


Implementing HL7 FHIR: The HL7 Standards Implementation Division Comes of Age

Charles Jaffe, Health Level 7 International, USA*

Daniel J Vreeman, Health Level 7 International, USA

 <https://orcid.org/0000-0001-5119-6531>

Diego Kaminker, Health Level 7 International, USA

Viet Nguyen, Health Level 7 International, USA

ABSTRACT

Fast Healthcare Interoperability Resources (FHIR), created by HL7 more than a decade ago, has become a global standard for exchanging data. Communities of interest have organized under the HL7 FHIR Accelerator Program to develop implementation guides and applications for patient care, health payment systems, public health, patient engagement, clinical and basic research, and social determinants of health. Despite efforts to coordinate the creation of applications in an ever-increasing diversity of use cases, there have been challenges to ensure semantic interoperability, security, privacy, consistent interpretation of the specifications, and the workforce capacity across the industry. In response to these challenges, HL7 created the Standards Implementation Division with the aims of developing a unique ecosystem for continuous testing and discovery, building a global education and certification program, and facilitating advancement across the diverse FHIR implementation communi

KEYWORDS

Access Programming Language, FHIR, Healthcare Standards, HL7, Interoperability

THE RECOGNITION OF HL7 FHIR

In 1987, Health Level Seven® (HL7) International was founded as a non-profit standards development organization (SDO), with an aim of delivering data for patient care and research when and where it is needed. Since then, it has become an ANSI-accredited SDO with members in more than 50 countries. With the emergence of version 2 (V2), HL7 became the global authority on interoperability for healthcare information technology. Since then, HL7 standards have become the most widely adopted interoperability platform in the world.

In 2010, the HL7 Fresh Look Task Force met to discuss the challenges of achieving true semantic interoperability. Institutions, health systems, and governments had interpreted and implemented the standards differently, often at the expense of intersystem data exchange. The world of integration engines and mapping exploded to attempt to meet those demands. Other industries, including banking, transportation, and communication had successfully adopted the concepts of RESTful web services

DOI: 10.4018/JHMS.316144

*Corresponding Author

This article published as an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0/>) which permits unrestricted use, distribution, and production in any medium, provided the author of the original work and original publication source are properly credited.

and open APIs (application programming interfaces). For HL7, the introduction of Fast Healthcare Interoperability Resources (FHIR) was meant to close that gap.

In over two decades from 1985 to 2019, HL7 version 2 (V2) became the industry standard for hospital-based ordering systems, as well as laboratory transactions. The HL7 version 3 (V3) standard and its implementation in the clinical document architecture (CDA) standard enhanced data exchange, especially for clinical documents. With the American Recovery and Reinvestment Act, enacted in February 2009, along with Health Information Technology for Economic and Clinical Health (HITECH) Act, the US federal government incentivized the use of electronic health records. The Meaningful Use 2 provisions for allowing patients to access a common clinical data set of electronic health record (EHR)-based data, which were articulated by CMS in 2014, provided the impetus for broad adoption of FHIR to support the common requirements facing EHR vendors.

FHIR Brought Open APIs to Healthcare

FHIR adopted the open API technology (Application Programming Interface) that other industries (commerce, banking, travel, media) had been using for a decade. FHIR standard leverages well-established upward technologies including application programming interfaces (API) and RESTful services which have been widely adopted in other industries such as travel, commerce, and banking. These technologies are the underpinnings of our modern web-based patient exchange. They are also well understood by experienced software developers and those entering the field. Our standard is both modernizing healthcare information exchange as well as opening door by a new generation of healthcare IT innovators.

In a broad sense, *semantic interoperability* is the ability of computer systems to exchange data with unambiguous, shared meaning (https://en.wikipedia.org/wiki/Semantic_interoperability). In the context of exchanging health data, semantic interoperability requires the use of standards that define the shape and format of data into common structures (these are often called “syntax standards”) together with vocabulary and model standards that provide a shared meaning of the health content inside those structures.

Some of the initial challenges that FHIR met were addressed by the emergence of a remarkable collaboration between the technology sector and healthcare delivery systems. It began in the fall of 2014 with the publication of the recommendations from the JASON Report Task Force (*JASON Report Task Force Final Report*, 2014). Their seminal publication asserted that the “Foundation of interoperability should be an orchestrated architecture based on Public APIs.” Shortly thereafter came the announcement of the **Argonaut Project** (*Argonaut Project Home - Argonaut Project - Confluence*, n.d.), which was established on the principle that the emerging FHIR specification best served the needs defined by the Task Force. Several years later, the Apple Corporation announced that it would incorporate the Argonaut FHIR implementation guide into the iOS operating system, in support of their Health Kit (Apple, Inc., 2018a). What began as a pilot among 12 academic health systems quickly grew to a world-wide system for empowering patients to aggregate their health data from disparate sources onto a single platform (Apple, Inc., 2018b).

Later that year, the HL7 Partners in Interoperability program (*HL7 Partners in Interoperability | HL7 International*, 2016) brought together a unique collaboration of providers and payers from both the private and public sectors to advance the goal of value-based care. Their intent was to begin to reinvent the broken US healthcare payment system. From that effort, the **HL7 Da Vinci Project** was born (*Da Vinci - Da Vinci - Confluence*, n.d.). To date, its efforts have been cited in US regulation and will ultimately help to achieve that goal.

THE HL7 FHIR ACCELERATOR PROGRAM

In 2018, a need was recognized to support a broad range of unique use cases that had been demanded by the global FHIR community. The **FHIR Accelerator Program** emerged from that need (HL7

International, 2019). It was designed to assist communities and collaborative groups across the global health care spectrum in the creation and adoption of high quality FHIR Implementation Guides or other standard artifacts to move toward the realization of true health data interoperability. In addition to the **Argonaut Project** and the **DaVinci Project**, six other projects have been added to the highly collaborative and integrated program. Participants in FHIR Accelerators include providers, payers, government agencies, consumers, pharmaceutical companies, health IT companies, platform developers, and others interested in using FHIR in specific contexts of use.

Gravity Project

The Gravity Project's mission is to create and maintain a consensus-building community to expand available Social Determinant of Health core data for interoperability and to accelerate standards-based information exchange by leveraging FHIR. In doing so, Gravity convened broad international stakeholder groups to identify and harmonize social risk factor data for interoperable electronic health information exchange.

CARIN Alliance

The CARIN Alliance is a coalition of providers, payers, consumers, pharmaceutical companies, consumer platform companies, health IT companies, and consumer-advocates who are working collaboratively with other stakeholders in government to overcome barriers in advancing *consumer-directed data exchange* across the U.S.

CodeX (Common Oncology Data Elements eXtensions)

CodeX has built a community to accelerate interoperable data modeling and applications leading to step-change improvements in cancer patient care and research. More recently, the remit of CodeX has grown to include the domain of cardiovascular diseases and genomics.

FAST (FHIR at Scale Taskforce)

FAST provides an infrastructure framework to be used across the FHIR Accelerator program. Although initially conceived and staffed by members of the Office of the National Coordinator for Health IT (an arm of the US Department of Health & Human Services), it has been integrated into HL7 and is supported by private-sector companies, academic health systems, and global not-for-profit organizations. FAST implementation guides identify standards to address security, identity, end-point directories and other, core capabilities of a national-scale health IT infrastructure.

HELIOS

After 3 years of collaboration with international public health organizations, the Helios Accelerator project has coalesced with other members of the FHIR implementation community. Helios has a broad-ranging remit to collect diverse public health data, enable interoperable knowledge resources among public health agencies, and to serve as a vehicle for seamless global data exchange.

Vulcan

The vision of the Vulcan Accelerator is to connect and align clinical research and healthcare. Vulcan is comprised of representatives from government agencies, academia, technology companies, standards development organizations, patients, and industry consortiums. Vulcan brings together stakeholders across the translational and clinical research community in order to bridge existing gaps between clinical care and clinical research, strategically connect industry collaboratives, maximize collective resources, and deliver integrated tools and resources.

Adoption of HL7 FHIR by the U.S. Federal Government

The growth in adoption of FHIR by the healthcare industry has been accompanied by growing support for FHIR by the U.S. federal government. The timeline, shown in Figure 1, below, provides a simple graphic representation of the processes, collaboration, and government support for FHIR.

Figure 1. Timeline of key milestones in FHIR adoption within the United States



December 31, 2022 marks a significant date for the health IT community (*An Upcoming Milestone in Our Interoperability Journey*, 2022). On this date, health IT vendors developing products (such as electronic health record systems) or modules that they wish to be certified under the ONC Cures Act must demonstrate a number of capabilities including support for:

- Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) Release 4.0.1
- FHIR US Core Implementation Guide (v3.1.1, v4.0.0, or v5.0.1)
- HL7 FHIR Bulk Data Access (Flat FHIR) (v1.0.1, or v2.0.0)
- SMART Application Launch Framework Implementation Guide Release (v1.0.0, or v2.0.0)

The capabilities defined in these specifications will provide both a standardized, open API (i.e., FHIR) and a defined content set known as the U.S. Core Data for Interoperability (USCDI). The USCDI includes data elements such as demographic information, allergies, medications, laboratory test results, and more. The full list is available from the ONC website. Together, these capabilities facilitate interoperability in clinical settings using certified health IT on a foundation fertile for innovation. Application developers are creating new approaches to ensuring that patients and their caregivers, health care providers, insurers, public health agencies, accountable care organizations, and others can access and use health data for managing and improving health.

The HL7 Standards Implementation Division

With the growing interest in FHIR throughout the world, organizations began to implement FHIR in unique and innovative ways. This engendered new communities with highly varied use cases and differing approaches to implementation. These unique and differing approaches were even evident within FHIR Accelerator Program participants. First, the programs a new, novel, and, in many cases highly innovative. The SID helps these new communities learn about and leverage FHIR. The other meaning is more like “divergent”. The SID helps establish and promote best practices that help scale preferred approaches throughout the ecosystem of implementers. Furthermore, many implementers

struggled with closing the gap between having a technical standards specification and implementing those standards in working software. To help address these unmet needs, HL7 created and launched a Standards Implementation Division.

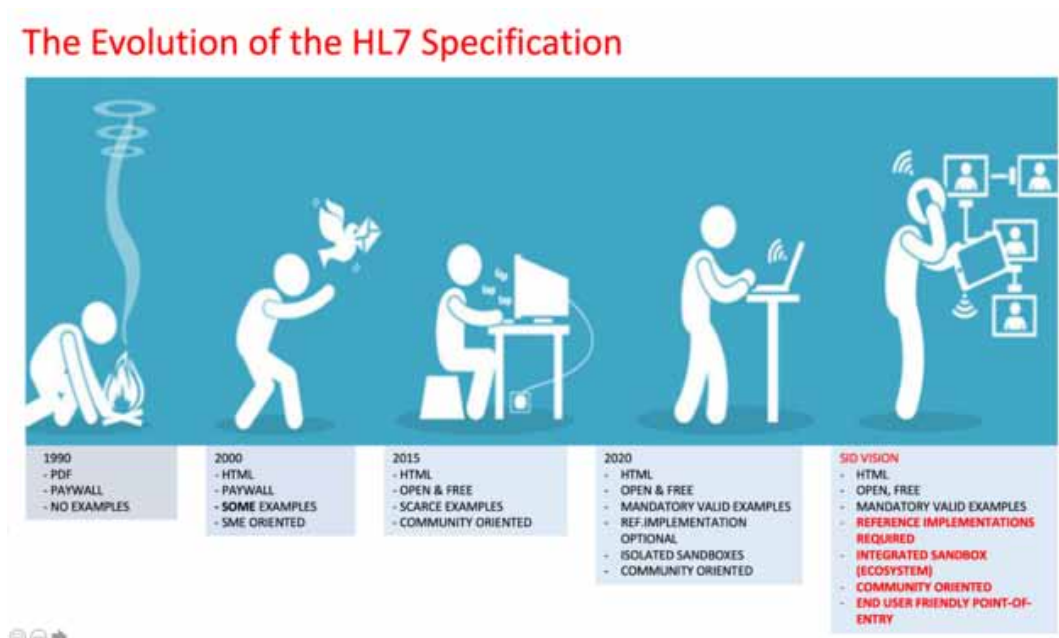
As a standards development organization, HL7 has as a primary focus the development of health data standards. The new HL7 Standards Implementation Division concentrates on helping communities discover, access and understand the specifications as well as test their implementations, while the HL7 Standards Development Division focuses on the development and maintenance of HL7 specifications. Virtuous cycles of feedback are the key to collaboration between divisions. Feedback from implementation experience helps identify areas where the standards development activities can continuously improve to advance the consistency and ease of implementation.

Because each locality, country or region have specific business and technical requirements, the Division was created with that perspective. Moreover, the sustainability, with both human and fiscal resources, was made a fundamental component of any program within the Division. Lastly, the new Division recognized that the voices of the community were paramount, and that success required a constant and consistent feedback loop.

Closing the chasm between the specification and its implementation acquired a new meaning.

Figure 2 illustrates the growth process of HL7 standards and the natural progression toward a Standards Implementation Division.

Figure 2. The evolution of HL7 specifications



At the heart of the development of the Division lay five key components: 1) *Program management*, 2) *Community outreach*, 3) *Best practices* programs, 4) diverse *Education programs* (with testing, certification, credentialing, and partnering), and 5) a flexible, expansive *Ecosystem* (with reference implementations, dynamic and continuous testing, innovative Connectathons, and an updated, easily accessible Sandbox). It is imperative that organizations and individuals will have a path for progressive adoption of these capabilities.

The new Standards Implementation Division will not emerge de novo or even all at once. Some programs will be in place by early in 2022 and throughout the year. Others will be developed, in close collaboration with our partners and communities, in 2023. We will review our challenges and celebrate our successes next year.

Program Management

The HL7 Standards Implementation Division will oversee the HL7 FHIR Accelerator Program to help ensure that they are well managed and coordinated with the HL7 community. In addition, it will provide services to projects including the FHIR accelerators.

Community Outreach

The outreach program of the HL7 Standards Implementation Division will expand opportunities with other industry organizations both commercial and academic to collaborate in promoting interoperability, developing workforce, aligning on policy initiatives, and educating the broader community.

Education

The HL7 Standards Implementation Division will expand our current educational offerings to include course offerings for different audiences including executives, analysts, architects, and developers. We will offer education and a variety of formats including in person, synchronous, asynchronous and hands on formats. HL7 will partner with academic, commercial and other industry organizations to expand the reach of standards of education.

We are expanding certification programs that will recognize individuals we have completed courses ranging from basic FHIR standards to more advanced skills such as SMART on FHIR or CQL. As FHIR adoption continues to grow, certification will identify individuals with the skills necessary to support organizations on their interoperability journey.

Best practice programs

The HL7 Standards Implementation Division is developing and promoting best practice programs to disseminate the knowledge and skills necessary to implement FHIR.

An ecosystem for discovery and testing

FHIR's ever-evolving community recognizes that standards require testing and ongoing improvements in the standard based on experience. Historically, standards organizations author standards and rely on the industry to interpret and implement them, while the HL7 Standards Implementation Division endeavors to create a community reference to unify these practices. Current FHIR standards process emphasizes the importance of regular testing of the FHIR core standard as well as implementation guides developed upon them. HL7 and community members regularly host Connectathons to support this testing.

A centerpiece of the HL7 Implementation Division's work is to create a testing ecosystem called *The Foundry* to support and expand this testing paradigm. In fact, it will offer a unique testing environment so critical to an expanding community of organizations implementing the standards and eager to leverage the implementation guidance. This will inevitably reduce inconsistencies and minimize conflicts among complementary implementations. *The Foundry* will initially include reference implementations based upon FHIR implementation guides as well as provide support for infrastructure components defined by FAST and others. In the future, the Foundry will provide an environment for testing commercial applications as well.

FUTURE CONSIDERATIONS

The FHIR interoperability standard will be the foundation by which we transform healthcare globally. The HL7 activities described in this article will be the catalyst for this transformation. In the very near future, the division will almost certainly foster an open and growing global community advancing FHIR. Moreover, the SID will rapidly promote the full diversity of perspectives of health information stakeholders (for example, patients and caregivers, developers of consumer-facing applications) in the context of intended use for our interoperability standards.

In the very near term, the division will become a recognize leader, if only by example, for growing the health and informatics workforce core competencies in interoperability standards. It is envisioned that the implementation division will promote the establishment a virtuous feedback cycle between standards implementation and development. The vision includes the seamless integration into a learning health system, to which so many have aspired. The division has already been working closely with global regulatory bodies to ensure that health interoperability standards are well suited for the contexts of national and jurisdictional use. In the future, healthcare data interoperability will be dependent upon that goal.

REFERENCES

- Apple, Inc. (2018a). *Apple announces effortless solution bringing health records to iPhone*. Apple. <https://www.apple.com/newsroom/2018/01/apple-announces-effortless-solution-bringing-health-records-to-iphone/>
- Apple, Inc. (2018b, March 6). *Institutions that support health records on iPhone and iPod touch*. Apple. <https://support.apple.com/en-us/HT208647>
- Confluence. (2022). *Da Vinci—Da Vinci—Confluence*. Confluence. <https://confluence.hl7.org/display/DVP/Da+Vinci>
- HL7 International. (2019). *HL7® Launches FHIR® Accelerator Program*. HL7. http://www.hl7.org/documentcenter/public/pressreleases/HL7_PRESS_20190211.pdf
- HL7 International. (2016, April). *Events*. HL7. <https://www.hl7.org/events/partners.cfm>
- JASON Report Task Force. (2014). *Final Report* (p. 21). Health IT Policy and Health IT Standards Committees. https://www.healthit.gov/sites/default/files/facas/Joint_HIT_JTF%20Final%20Report%20v2_2014-10-15.pdf
- Procious, J. (2022). *Argonaut Project Home—Argonaut Project—Confluence*. Agronaut. <https://confluence.hl7.org/display/AP/Argonaut+Project+Home>
- Smith, J., Myers, T., & Paul, P. (2022). An Upcoming Milestone in Our Interoperability Journey. *Health IT Buzz*. <https://www.healthit.gov/buzz-blog/healthit-certification/an-upcoming-milestone-in-our-interoperability-journey>

Charles Jaffe, MD, PhD is the CEO of HL7. He has served in various academic positions in the Departments of Medicine and Pathology, as well as in the School of Engineering. Prior to joining HL7, he was the Senior Global Strategist at Intel. In addition, he led a national research consortium, founded InforMed, a consultancy for research informatics, served as the VP of Medical Informatics at AstraZeneca, and the VP of Life Sciences at SAIC. Currently, he is the Visiting Scholar at the University of California San Diego. Dr. Jaffe has been the contributing editor for several journals and has published on clinical management, informatics deployment, and healthcare policy.

Daniel Vreeman, PT, DPT, MS, FACMI is a biomedical informatician, clinician, and expert in health data standards. Prior to joining HL7, Dan was the Director, LOINC and Health Data Standards with the Regenstrief Institute, Inc. and the inaugural Regenstrief–McDonald Scholar in Data Standards at the Indiana University School of Medicine. From 2006 to 2019 he led the development of LOINC, an open vocabulary standard for health measurements, observations and documents that is now used in more than 175 countries. Dan has published numerous scientific papers, guides and articles, and is the author of the book LOINC Essentials. He is currently the Chief Standards Development Officer at HL7.

Diego Kaminker is the founder of Kern IT, in Buenos Aires, Argentina. More than a decade ago, he created the HL7 Distance Learning Program, which now provides education and training to thousands of students on five continents. Throughout his career, he has been on the faculty of universities around the world. For these accomplishments, he has been elected as a Fellow of the International Academy of Health Sciences Informatics. Currently, he is the Deputy Chief Standards Implementation Officer of HL7.

Viet Nguyen, MD, MS is the founder and principle of Stratametrics, a consultancy for medical informatics that focuses on value-based care and healthcare quality. Prior to that he was initially the CMIO of Lockheed Martin and later the CMIO of Leidos, a consultancy to both the government and private sectors. He is the technical lead for the Da Vinci Project and the first Chief Standards Implementation Officer of HL7.