HL7 FHIR in the Real World Reducing Physician Burden & Enabling Patient Engagement

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AMDIS Ojai 16 June 2022





Agenda

- Introduction to FHIR: Origins, Community, Growth
- bFHIR & other standards
- FHIR Toolbox
- FHIR Implementation Division
- FHIR Enablement: Clinician & Patient empowerment
- FHIR in Government Regulation
- FHIR Accelerators
- Public Health on FHIR
- FHIR R5

How will we cover that in 45 minutes?

To the dismay of many and to the delight of some, we will not have the annual "Inside the Beltway"*.



*Ask Howard if you really need to know.



Introduction to FHIR



The API Economy

The idea of an *API economy* is over a decade old¹...

and many established enterprises correctly view APIs

as a key to unlocking their digital transformation.²

¹ K Lane, API Evangelist, Sep 2010
² T Wang & M McLarty, HBR, Apr 2021



FHIR is the Keystone of the Healthcare Ecosystem

After 35 years of making the standards

that powered half of all healthcare data around the globe,

HL7 reimagined data sharing the way other industries

had successfully done...open APIs.



Why is FHIR unique in healthcare?

FHIR is more than the API.

FHIR is both the technology and the agreement on the meaning of the data.



What really is FHIR?

- FHIR Fast Healthcare Interoperability Resources®
 - An HL7 next generation standard
 - Enables two or more computer systems to exchange data
- FHIR "resources" are standardized & reusable
 - Patient, practitioner, organization, device request
- FHIR supports common exchange methods
 - REST, messaging, documents and services
- FHIR supports the spectrum of integration
 - Mobile phone apps, EHR-based data sharing, institutional solutions
- FHIR enables existing use cases & provides for future innovation



The Emergence of HL7 FHIR

The growth of FHIR has been an organic process, enabled by a global community of dedicated developers, and accelerated by diverse groups of independent stakeholders and government agencies that were committed to FHIR implementation.





Diverse Support for FHIR

Technology Vendors & Manufacturers **Global Health Systems & Universities** Healthcare Providers & Users Associations & Professional Societies Public & Private-sector Researchers **Government Agencies & Regulators** Payers: Public & Private Pharma Industry Patients!



From the start, HL7 FHIR was a global phenomenon

More than 50 countries around the world participate in the development, implementation, support, and education of the FHIR standards. The communities are more than international. They are diverse and supportive of an open process and an open standard that is provided free of charge or royalty.



HL7's Global Reach



- 50+ Countries
- 1600+ Individual Members
- 500+ Corporate Members
- 4000+ Volunteers

HL7 FHIR Timeline





Content: What does a Resource represent?

• Clinical Perspective:

The resource content defines a small amount of focused clinical and administrative information.

• Implementer Perspective: Additional Infrastructural stuff too.





A tour of a FHIR Resource Definition*

- Scope and Usage Notes
- Resource Content (UML and XML)
- Terminology Bindings
- Constraints
- Implementation Issues
- Search Parameters
- Examples, Profiles, Formal Definitions
- Mappings to RIM, CDA, v2, etc

Do it yourself: http://hl7.org/fhir/patient.html

Discussion: FHIR BASE SPEC vs. FHIR NATIONAL SPEC http://hl7.org/fhir/us/core/stru cturedefinition-us-corepatient.html

*These are just the names. This concept is covered in two hours in a much more in depth course.



Exchanging Resources

FHIR supports 4 exchange mechanisms, or maybe 8.





Subscription

The content is unchanged regardless of the paradigm or exchange method.





HL7 is built by ever-growing Communities



The further from the center, the larger the community, and the more removed from standards development.





FHIR APIs & Resources



FHIR Resources







FHIR Toolbox



FHIR Tool Box



HIR

The FHIR Toolbox

- HL7 FHIR Core Spec
- HL7 FHIR Base IGs
- HL7 FHIR IGs
- Smart-on-FHIR
- CDS-Hooks
- Bulk FHIR Data Access
- CQL





Applying Knowledge to the FHIR Tool Box

- How can we apply medical knowledge in daily practice?
- How can we overcome limitations of our EHRs and use/integrate other apps or services?
- Which are the different scenarios?
- Which FHIR tools apply?



Applying CDS Hooks for Clinicians & Patients

Independent Knowledge (CDS) Service

Provide any EHR with a service: given context and data, apply knowledge and recommend a course of action

Embedded/Shared User Interface

Show information in a different way, integrated with the EHR/Patient Portal





Applying CQL for Clinicians & Patients

Data Extraction

Extracting data from the EHR for research, or apply discovery algorithms, or to calculate quality clinical / epidemiological measures

Population Health Measures

Leveraging a service to calculate measures on a given population -> (numerator / denominator)









Who leverages CDS Hooks









From the very beginning of FHIR development, it was clear that there was a significant gap between the creation of the standard and its implementation.



HL7 Implementation Division: Closing the chasm





Achieving the Mission of the Implementation Division

Our aim is to create a cohesive set of programs, which we call *Value Propositions* and which were launched in phases, beginning in Q1 2022.



Achieving the Mission

- Implementation program management: Accelerators and community
- Community outreach programs: Access and Discovery of the Specs, Proactive outreach of specific stakeholders, Special Events
- Best practices programs: Playbooks "from the spec to the wire", Cybersecurity
- **Reference implementation programs:** Dynamic, continuous API testing beyond examples from Connectathons, Sandbox, and Ecosystem
- Education programs: Certification Testing, Credentialing, Partnering





FHIR Ecosystem: Code name "The FHIR Foundry"



FHIR

Foundry Timeline

Current activities (2021-22)

- Evaluating the contents, refining our requirements and roadmap.
- Proposed goals
 - "End-user" Discovery of Reference Implementation
 - Automated Testing
 - Evaluating internal clients without deploying reference servers

Proposed Roadmap

- Q3/Q4 2022
 - Complete the transfer of Logica Sandbox to HL7
 - Integrate existing Reference Implementations
- 2023: Testing capabilities.
 - Aspiration: All Reference Implementations in the Foundry
- 2024: Foundry available for external projects







Global Community Outreach

New Virtual Events

• FHIR in the sky with Clouds

- How to do "the same basic chores" using cloud vendors offerings.
- Pilot in September WGM

• FHIR Data Science Institute:

- From Bulk FHIR to R/Python, OMOP, FHIR+ML
- Cybersecurity Specific Event: API
- Patient Empowerment Specific Event:
 - Patient Empowerment (Access / Control / Collaboration) through HL7 Standard based solutions (FHIR for Patients)



Integration of Standards Development & Implementation Divisions




FHIR for Clinicians & Patient Empowerment



Impact of FHIR on CMS Technical Standards



*CMS Payer to Payer API not enforced in 2022



FHIR in ONC Technical Standards

HL7 FHIR R4F

Health Level 7 HL7 Version 4.0.1 Fast Healthcare Interoperability Resources URL: <u>http://hl7.org/fhir/R4/</u>

SMART IG / OAuth 2.0

SMART Application Launch Framework Implementation Guide Release 1.0.0, November 2018 URL: <u>http://hl7.org/fhir/smart-app-launch/history.html</u>



OpenID Connect

OpenID Connect Core 1.0 Incorporating Errata Set 1, November 8. 2014 URL: <u>http://openid.net/specs/openid-connect-core-1_0.html</u>

Content & Vocabulary Standards

USCDI United States Core Data for Interoperability USCDI, February 2020
URL: https://www.healthit.gov/isa/us-core-data-interoperability-uscdi



HL7 FHIR Communities



The further from the center, the larger the community, and the more removed from standards development.



The FHIR Ecosystem: Diverse and Expanding

• Developers

Servers, applications, middleware, devices, analytics pipelines, & standards

• (End) Users

Clinicians and care providers, patients, administrators, payers public health, & researchers

 Boundary spanning roles Informaticians, policy-makers, innovators and other ruckus-makers





FHIR in Clinical Research

- FHIR-OMOP Initiative
 - HL7 and OHDSI have a comprehensive SOU for collaboration
 - Connect the FHIR data resources to the OMOP data model
 - <u>https://omoponfhir.org/</u>
- FHIR at NIH
 - <u>https://datascience.nih.gov/fhir-initiatives#:~:text=Using%20FHIR%20to%20Catalyze%20Biomedical%20Research&text=It%20enables%20researchers%20to%20more,analyzed%2C%20shared%2C%20and%20combined.</u>
- FDA Real-world evidence
 - <u>https://www.fda.gov/media/151833/download</u>
- FHIR Accelerators: CodeX, Vulcan
 - <u>https://confluence.hl7.org/display/COD/CodeX+Home</u>
 - <u>https://confluence.hl7.org/display/VA/Vulcan+Accelerator+Home</u>



Implications for Clinical Care & Research

- Standardization of data collected and shared across EHRs
- Interoperable applications: FHIR data and APIs (SMART on FHIR)
- Standardized clinical decision support algorithms (CQL)
- Reducing burden of *prior authorization*
- Reducing burden of *quality measure reporting*





Courtesy: Monty Python

Reducing Clinician Burden

Clinical workflow: EHR Workgroup

Getting the right data when and where it is needed in the format in which it can be used.

• Prior authorization: Da Vinci Project

A common, but often inefficient process. FHIR can enable direct submission from the EHR See: <u>Da Vinci Prior Authorization Support (PAS) FHIR IG</u>.

• Standards Implementation: Clinical Interoperability Council

An HL7 Work Group intended as nexus of communication and bridge between standards development activities and the clinical community.



FHIR Accelerator Program: Clinician Impact



Patient Engagement: Whole Person Health*

Coordinated health, behavioral health, and social services in a person-centered manner.

Developed by the Gravity Project

Enabled by academic health systems, VA, Departments of health, patient advocacy groups

* NIH National Center for Complementary & Integrative Health



How FHIR enables Whole Person Health

Gravity Project FHIR Implementation Guide for connecting and communicating social determinants of health data



Patient Engagement: Health System Support

- Patient requests
 - Clinical record access HIPAA Individual Right to Access, Information blocking, highly variable state laws
 - Record portability
 - Patient reported outcomes & patient contributed data
 - Advanced directive
- Record change management
 - Policy before technology
 - Technical solutions alone cannot resolve issues of authentication, data burden, provenance, and clinical implications.
- Collaboration with legal departments, public agencies, patient advocacies is critical.







If you work with health data, life will be messy.





Syntax Standards

Messages, Documents, APIs, CDMs

HL7v2, C-CDA, 🌰 FHIR, OMOP

Semantic Standards

Vocabulary/code systems

LOINC, RxNorm, HPO, ICD, UCUM

Making sense of the mess requires multiple data standards.



Using codes in FHIR Resources

Example: SARS-CoV-2 Test

Observation

Here we use a term from <u>LOINC</u> to identify what specific lab test this specifies.

And a term from <u>UCUM</u> to identify the units of measure in computable form.



{				
····"resourceType": "Observation",				
"id": "5578e199-8cc9-4c4f-817f-9bc95db9a5cf",				
····"status": "final",				
<pre>"category": [{"coding": [{ "display": "laboratory"}]}],</pre>				
····"code": {				
····"coding": [
····{····{				
"system": "http://loinc.org",				
····· ·code": "94505-5",				
display": "SARS-CoV-2 (COVID-19) IgG Ab [Units/volume]				
in Serum or Plasma by Immunoassay"				
·····]·····]·····]				
·····],				
•••••"text": "SARS-CoV-2•(COVID-19)•IgG•antibody, Blood"				
·····},				
<pre>"subject": {</pre>				
····· "reference": "Patient/b8afcc95-c6f5-418a-b14d-800eac18ad8c"				
····},				
····"encounter": {				
···· "reference": "Encounter/58d03aa8-9acc-4a41-81eb-12efbb2ef697"				
••••},				
····"effectiveDateTime": "2021-08-03T17:26:37-05:00",				
····"issued": "2021-08-03T17:26:37.091-05:00",				
····"valueQuantity": {				
····"value": 56.8,				
····"unit": "AU/mL",				
<pre>"system": "http://unitsofmeasure.org",</pre>				
<pre>''code": "[arb'U]/mL"</pre>				
····}				
} 15				

"CodableConcept" in FHIR Resources

Coding

System Identity of the code system

Code Symbol defined by the code system

Display Representation defined by the code system

Version (Optional) Stated version of the code system

Text Plain text representation of the concept





US Core Data for Interoperability v2





Life is hard

Use of standard terminologies not ubiquitous (yet).

Mapping to standard terminologies is non-trivial.

This is not (just) an I.T. problem.

Benefits don't always accrue to those who have to do the work of standardization.



Clinical Measures: Variation Abounds

CODE 34626D 39312D ARTDIASBP nvArtBP 25284D 2737317 6881D 3800DBP 77934D 919109 DiastBP PBPD POBPD

NAME

Arterial BP Diastolic ABP Diastolic Arterial Diastolic BP Arterial BP DBP BP (NIBP) **Diastolic Blood Pressure #1 BP** Diastolic BP **BP** Manual Diastolic **Diastolic Blood Pressure** Diastolic Pre-blood Pressure Diastolic Post-blood Pressure Diastolic



Units of Measure: Variation Abounds

Blank %	FL K/CMM	TH/UL THOU/CMM	X10(3) 1000/UL
/100 W	K/CCM	thou/cmm	X10(3)/MCL
/CMM	K/CU MM	thou/mm3	X10(3)/UL
СММ	K/CUMM	THOU/UL	X10(6)/MCL
10 3 L	K/MCL	THOUS/CU.MM	X10*9/L
10X3UL	K/mcL	THOUS/MCL	X10E3/UL
10^3/UL	K/UL	THOU/mcL	X1000
10*3/uL	k/uL	THOUS/UL	X10X3
10?3/uL	KU/L	THOUS/UL	X10^3/UL
10E3/uL	K/MM3	THOUSAND	x10
10e3/uL 10e9/L	K/mm3 LB	THOUSAND THOUSAND/UL	X10 3/ul X10E3/UL
E9/L	PLATELET COUNT	U	X10E3
BIL/L	T/CMM	X 10(3)B/UL	K/A L
BIL/L	TH/MM3	X 10(3)/UL	K/B5L
CU MM	TH/MM3	X 10(3)	

Raebel MA, Haynes K, Woodworth TS, et al. Electronic clinical laboratory test results data tables: lessons from Mini-Sentinel. Pharmacoepidemiol Drug Saf. 2014 Jun;23(6):609-18.







FHIR also defines Terminology Services

CodeSystem

Defines the existence, metadata, and content (optionally) of a code system.

ValueSet

A set of codes drawn from one or more code systems.

ConceptMap

A statement of relationships from one set of concepts to another set.

4.0.2 Index The Terminology Module covers the following: Resources CodeSystem ConceptMap TerminologyCapabilities NamingSystem ValueSet **Terminology Service** Terminology Service Documentation Operations CodeSystem ValueSet ConceptMap \$lookup \$expand \$translate \$validate-code \$validate-code \$closure \$subsumes \$find-matches



FHIR supports other Standards and Standards Platforms

- Foundational web standards: JSON, XML, HTTP, OAuth, and others
- SMART App Launch: Client App to server
- SMART Backend services: Server to server
- FHIR integration with other HL7 standards: V2 and CDA
- Direct Secure Messaging: FHIR Resources as a payload
- TEFCA: FHIR point to point exchanges or broker FHIR-based exchanges
- OMOP: FHIR API functionality delivers OMOP-sourced data
- Other components of the FHIR platform:
 - CDS Hooks (clinical decision support)
 - Clinical Quality Language (CQL)
 - FHIR Path (e.g., Fetching templates)





FHIR in Government Regulation



US Federal Agencies Accelerated FHIR Adoption through Regulation

On a global scale, government agencies embraced the implementation of FHIR through commitments to national interoperability programs.

In the US, two agencies were instrumental in the implementation of FHIR through regulation.

Increasingly, the DHHS has recognized FHIR beyond the legislative boundaries created two decades ago.



CMS INTEROPERABILITY & PATIENT ACCESS FINAL RULE





ONC Final Rule establishes the requirement for FHIR for EHR certification¹

"The API certification criterion requires the use of the Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard Release 4..."



¹Required by December 2022



FHIR Accelerators



HL7 FHIR Accelerator Program

Begun nearly 5 years ago, the program assists

implementers across the healthcare and research

spectrum in the creation of FHIR implementation guides

and critical public- and private-sector solutions.



















The Argonaut Project was formed only days after the JASON Task Force report identified open APIs as the future of interoperability.

This private sector initiative is committed to advancing industry adoption of modern, open interoperability standards.







The CARIN vision is to rapidly advance the ability for consumers and their authorized caregivers to easily get, use, and share their digital health information when, where, and how they want to achieve their goals.





Member-driven HL7 FHIR Accelerator, building a community to accelerate interoperable data modeling and applications leading to step-change improvements in cancer patient care and research.

Codex is now expanding its remit to include cardiovascular diseases and genomics.





A private sector initiative that addresses the needs of the Value Based Care Community by leveraging the HL7 FHIR platform. Da Vinci operates as a unique collaboration between payers and providers. Its work has been cited in CMS regulation.





The FAST Accelerator was developed over 3 years as a collaborative effort within ONC.

FAST will identify FHIR resources, scalability gaps and possible solutions, as well as analyses that will address current barriers and accelerate FHIR adoption at scale.



To create and maintain a consensus-building community to expand available SDOH core data for interoperability and accelerate standards-based information exchange by using HL7 FHIR.

Gravity not only provides the data sets for social determinants of health, but leverages FHIR to enable integration into clinical workflow.




Before becoming a FHIR Accelerator, the CDC developed FHIRenabled technologies over the last 4 years. The goal of Helios is to help overcome barriers to adoption and to promote market-based solutions that are compatible with nationwide interoperability priorities, and ensure scalability and long-term sustainability of data modernization.

https://confluence.hl7.org/display/PH/Helios+FHIR+Accelerator+for+Public+Health+Home





Vulcan was envisioned as a means of connecting the data from clinical research and healthcare

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.





Public Health on FHIR



Public Health on FHIR





Helios Public Health FHIR Accelerator

- Priority 1: Make public health data available at scale
 - Bulk Data on FHIR supporting R4B data elements
- Priority 2: Align and optimize data sharing
 - Near real-time from EHR FHIR endpoints
 - CDC Death on FHIR (morbidity and mortality data) pilot in 7 states
- Priority 3: Deliver aggregate data to public health
 - Bed count, ER status, critical supply (ventilator)
 availability





HL7 Public Health Work Group

- Immunization Decision Support Forecast (ImmDS)
- Reporting (eCR Now Electronic case reporting)
- NHSN Reporting: Adverse Drug Events
- Occupational Data for Health (ODH)
- WHO Emergency Care Guideline (SMART Antenatal Care)
- Clinical Decision Support for Chronic Pain Management and Shared Decision-Making
- Bidirectional Services eReferrals



HL7 Public Health Work Group (2)

- SMART Health Cards: Vaccination & Testing
 - QR codes & human-readable text for any portion of the clinical record
- Situational Awareness for Novel Epidemic Response (SANER)
 - SARS-Covid demand for hospital beds, vital equipment
- Vital Records: Birth and Fetal Death Reporting
- Vital Records: Mortality and Morbidity Reporting
- Vital Records: Common Profiles Library



myvaccinerecord.cdph.ca.gov

Personal Digital COVID-19 Vaccine Record

GON

State of California



Vaccination Information:

Name: Charles Jaffe

Dose #1 Date: 01/13/2021 Dose #1 Type/Mfr.: Moderna

Dose #2 Date: 02/10/2021 Dose #2 Type/Mfr.: Moderna

SMART

Digital Documentation of COVID-19 Certification (DDCC)

- Verifiable, validated confirmation of immunization, available on smart phones as readable records or as QR codes
- Consistent with WHO Guidance in March 2021
- Now available in 28 states and 8 countries
- Supported by ONC and over 300 privatesector organizations

https://smarthealth.cards/



CDC Computable Care Guidelines

- SMART
- FHIR
- CQL (Clinical Query Language
- Terminology Standards

🖲 🔘 🔍 🚥 Pain Management Summary	•				
4 P C B B B	hrq-cds.github.lo/AHRQ-CD5-Connect-PAIN-MANAGEMENT-SUMMA	RY/		1 🗢 🗚	😧 🖈 🗅 🗄
🍘 CDS Connect	Brenda Jackson		5	Total Entries	Total Flags
Pertinent Medical History	Factors to Consider in Managing Chronic Pain				
Conditions Associated with Chronic Pain Risk Factors for Opioid- related Harms	TAKE NOTICE: This summary is not intended for patients who are undergoing end-of-life care (hospice or palliative) or active cancer treatment.				
Pain Assessments (0)	🔋 Pertinent Medical History (5) 🧿				~
Historical Pain-related Treatments (0) Risk Considerations (0)	Conditions Associated with Chronic Pain O				
	Name #	Status @	Start	End e	Recorded #
	Fibromyalgia (disorder)	active	2013-Apr-05 (age -9)		2013-Apr-05
	Lumbar post-laminectomy syndrome (disorder)	active	2012-Feb-01 (age -10)		2012-Feb-16
	Low back pain	active	2008-Nov-12 (age -13)		2008-Nov-12
	Risk Factors for Oploid-related Harms (
	Name #	Status •	Start Ø	End e	Recorded #
	Ø Moderate major depression (disorder)	active	2016-Dec-02 (age -5)		
	0 65 years or older	active			







FHIR R5



The Future of R5

- Timeline for release
 - Ballot September 2022
 - Publication Q1 2023?
 - Why did it take 4 years to ballot? The short answer: Everyone was too busy implementing and further profiling R4
- Subscriptions (framework + resources) Draft
 - Normative in R4b
- Patterns (relationships between resources) Informative
- Evidence Based Medicine (new resources) Draft
- Permission (new resource) Draft



Future of FHIR: Beyond R5

- Health data lives in the cloud. FHIR enables its transitions.
- All patient care is driven by evidence. Care is enabled by FHIR-based tools and supported by AI.
- FHIR facilitates a virtuous Learning Health System.
- FHIR enables the seamless integration of clinical care data and public health systems.
- Clinical documentation is supported by FHIR-enabled voice-to-text entry, including patient-reported symptoms.
- FHIR reduces the barriers between patient care and real-world clinical trials.
- Clinical systems support the development of next-generation releases of FHIR.
- FHIR utilization becomes as ubiquitous as other APIs, so that its use no longer will be mandated, but adopted by the universe of end-users.



"FHIR utilization becomes as ubiquitous as other APIs."

Civilization advances by extending the number of important operations which we can perform without thinking of them.

> Alfred North Whitehead British Mathematician





Alfred North Whitehead

Edited by David Ray Griffin and Donald W. Sherburne



Questions



Thanks





