simple/Primitive data types and Complex data types.

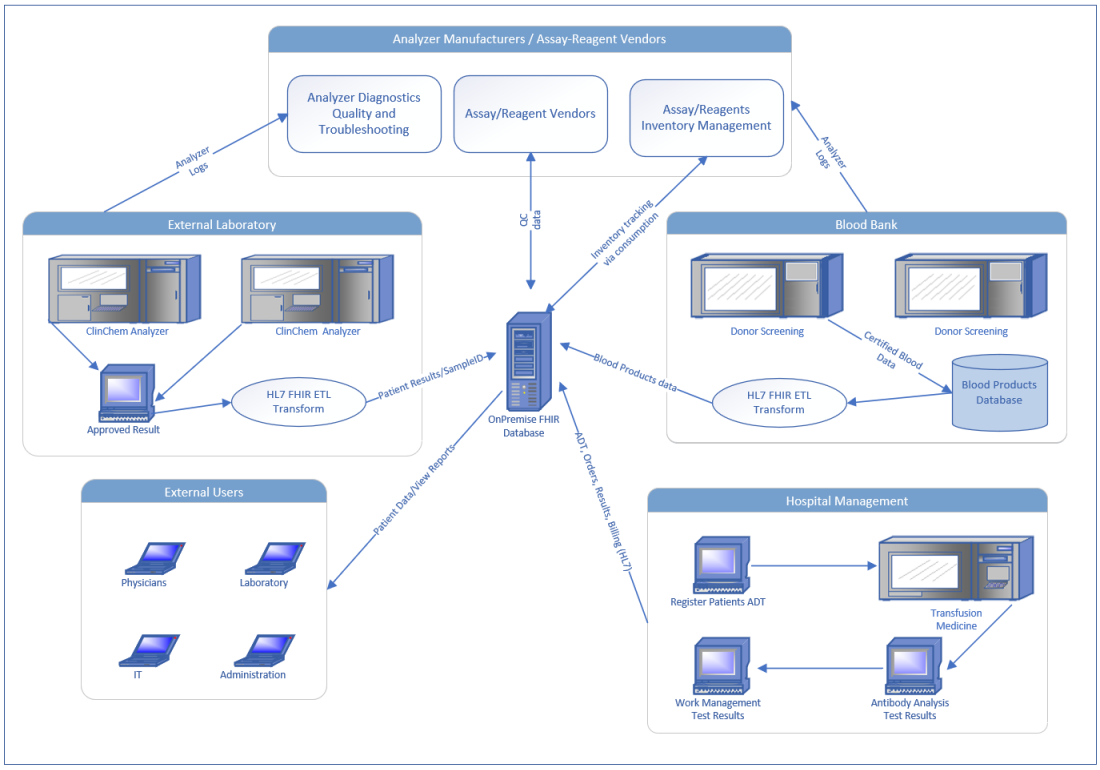

Figure 5. FHIR Levels referenced from hl7.org

The importance of the Star model of FHIR interoperability solution either On Premise or Cloudbased solution can be seen in the above diagram. The FHIR standard is integrated into the platform, facilitating easy data exchange between healthcare systems through a REST API. The FHIR server stores data or acts as a facade for existing hospital Laboratories, Analyzer manufacturers, Assay/Reagent vendors, Blood bank etc, promoting data accessibility and interoperability. The scope of various stakeholders and users that use the interoperable solution improves drastically. The Patients are given a seamless experience during transfer to other specialists or hospitals. For every single point of healthcare data generated for a patient costs money. A doctor's opinion, X-ray, MRI, blood report. The patient pays for each data point that is collected. Healthcare data is rich in information. Every single data point is representative of a condition or a disease pertaining to a patient. Profiling and learning from disease patterns given a diagnosis becomes a reality. The utilization of data-driven decisions in healthcare is immense, cost saved, longer life span, healthier society.

By adhering to established open standards such as openEHR, FHIR we achieve uniformity and consistency in the way data is collected, stored, processed, and exchanged. In the realm of healthcare, where lives are at stake, standardized data becomes paramount as it ensures seamless communication and interoperability between various healthcare systems. This not only reduces errors and inefficiencies but also empowers clinicians and researchers to derive meaningful insights from vast pools of information. Many companies store details about your online browsing history, location tracking etc etc, to increase their ad revenue, Hospitals that can utilize data for efficient diagnosis, mostly store in desperate systems or worse yet just write this down on paper. And every time a patient is transferred to a specialist in another hospital, most of the data collected about them from the previous hospital is

disconnected, except for the discharge summary, which may not have detailed information. And the patient must pay for all this data to be collected all over again.

The standards like FHIR is a means to reuse healthcare data. And the patient who pays for generating this data like Xray, MRI, mammogram etc should become the owner of that data. The patient can take deeper study of their own health condition and be more health conscious in a more proactive matter, and also give physicians inputs about their relevant condition. They can also have third party apps giving them alternate drug prescriptions from another brand which can save costs. For the physicians perspective it is great decision support system and reduces paperwork for insurance claims. Also these system helps the healthcare professionals to adhere to legal regulations. Also, the Artificial Intelligence algorithms which are trained on data outcomes of millions of other patients gives suggestions and guidance on best course of action based on patient conditions.

To make health care data interoperable need to Standardize Terminology, Format and Transmission methodology. The medical terminology is varied for the same condition or use a specialized term that may have a broader term. e.g. Atresia which again has specialized terms like Pulmonary atresia, Tricuspid atresia. SNOMED International determines global standards for health terms and LOINC for terminology standard for health measurements, observations, and documents. Pretty much any condition or medication can be represented by these two together.

The format of the medical data forms must have standards, and the newly generated data have to follow these formats. Based on patient's consent, Institutions should use the same form of communication and access control to transmit medical information to requesting third parties. OpenEHR for clinical data, FHIR is new and wide adoption takes time. FHIR represents data as simple resources and stores it in a RESTful server, and transmits it through its RESTful interface. Hospitals should be equipped with electronic health record systems speaking openEHR and FHIR.

5. Conclusion

In conclusion, as healthcare systems continue to grow in complexity and volume, the need for a robust, scalable, and standardized interoperability solution becomes critical. Traditional HL7 versions like v2 and CDA, while foundational, fall short in today's multi-system, data-driven environment. The introduction of HL7 FHIR addresses these challenges by enabling modern, API-driven data exchange with a focus on real-time access, flexibility, and scalability. While adoption is ongoing and certain FHIR resources are still maturing, it offers a path toward true interoperability across diverse healthcare stakeholders. The move toward FHIR signifies a strategic shift from fragmented and proprietary integration models to a more unified and collaborative healthcare data ecosystem.

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