

HL7[®]
International

THE OFFICIAL PUBLICATION
OF HEALTH LEVEL SEVEN[®] INTERNATIONAL

NEWS

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Keeping Us Together While Apart

Patient Empowerment Work Group

European mHealth Hub

FAIR4Health Research

New Federal Final Rules



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HL7 News

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Update from Headquarters

The Impact of COVID-19



By Mark McDougall,
HL7 Executive Director

COVID-19 Prompts Cancellation of Events

One week before the HIMSS conference was scheduled to start, HL7 leadership made a bold decision to not staff or produce our usual theater of about 30 presentations within our booth at the HIMSS convention. This decision was made due to concerns and risks related to the outbreak of COVID-19 (coronavirus) and out of an abundance of caution for public health and safety. At the time HL7 leadership made this decision, there was only one other company (Cisco) that had publicly announced that they were withdrawing from the HIMSS convention. Later that week, following dozens of additional companies announcing that they too were cancelling their booth, HIMSS announced they were cancelling their convention due to widespread concerns of COVID-19. I applaud HL7 leadership for making the bold decision to be one of the first organizations to announce withdrawal of our participation in the exhibit hall for public health reasons.

Given that the COVID-19 continues to spread and is causing so many deaths, HL7 leadership also made the appropriate decision to cancel our May Working Group Meeting scheduled for San Antonio and the June FHIR DevDays scheduled for Cleveland. In both cases, those who registered for the events received a full refund.

Virtual Activities in Lieu of the May WGM

While the WGM is cancelled, our important work will continue. The May 2020 ballot will proceed as planned. To support ballot reconciliation, HL7 is supporting additional conference calls and Zoom accounts which offer more features. Additionally, we will continue to support the HL7 community by enhancing our tooling platforms, providing online education opportunities and looking for other opportunities to support work groups.

Virtual FHIR Connectathon

Since connectathons are so critical to developing and testing our standards, HL7 produced a virtual FHIR Connectathon on May 13-15. The Virtual FHIR Connectathon will include three days of hands-on FHIR development and testing. This event provides a great opportunity for implementers and developers to gain hands-on experience developing FHIR-based solutions by participating in one of many tracks. As of this writing, over 650 individuals had registered for the event.

To learn more about the FHIR Connectathon, visit the HL7 FHIR Connectathon at:

<https://confluence.hl7.org/display/FHIR/2020-05+Connectathon+24>

Board Changes

As previously announced, we are pleased to welcome three new directors of the HL7 Board of Directors, each serving two-year terms: Viet Nguyen, MD, Julia Skapik, MD and Peter Jordan. Floyd Eisenberg, MD, has also started a two-year term as the Treasurer.

During the January WGM Board Chair, Walter Suarez, MD, thanked Calvin Beebe for his fine leadership as the Board Chair the last two years. He also welcomed the new members of the board of directors and recognized the exceptional contributions over many years from these outgoing board members whose terms concluded December 31, 2019:



Jennifer Covich Bordenick



Russ Leftwich, MD



Nancy Orvis



Line Saele



Mary Ann Slack

We look forward to working with the new board members along with the entire 2020 HL7 Board of Directors that are listed on page 42. On behalf of the HL7 organization, I thank each member of the board for their ongoing leadership, contributions and dedication to HL7.

Nomination Announcement | Dates & Positions

HL7 leadership is critical to supporting the community and advancing interoperability. Nominations for leadership positions will be open May 1-June 15, 2020 and instructions will be emailed on May 1, 2020. Please consider nominating individuals for the following openings.

- Nominations for Board positions, including:
 - Chair-Elect
 - Secretary
 - HL7 Directors (2)
 - Affiliate Director
- Nominations for the following TSC positions:
 - Affiliate representative (1)
 - Administrative Steering Division Co-Chair (1)
 - Clinical Steering Division Co-Chair (1)
 - Infrastructure Steering Division Co-Chair (1)
 - Organizational Support Steering Division Co-Chair (1)
- Nominations for International Council Co-Chairs (2)
- Nominations for various Work Group Co-Chair positions

To make nominations online, please visit: <https://bit.ly/2zYNTis>

Virtual HL7 FHIR DevDays

Now more than ever, it is crucial to continue the important work around the FHIR standard, convene the community and advance interoperability. In support of this, HL7 and Firely are organizing a virtual HL7 FHIR DevDays on June 15-18. Just like the in-person edition, the virtual event will deliver strong educational content including keynotes and tutorials, plus specialty tracks including patient innovation, startup and community tracks. Additional details regarding the program and registration are available at:

<https://www.hl7.org/events/fhir-devdays.cfm?>

For highlights of the 2019 DevDays event produced at the Microsoft Conference Center in Redmond, Washington, you are invited to view a 5 minute video containing brief interviews and insights to DevDays:

<https://www.youtube.com/watch?v=rkhnoYmneXk>

February WGM in Sydney

About 250 attendees participated in our February Working Group Meeting (WGM) and FHIR Connectathon in Sydney, Australia, February 2-7, 2020 at the ICC Sydney Convention Center located at Darling Harbor. The WGM covered the usual activities such as work group meetings, tutorials and a FHIR Connectathon. The WGM also featured a wonderful evening dinner cruise with incredible sightseeing and stunning views of the Sydney Opera House from the ship. The Sydney WGM was produced by HL7 Australia under the leadership of their chair, Jason Steen, who dedicated countless hours to plan and produce the WGM. HL7 is pleased to recognize Jason and his team for producing the Sydney WGM. The photos below provide highlights from the enjoyable event.

Scenes from the February 2020 Working Group Meeting in Sydney, Australia.



Milestones Reached

We are pleased to recognize key milestones among our members and HL7 affiliates.

Congratulations to these HL7 affiliates who have been in operation for more than 20 years:

- HL7 Australia
- HL7 Canada
- HL7 Finland
- HL7 Germany
- HL7 Japan
- HL7 Netherlands
- HL7 New Zealand
- HL7 UK

HL7 members for 25-29 years:

- Hans Buitendijk, FHL7
- Albert Edwards
- Ted Klein, FHL7
- Virginia Lorenzi, FHL7
- Charles Meyer, FHL7
- Doug Pratt, FHL7
- John Santmann
- Mead Walker, FHL7

HL7 members for more than 30 years:



Gary Dickinson, FHL7



Ed Hammond, PhD, FHL7



Clem McDonald, MD, FHL7

Congratulations and a thousand thanks for reaching these incredible milestones and for their tremendous dedication to HL7 and the industry.

Distance Learning Courses

Given the lockdown that many of us are experiencing, it is timely to make you aware of two valuable online courses that will start soon. Please visit the URLs for additional information on these online classes that are direct for the source, HL7.

HL7 Fundamentals

May 28 – August 20, 2020
12-Week Online Course
www.hl7.org/training/hl7-fundamentals.cfm

HL7 FHIR Fundamentals

July 16 – August 13, 2020
4-Week Online Course
www.hl7.org/training/fhir-fundamentals.cfm

Benefactors and Supporters

We are very appreciative of the organizations for their ongoing support of HL7 through their membership at the HL7 benefactors and gold member levels, who are listed on page 17. Their support is very much needed and sincerely appreciated.

We are pleased to recognize our benefactors in all of our HL7 newsletters, on the HL7 website and at all of our HL7 WGMs. A special thank you is extended to the list of firms that represent our 2020 HL7 benefactors and gold members.

Organizational Member Firms

HL7 is proud of the impressive list of HL7 organizational member companies listed on pages 28-31. We appreciate their

ongoing support of HL7 via their organizational membership dues.

In Closing

As of May 5, there were over 3.5 million confirmed cases of COVID-19 along with over 250,000 deaths. Since there continues to be a shortage of testing kits, the actual number of cases and deaths are certainly much larger. Clearly, this experience has impacted most of us and will be a period in our lives that we will always remember. While I previously credited Karen Van Hentenryck's mother during challenging times like these, I now realize that it is a Persian adage from the early 1800s: *This too shall pass.*

Member Spotlight on Carol Macumber

Professional Life

Carol Macumber began her career working as an informatics analyst at Apelon in 2002, eventually making her way up the terminology company hierarchy to leading technology and operations as Vice President. She says she found herself in the field of informatics, terminology in particular, on accident. After she defended her thesis, Carol had two more months of research assistant duties remaining. Thus, she did what any graduate student in the late 90's would do – worked in a lab and made mixed CDs for her fellow classmates. Amidst those responsibilities, she applied for any job that had the words engineering and medical in them. Carol had always assumed she would either a) get a doctorate or b) work more directly with medical devices. Thus, when Apelon offered her the opportunity, she was just as enticed by relocating to the East coast as she was by this “new” field of informatics and standardized terminology that was more about computers than anything else. It turned out her type A, detail-oriented personality worked well in the field of informatics.

While at Apelon, she participated in the following projects, among others:

- **Canada Health Infoway** – Aided in implementing tooling and workflows to support Infoway's national release center for the Canadian edition of SNOMED CT
- **US Department of Veterans Affairs** – Managed conflict resolution and change management during the authoring of NDF-RT. Currently serves as a subject matter expert, participating on the VA's behalf in HL7 activities
- **National Committee for Quality Assurance** – Helped deploy an information modeling approach and tooling to manage quality measurement related concepts and value sets
- **US Food and Drug Administration** – Supported efforts to index structured product labels for indications, limitations and conditions of use

Carol began a new position with Clinical Architecture as the Executive Vice President of Professional Services in December 2019. Clinical Architecture

delivers innovative solutions that maximize the effectiveness of healthcare. In this role, she leads professional services, helps organizations implement standards, such as HL7, and standard terminologies. Carol works with integrated delivery networks, electronic medical records vendors, payers, government agencies, health information exchanges, content publishers and more, to deliver solutions that help their clients take control of their data quality. She states that the work in this industry is aimed at improving patient care and outcomes. She looks forward to further honing and utilizing her standards and terminology skills on a massive scale towards those goals in her new role with Clinical Architecture.

Carol received her MS in Biomedical Engineering from the joint program at the University of Tennessee and University of Memphis. She is also a certified Project Management Professional (PMP) and a Fellow of the American Medical Informatics Association (FAMIA).

HL7 Activities

Carol began her involvement with HL7 in the early 2000s as a newly minted informatics analyst at Apelon, where she attended her first HL7 working group meetings (WGMs). She remembers being very lost (what is standards development?) and in awe of the subject matter expertise in the small work group meetings. The early days at HL7 played a large part in Carol's on-the-job experience and set her up for continued success in the future.

Carol believes HL7 is a unique organization powered by a passionate community of volunteers and the epicenter of standards development expertise. At HL7, she has been fortunate to be mentored (sometimes in the form of heated discussions) by, and work with, amazing and smart individuals. This group includes Rob McClure, Ted Klein, Julie James, Stephen Coady, Mark Tuttle, John Carter, Charlie Harp, Shaun Shakib and many more. It's important to Carol to 'pay it forward' and mentor/engage in discussions with as many people as possible, especially those new to HL7 and/or informatics world.

Carol currently serves as a Co-Chair of the Vocabulary Work Group and the Vice Chair of the HL7 Terminology Authority. In these roles, she has the



Work takes Carol All Over The World. The HL7 community has become a second family. Spare time is spent traveling with friends and family.

opportunity to help influence how terminology continues to play an integral role in HL7 standards, including FHIR. It is critically important that terminology content and services are defined in a way that doesn't increase the barrier to implementation and secure information exchange, while also being cognizant that getting the governance of all the terminology resources right can be complicated!

Personal Life

Carol's family of five lives in southwestern Connecticut. Lincoln (11) and his twin sisters Campbell and Avery (9) keep their very busy with activities such as travel soccer, basketball, softball and karate. Carol coaches both her

son's and daughter's basketball teams. Her family enjoys the outdoors and can be often be found hiking and kayaking.

As native Midwesterners, born and raised in the Northwest suburbs of Chicago, Illinois, Carol's family makes an annual pilgrimage in the summer to see loved ones. Work has also taken her around the globe, including places she never thought she'd see, such as Tanzania, Myanmar, Ethiopia, Singapore, Indonesia, Bratislava, New Zealand and more. Though work travel can take up quite a bit of Carol's time, her family loves traveling and spending time with family and friends. Many of those friends include members of the HL7

community, especially those that have a profound love of karaoke, which always makes the WGMs interesting after hours.

Over the last few years, Carol has participated in the OpenHIE Community of Practice. OpenHIE is geared towards lowering implementation barriers and enabling publicly available interoperability solutions in low- and middle-income countries. Contributing to this community, providing expertise in areas such as HL7 standards, leading working sessions at the annual community meetings, etc., has been a highlight of her career thus far. Seeing the impact of OpenHIE in various countries has been inspiring. ■

News from the HL7 Project Management Office

ONC Grant Funded Project Update



By Dave Hamill,
Director, HL7 Project
Management Office

Confluence/Jira and the Project Scope Statement (PSS)

We're learning about new features and constraints every month with the Project Scope Statement and Confluence. Hence, continuous improvement is happening for the PSS form within Confluence. The PMO is working with HL7's Applications Manager, Josh Prociou, to have the form reside in Jira. Ultimately, this will be the foundation of a new project database and will replace Project Insight and the associated 'HL7 Searchable Project Database.' Additionally, having the form in Jira should provide an improved, systematic PSS review/approval workflow and process. We learned a lot from our 2018 pilot and will apply those lessons to the new process in Jira. Until this new Jira form is available, PSS's should still be created within Confluence and they can be viewed at <https://confluence.hl7.org/display/PSS/Project+Scope+Statement>.

ONC Grant Funded Project Update

Work continued on projects funded by the Office of the National Coordinator for Health IT's (ONC) 2020 \$1,360,000 grant for Maturing C-CDA and FHIR standards. As of Q1, 2020, efforts underway included the following:

1. Implement the Unified Terminology Governance (UTG) process and tooling
2. Complete improvements to the FHIR Jira ballot process
3. Continued support for FHIR IG publishing and balloting processes
4. Continue to provide administration for the FHIR Connectathons
5. Continue work on Bulk Data Access and Push
6. Produce additional HHS FHIR fact sheets and other educational material
7. Publish updates to the US Core Implementation Guide
8. Publish the FHIR Implementation Guide for International Patient Summary
9. Continue support for the FHIR Terminology Server
10. Support for the HL7 FHIR Build and Implementation Guide Publishing tasks
11. Conduct a survey to inform the ONC about the current and envisioned uses of the HL7 FHIR standard
12. Perform enhancements to the FHIR Registry
13. Conduct additional C-CDA Implementation-A-Thons
14. Quality assurance and editing of the C-CDA sample files
15. Reconcile and publish the HL7 Informative Document: C-CDA Rubric, Release 1

Details and deliverables for the above ONC funded projects can be found on HL7's Confluence space at:

<https://confluence.hl7.org/display/PMO/ONC+Grant+Project+Page>.

HL7 appreciates ONC's continued support of C-CDA and FHIR for 2020 and beyond. ■

Process Points by PIC

Work Group “Steering” Documents: Mission, Charter and Decision-Making Practices

Whether you are someone who is a regular, longtime contributing member to HL7 or a fairly new attendee, there are some foundational documents that help scope, frame, and govern what happens at a work group level. This article will describe each of these, their purpose as well as how and why they might be revised. Note that the working descriptions here are for general consumption, but the governing document is the HL7 Governance and Operations Manual (GOM), which is the authoritative source if/when issues arise. That said, most people don’t take the time to read the GOM for sport, so this will give you the gist.

Work Group Mission

The mission articulates in a few paragraphs the originating intent and ultimate goals of the work group. While the mission can and will adapt over time, generally these are incremental adjustments to accommodate changes within the industry or the HL7 landscape. Moreover, the mission should have a low volatility, changing only infrequently. This is a good place to remind oneself of the purpose of the group, and to keep things grounded.

It is a recommended best-practice for work groups to take a few moments at the beginning of each working group meeting (WGM) to review the mission and charter, both to acclimate new members and to remind returning members of the scope and purpose of the group.

Work Group Charter:

Just as the mission articulates the goals of a work group, the charter defines its objectives. The charter is finer grained than the mission. It identifies high level priorities or themes and enumerating key relationships across (and sometimes outside of) HL7. In some instances, the charter will define work products or categories/families of products. By its nature, the charter is an extension of the work group mission, providing elaborating detail.

As mentioned in the section above, it is a best practice to review the work group charter at the beginning of

WGMs to remind attendees of scope, objectives and responsibilities of the group.

Decision-Making Practices (DMP)

HL7’s GOM is the authoritative source for how HL7 operates as a whole. The Decision-Making Practices (DMPs) exist as an extension of the GOM, detailed to govern operational processes of the work groups themselves. The DMP serves as a “Bill of Rights” for the attendees. It defines expected behaviors, instituting checks-and-balances to assure openness, transparency and fairness throughout all work group activities.

DMP processes are essentially standardized across all work groups, though they allow for “parameters” to be set work group by work group to accommodate some specific needs and circumstances (e.g., “quorum” calculations).

What is the Role of the Process Improvement Committee (PIC) in Work Group Activities?

PIC stands ready to help in process clarification or adjudication should the need arise. We can serve as a neutral arbiter, advocate for issues that need resolution or a counselor for advice when necessary. We have no responsibility or authority with regard to work group scope or purpose but can be helpful in driving an organizational decision when mission or scope conflicts arise. Given our relationship with the Technical Steering Committee, the Board and the HL7 executive leadership, PIC is frequently engaged in navigating issues that do not clearly fit within established responsibilities. For work group chairs, we are a place to go to resolve issues or concerns. For work group attendees, we can provide assistance, clarification, education or (if needed) intervention.

Note: This process point has been brought to you courtesy of the HL7 Process Improvement Committee. Our role is to help keep HL7 working smoothly and to advocate on behalf of the membership to help address issues and concerns that are raised. We are available at working group meetings, or at pic@lists.hl7.org.



Tooling Update

Keeping Us Together While Apart

During this time of global crisis, it's worth remembering the critical importance of what we at HL7 are doing to improve global health by making health information more available and useful.



By Wayne Kubick,
CTO
HL7 International

While so many are struggling with social distancing, we already have a culture that long ago learned to work together remotely on our common goals. But now with fewer opportunities to meet together in person, we need to move ahead to finish much of the work we've been doing over the past few years—so we're better prepared to work together even more effectively, while knowing we must be further apart geographically.

Improving Collaboration

As the necessity of getting the most out of our virtual meetings increases, we have reviewed our web conferencing solutions, and have decided to move to Zoom as a new conferencing platform. As one of the most advanced conferencing platforms, Zoom offers improved quality and reliability, as well as a wealth of features we can use to improve our meeting management practices. Initially, we will convert work groups (WGs) who meet

frequently to Zoom to replace Free Conference Call (FCC) and GoToMeeting and will offer it as an additional option to other work groups and projects. We hope to get all HL7 work groups, committees and projects to the new platform by end of summer.

On a separate note, we also plan to provide guidance to meeting facilitators on best practices for using Zoom to conduct more effective web meetings. For

example, by using the “Raise Hand” feature we hope to make it easier for attendees to get a turn to join conversations.

Our recent consolidation of our Zulip chat.h17.org instance into chat.fhir.org was another step toward simplifying the HL7 tooling environment. We’ll continue to look for opportunities to converge on a smaller set of high performing collaboration tools.

While we adapt these tools, we’ll keep working to make it easier to find essential information while culling out what’s inaccurate, obsolete or redundant to create a simpler, more effective environment. We’re preparing updated guidelines for how to manage information in Confluence and the website. At this point, we expect all WGs are using Confluence for meeting agendas and minutes—which can be accessed through a link on the WG website page. All WGs should be using Confluence for new content instead of the old wiki.

Ultimately, through a combination of using common platforms and practices for all HL7 meetings, we hope to make it easier to work together more effectively.

The Next Generation of Harmonization Is Here

The Unified Terminology Governance (UTG) project team has dived headfirst into implementation, so the May 2020 ballot cycle will be the first in a long while without a harmonization meeting. The final mile of the rollout process – including substantial testing, software improvements and detailed planning for a projected May go-live date—was well in progress at the time of this writing.

Of course, like all new technologies, we can expect some growing pains as we proceed, and will expect to provide incremental improvements as we move forward. However, providing UTG as another way to use collaboration tooling on an ongoing basis will help us interact better on a global scale, while also bringing a single method to support current and future HL7 terminology needs.

Jira for All

If 2019 was the year of Confluence, 2020 is our time for Jira. Having successfully migrated FHIR tracking to Jira, we are proceeding to transition other products and WGs to the Jira platform for issue tracking. Similarly, we’ll be moving the [STU Comment website page](#) to Jira. We’re also working to complete activities necessary to allow Jira to be our primary platform for recording and resolving ballot comments, along with other activities to re-engineer our entire ballot management systems infrastructure.

Jira workflow is critical to improving our processes for getting work done at HL7. The new PSS online process is now being actively piloted, and TSC plans to begin to make it available to all WGs during 2020. Jira workflow will also begin to be applied for other forms and processes. As we gain more familiarity with the platform, we’ll likely discover many other ways in which it can improve the way we conduct our standards work at HL7.

As usual, you can stay informed of new functions and helpful tips at confluence.hl7.org.

Publishing

The FHIR IG publisher continues to be refined and enhanced to support reliable, efficient publishing of standards on a wider scale. It is being used to publish UTG terminology and is also being used by other organizations – notably IHE – who can now define their own templates. We’re proceeding with a project to produce Consolidated Clinical Document Architecture (C-CDA) templates using the FHIR StructureDefinition resource. A Version 2 (V2) group is exploring using the IG Publisher to produce an enhanced web version of V2. We expect the IG Publisher to be the baseline tool for publishing many more HL7 standards in the near future.

Balloting

While we continue to work to move all WGs and products to Jira, we’re also continuing development of a new ballot comment system and process using the Jira platform. We’re expecting to do an initial pilot ballot for the September ballot cycle, and I’ll be discussing more detailed plans for changing our ballot-related systems in a future update.

Crossing Over

During this critical and pivotal year, our ambition is to complete the transition to many of these new tools and processes to realize the vision of a better HL7. We recognize that this will be an initial burden for many of you, but we are also confident that once you cross over, you’ll be very glad we made the journey. Finally, all of this is only possible thanks to you, our dedicated HL7 community. ■

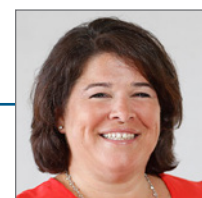


GET INVOLVED. LEARN MORE. JOIN THE COMMUNITY.

hl7.me/davincinews

Da Vinci Project Brings Community Together

Solving Data Exchange Challenges By Using HL7® FHIR®



By Jocelyn Keegan,
Program Manager, HL7 Da
Vinci Project, and Lead,
Point-of-Care Partners
Payer Practice

Since the inception of the HL7 Da Vinci Project, industry-leading providers, payers and partners have worked together to accelerate the adoption of HL7 FHIR (Fast Healthcare Interoperability Resources) as the standard to support and integrate value-based care (VBC) data exchange across communities in real time.

Meaningful progress is being made; project sponsorship grew from 28 to [45 members](#), the team held seven Connectathons from January 2018 to date and members are bringing initial Da Vinci based APIs live in production as we write this article.

In March, the Da Vinci community transformed dozens of planned in-person HIMSS20 sessions to virtual meetings featuring four panels and five deep dive sessions outlining their journey with HL7 FHIR, the [use cases](#) and implementation guides. More than 500 attendees joined the live panel and deep dive presentations.

In addition, more than 400 attendees viewed eight variations of the 2020 Da Vinci Clinical Scenario of technical demonstrations, showcasing how FHIR and Da Vinci can improve a patient's journey through their healthcare interactions. Implementers from providers, EHRs, vendors and payers highlighted how they utilized emerging standards to reduce provider burden and friction between payers and providers, streamline prior authorization and automate data exchange.

"The community's hard work at the connectathons, coupled with the real-world applications of



our members, were showcased across this year's clinical scenario. Their applications provided tangible benefits of the Da Vinci FHIR implementation guides and interoperability," stated Da Vinci Project Technical Director, Viet Nguyen, MD.

To see Da Vinci in action, please find recordings of sessions on [Da Vinci 2020 Calendar](#).

As Da Vinci moved into a more active implementation phase and builds on positive feedback from virtual HIMSS, the team announced a monthly industry community roundtable open to the growing FHIR community.

"Da Vinci is building on the flexibility and power of HL7 FHIR; we invite everyone to join the community of early adopters and become part of the efforts to solve data exchange challenges," said Da Vinci Project Program Manager Jocelyn Keegan.

Held on the fourth Wednesday of every month at 4 p.m. ET, the 90-minute forums will highlight how members are using Da Vinci use cases and implementation

	QUALITY		BURDEN REDUCTION			MEMBER ACCESS AND/OR CLINICAL DATA EXCHANGE						PROCESS IMPROVEMENT
	Data Exchange for Quality Measures	Gaps in Care & Information	Coverage Requirements Discovery	Documentation Templates and Payer Rules	PA Support	Clinical Data Exchange	Payer Data Exchange	Formulary	Directory	Payer Coverage Decision Exchange	Notifications	Member Identification
Anthem/Care Evolution	•					•	•				•	
Availity					•	•						
Cambia	•		•	•	•		•		•			•
Cerner	•		•	•			•					•
Cigna	•		•	•	•	•	•				•	
CMS/Mettle/Mitre			•	•	•	•				•		
Edifecs	•	•	•	•	•	•	•	•	•	•	•	
Epic			•	•								
GuideWell	•	•	•	•	•	•	•	•	•	•	•	
Healow Insights	•											
Humana	•	•	•	•	•	•	•	•	•	•		•
Independence BC	•		•									
MultiCare	•											•
OHSU			•	•	•		•					
Pulse8	•											
RUSH			•	•	•							
United Healthcare	•		•	•	•		•					
ZeOmega			•	•	•		•					

guides to solve long standing challenges between partners. The inaugural forum was held March 25 and featured deployment member Availity, Da Vinci founder Cambia Health as well as one of their EHR partners to highlight how Da Vinci guides help prior authorization workflows and streamline clinical data exchange.

Join the Da Vinci Community Forum

Visit hl7.me/davincinews to learn more and sign up for the Da Vinci listserv, which will notify you of upcoming community forums, news and events. ■

PROVIDERS



EHRs



PAYERS



VENDORS

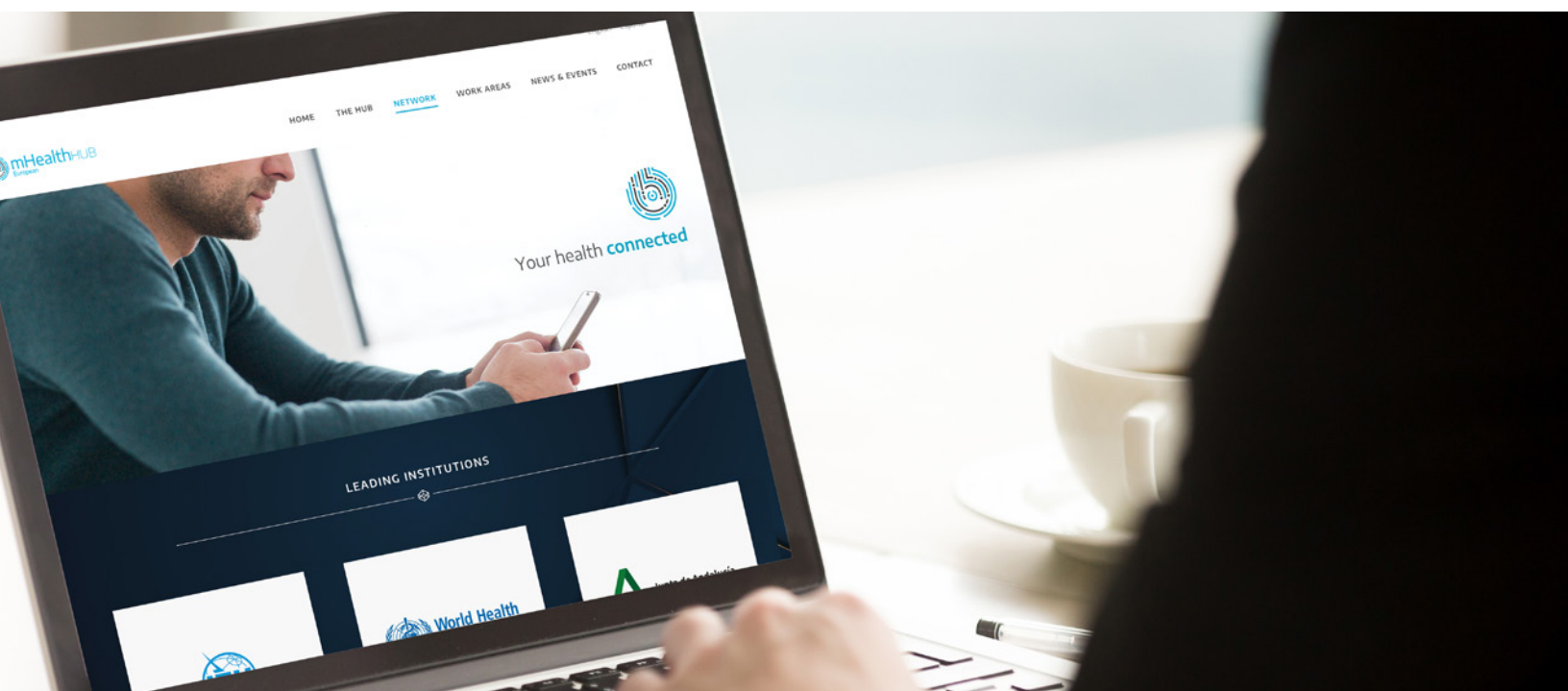


DEPLOYMENT



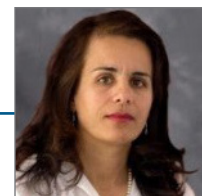
INDUSTRY PARTNERS





mHealth Hub Launch Event

European mHealth Innovation and Knowledge Hub



Catherine Chronaki, FHL7,
Secretary General, HL7
Foundation

The International Telecommunications Union (ITU) and the World Health Organization (WHO) hosted the launch event of the European mHealth Innovation and Knowledge Hub on February 17-19, in Geneva, Switzerland.

In its first phase, the European mHealth Hub will work on three main areas:

- mHealth assessment frameworks
- A knowledge tool for diabetes
- mHealth Hub innovation and policy framework.

In the mHealth assessment framework topic area, synergies with the CEN project in ISO/IEC82304-2 have been pursued. The project is led by Charlie McKay. A large number of HL7 community members are participating, ensuring links to the HL7 Mobile Health Work Group, as its co-chair, Franck Ploeg, is a member of the CEN TC251 team.

Petra Hoogendoorn, from the Dutch Living Lab at Leiden University, member of the CEN team, and a prominent patient advocate in the Netherlands, presented current efforts and progress toward establishing a label for mHealth apps. Inspired by Nutri-score, an energy label and over-the-counter medicine label, Petra demonstrated a first draft of the mHealth Label. The next stage of the project is a Delphi study with approximately 150 participants, which will evaluate the different components of the label with a questionnaire.

In parallel, the mHealth Hub identified more than 30 mHealth app assessment frameworks

and carried out a comparison. A registry of the frameworks will be prepared during the course of the project.

The second focus area for the mHealth Hub is a knowledge tool for a noncommunicable disease, most likely diabetes, which will be implemented in selected European countries/regions in the WHO-EURO area.

The ongoing work of the “Be He@lthy Be Mobile” program at WHO, and the experience gained in European Union (EU) initiatives such as the European Innovation Partnership on Active and Health Aging (EIP-AHA), will provide valuable input to this activity. In particular, the idea of twinning



Participants at the launch of the European mHealth Innovation and Knowledge Hub on February 17-19, in Geneva, Switzerland.

regions to share experiences in tested policies as well as successes and failures, may also be used at the level of programs, but also the mHealth Hub itself.

In my presentation, I focused on the activities of the HL7 Mobile Health Work Group, the HL7 FHIR Accelerator Program, and the HL7 Fast Healthcare Interoperability Resources (FHIR®) international patient summary (IPS) project. I then referred to cross-SDO cooperation on the IPS and the results of the recently concluded EU funded project, Trillium-II, on the large-scale adoption of patient summaries. I stressed the importance of “Thinking global and acting local” to adapt to the culture and meet the needs of specific communities with mHealth apps, while aligning and sharing experience to accelerate adoption with a global community of innovation throughout my talk.

HL7 Europe supports the Fundacion Progreso y Salud in the

Spanish region of Andalusia for several tasks in the mHealth Hub setup phase in 2020 and 2021. The engagement of HL7 involves monitoring trends in the mHealth innovation landscape and the integration of these innovations in the healthcare systems of selected countries/regions in Europe.

HL7 will also contribute to developing a portfolio of mHealth services for large scale deployment and the associated policy framework to facilitate adoption.

Finally, HL7 Europe will participate in the creation of

the business model for the sustainable development of the mHealth Hub, defining synergies with operational frameworks and mechanisms for attracting additional funds after the conclusion of European funding.

The European mHealth Hub is funded by the European Commission under the Horizon 2020 research and innovation program, under the action “Establishing EU mHealth Hub including evidence for the integration of mHealth in the healthcare systems” (Grant Agreement No 737427). ■

For more information:

European mHealth Hub: mhealth-hub.org

European Partnership on Healthy and Active Aging: hec.europa.eu/eip/ageing/home_en

WHO Be-Healthy Be-Mobile: www.who.int/nmh/publications/be-healthy-be-mobile/en

Relevant Patient Information on Antibiotics Resistance



By Robert Stegwee, Owner
and Principal Consultant,
Transformational Consulting
in eHealth

November is the time of the World Antibiotics Awareness Week. It is a good opportunity to reflect on the need for information on antibiotics for patients and professionals.

In my role as strategic information manager for the Antibiotics Resistance program within the National Institute for Public Health and the Environment in the Netherlands, I spend a lot of time discussing this topic.

Fighting Antibiotic Resistance

The global strategy in fighting antibiotic resistance is based on two pillars: 1) ensuring that the development of antibiotics resistance doesn't increase, and 2) making sure that the spreading of resistant bacteria is contained. Surveillance and research are strengthened to know what we're up against, but personal and professional action must deliver the actual results. The first pillar has to do with awareness and ensuring that antibiotics are used appropriately. The second pillar has to do with infection prevention, making sure the right measures in personal hygiene are considered when dealing with individuals that carry resistant bacteria. Both pillars have an information component for patients and professionals. In this article, I will highlight three perspectives: product information, history of antibiotic use and carrier status of resistant bacteria.

Antibiotic Product Information

Depending on the country where you live, it may be your own choice whether to use antibiotics or

not. When considering the use of antibiotics, it needs to be very clear when it is an appropriate action. Inappropriate use of antibiotics will not help alleviate the problems that you are experiencing, but it will speed up the development of resistant bacteria. Similarly, the dosage and timing of an antibiotic treatment is essential to ensure all bacteria are effectively killed. If not, the least susceptible bacteria can survive and develop themselves into a resistant strain that can no longer be cured. Information on appropriate use, dosage and timing of an antibiotic product needs to be easily accessible by both patients and professionals. This information will often be dependent on patient demographics – including age and weight – and should extend to alerts and warnings of inappropriate use.

History of Antibiotic Use

Exposure to antibiotics leaves its mark on a patient, even months after a course of antibiotics has been taken. Often, bacteria will be found that are resistant to the specific antibiotic administered in much higher percentages than in the open population. Taking this information into account can lead to a different choice of antibiotics in order for repeated treatment to be effective. Therefore, it is argued that the patient medication section in a patient summary

record, such as the International Patient Summary (IPS), should be extended to include a history of antibiotic use rather than just the current medication. This history can be seen as an antibiotic card for the patient, to be consulted by the prescribing physician when considering antibiotic treatment.

Resistant Bacteria Carrier Status

Infection prevention guidelines have been developed to provide the proper personal hygiene measures depending on the type of resistant bacteria that a person is carrying. These measures range from simple but strict hand hygiene to the full isolation of a patient. Research has been carried out to establish the robustness of these guidelines, while not enforcing too strict a regime onto the patient. In order to take the proper measures, one must be aware of the carrier status of the patient beforehand. Otherwise, a screening test must be carried out; this can take several days to complete, during which time the patient is kept in strict isolation. We are exploring the use of the Dutch version of the IPS in the Netherlands as part of the referral or transfer documentation for the receiving healthcare professional to communicate the individual carrier status of a patient. To this end, we have extended the Alert section of the Dutch IPS to include a code for the carrier status of different

groups of resistant bacteria and have established SNOMED-CT codes to convey that information. Detailed lab results of cultures and antibiotic susceptibility tests can be communicated as well; however, these are often difficult to find and interpret for the nurse or informal care giver that needs to take the necessary precautions against the spreading of resistant bacteria.

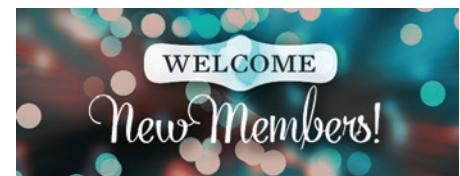
Relevant Information

Given the three areas of information discussed, it is important to develop and test a combination of product information on antibiotics with the information contained in the IPS. For appropriate use of antibiotics, the IPS will provide the parameters for calculating the correct dosage and duration of the treatment. The history of antibiotics use, as an elaborated medication section of the IPS, will enable the selection of the most appropriate antibiotic for this patient. Finally, including an alert for resistant bacteria carrier status will allow both professionals and informal caregivers to apply

appropriate measures for infection prevention and hygiene.

Sensitive information

I would like to emphasize the fact that information on resistant bacteria, whether in the context of a healthcare provider organization or a patient, can be very sensitive. News of, for instance, an outbreak of resistant bacteria in a nursing home may lead to people staying away (new patients, as well as relatives of current patients, and personnel) if this news is not accompanied by clear instructions on how infection prevention is being handled. Also, a person carrying a resistant bacteria may not show any sign of illness, but may be treated as an outcast by family and friends should their status be known to them. Again, there is no need to be alarmed as long as the appropriate measures for infection prevention and hygiene are observed. A more compelling case for antibiotics awareness cannot be made! ■



HL7 Welcomes New Members

Benefactor

- CVS Health

Gold

- American Academy of Neurology
- Cigna
- CORMAC Corp
- Intelligent Medical Objects (IMO)
- Northwestern Medicine
- OCHIN
- Oregon Health and Science University
- Rimidi, Inc.
- Tata Consultancy Services
- Vizlitics Inc.

Organizational

- AcuStaf
- B3 Group
- CDISC
- Comet Information Systems
- Daytoday Health
- IPRD Solutions, Inc.
- MedX Open Systems
- MoledularDX, LLC
- NYSTEC
- Parexel International
- Retarus
- Tesia Clearinghouse
- TriMed Technologies Corp.

HL7 Standards Approved by ANSI Since December 2019



Name	Designation	Date
HL7 Clinical Document Architecture, Release 2.1	ANSI/HL7 CDA, R2.1-2019	12/6/2019
Health Level Standard Version 2.9 - An Application Protocol for Electronic Data Exchange in Healthcare Environments	ANSI/HL7 V2.9-2019	12/6/2019
HL7 Service-Aware Interoperability Framework: Canonical Definition Specification, Release 2	ANSI/HL7 SAIF CANON, R2-2014 (R2019)	12/30/2019
HL7 Version 3 Standard: Laboratory; Result, Release 1	ANSI/HL7 V3 LBRESULT, R1-2009 (R2020)	1/10/2020
HL7 Cross-Paradigm Specification: FHIRPath, Release 1	ANSI/HL7 NMN R1-2020	1/16/2020
HL7 EHRS-FM Release 2: Immunization Functional Profile, Release 1	ANSI/HL7 EHRS IFP, R1-2020	3/17/2020

FAIR4Health: An HL7 FHIR Based Solution

Improving Health Research Through FAIR Data

This article describes the design and the implementation of the FAIR4Health Platform and Agents developed by the European project FAIR4Health [1] for supporting the sharing and the reuse of FAIR (Findable, Accessible, Interoperable and Reusable) data within the European Union (EU) Health Research community. A brief introduction to the FAIR principles is provided, as well as to the capabilities of HL7 FHIR to support the implementation of the FAIR principles. The general technical solution is outlined, highlighting how the Privacy Preserving Data Mining, on top of the distributed FHIR Repositories, has been realized.

Introduction

The *FAIR Data Principles* refers to a set of principles aiming to ensure that the data is findable, accessible, interoperable and reusable by humans, applications and computational agents. Although FAIR emerged from a workshop for the life science community, the principles are intended to be applied to data and metadata from all disciplines in a way that findability and accessibility are addressed at the metadata level, while interoperability and reusability are handled at the data level.

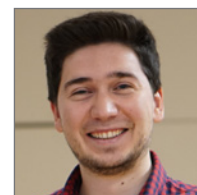
After the first draft of the *FAIR Data Principles* was published in 2014, it was first formally released by the FORCE11 [2] community in 2016 [3]. Later that year, the European Commission published the Guidelines on FAIR Data Management in Horizon 2020 [4] and then updated the data management guidelines to introduce the notion of FAIR in 2017. In May 2017, the GO FAIR

initiative [5] emerged to help individuals, institutions and organizations in the transition to FAIR by building an open and inclusive ecosystem through implementation networks so they could work together. The principles are also explicitly mentioned in the new Open Data and Reusable Public Sector Information (PSI) directive [6], and the Implementation Roadmap for the European Open Science Cloud (EOSC) [7], which emphasizes the central role of FAIR data.

The *FAIR Data Principles* have been adopted by several research disciplines worldwide. In the US, the American Geophysical Union (AGU), together with partners, has been managing a project named CODPES [8] to enable FAIR Data across the earth and space sciences. Several working groups such as EOSC FAIR WG [9], Research Data Alliance (RDA) FAIR Data Maturity Model WG [10], and RDA FAIR Sharing



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“...the FAIR4Health project aims to show the benefit of using HL7 FHIR at the core of the FAIRification process.”

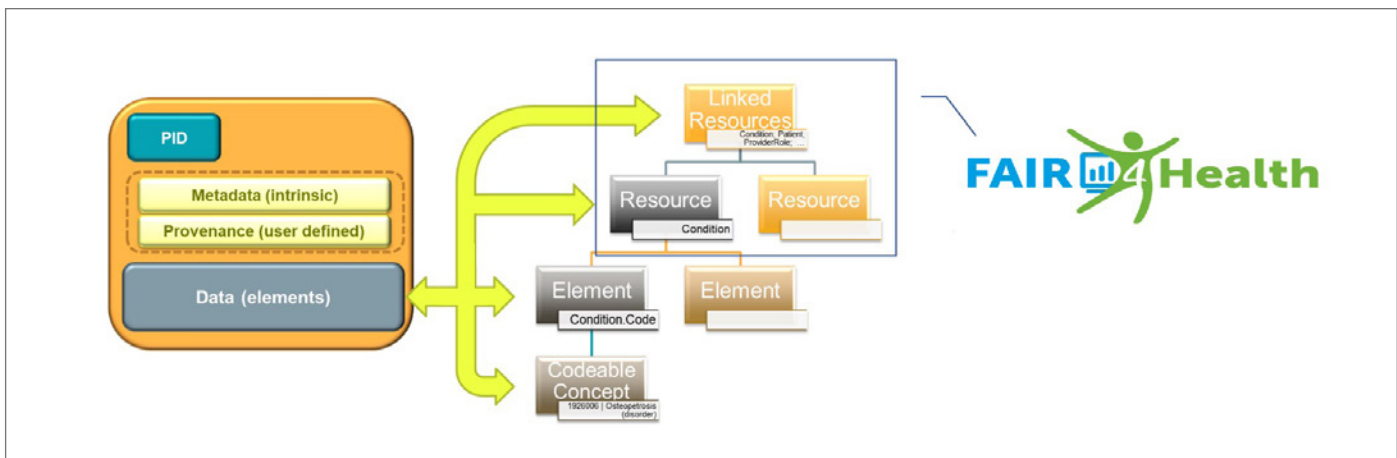


Figure 1. Representing FAIR data elements in HL7 FHIR

Registry: connecting data policies, standards & databases WG [11] have been established to develop guidelines for researchers on how to be FAIR in fields as diverse as agricultural data and small unmanned aircraft.

Although the FAIR concept has been widely understood and accepted, there are still many implementation challenges in various domains due to different interpretation of principles in a technical point of view. Technical interoperability challenges arise when there are gaps in the infrastructure and a lack of standards in several disciplines. Therefore, specific effort must be spent to overcome these challenges.

Launched at the end of 2018, The FAIR4Health [1] is a 36-month EU funded project. It aims to implement *FAIR Data Principles* in the field of health and social care research. The overall objective of FAIR4Health is to facilitate and encourage the EU health research community to FAIRify (make data findable, accessible, interoperable

and reusable) as well as share and reuse their data sets derived from publicly funded research initiatives through the demonstration of the potential impact that such strategy will have on health outcomes and health research. In this regard, an intuitive, user centered FAIR4Health Platform is being developed to enable the transformation of raw datasets into FAIR datasets.

A wider description of this project was given in the HL7 Europe newsletter [12] published in May 2019.

FAIR Principles and HL7 FHIR

Together with the FAIR principles described above, the FORCE 11 group introduced the concept of FAIRPort, intended as “Any machine-oriented data repository that contains FAIR Data Objects (to be judged by the endorsing authority),” specifying a set of requirements and actions to be taken for realizing it. Conceptually, a FAIR Data Object includes the following:

1. A Persistent¹ Unique Identifier² (**PID**)
2. **Data Elements** that represent the actual data (single association between two concepts, images, raw data, etc.). They are practically, although not technically, distinct from their metadata
3. **Metadata** providing the context of the data. “A Data Object should minimally contain basic machine actionable metadata that allows it to be distinguished from others” and it “should be sufficiently rich that a machine³ or a human user, upon discovery, can make an informed choice about whether or not it is appropriate to use that Data Object in the context of their analysis” [13]
4. **Provenance** that “Describes entities and processes involved in producing and delivering or otherwise influencing that resource” [14] [15]. Provenance is key for FAIR data.

Continued on page 20

¹ “Persistence is an organizational property; effectively, it is an obligation, formally or informally, that an organization guarantees that something will be maintained.” [13]

² “There are ongoing and fierce debates on what exactly constitutes a ‘persistent’ identifier. <...> We propose to allow many identifiers in FAIR data publishing environments as long as an identifier is uniquely referring to only one concept and the publisher provides a clear policy and description on the maximum achievable guarantee for persistent resolving of the identifier to the correct location/meaning. [13]

³ Metadata being machine readable is a *conditio sine qua non* for FAIRness. [13]

Continued from page 19

Improving Health Research Through FAIR Data

A two step assessment process was therefore accomplished by the FAIR4Health project to:

1. Highlight the relationships between the FAIR data object conceptual components and HL7 FHIR
2. Evaluate how the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard may support the implementation of the FORCE11 facets, principles and *FAIRPorts*

Each component of the FAIR data object conceptual representation (e.g., PID, data, provenance) is generally associated with a multitude of objects and attributes when implemented. For example, with HL7 FHIR, a FAIR data element can be represented by a single data element up to a set of linked FHIR resources. FAIR4Health focused on the resources level mapping.

Each FORCE11 facet and principle was analyzed distinguishing between those that are fulfilled by FHIR by design⁴ and those that may be realized by HL7 FHIR under specific conditions. For example, HL7 FHIR supports “rich metadata,” but what “rich metadata” means, and the capability to provide them, is an organizational responsibility that could be technically expressed by profiles and conformance resources.

The detailed results of this assessment have been collected in a dedicated report [16] and

were presented and discussed with a larger community during a dedicated session at the Medinfo 2019 Workshop “FHIR for FAIR: Advancing interoperability for health data” [17].

This analysis showed how the HL7 FHIR standard is an enabling factor for the technical implementation of the FAIR principles, even though implementing HL7 FHIR data is not sufficient condition for FAIR data.

The FAIR4Health Solution

The FAIR4Health Project designed the FAIRification workflow by focusing on specific requirements of the health research community. The project has designed a set of tools and started implementation to cover the workflow, specifically the newly introduced steps. The main objective is to help organizations FAIRify their raw healthcare and/or health research data sets with the help of easy-to-install and easy-to-use software. Moreover, the FAIR4Health project aims to show the benefit of using HL7 FHIR at the core of the FAIRification process. To do this, a platform agent based distributed architecture has been designed so that data mining algorithms can be executed, thereby not allowing essential health data out of the local FHIR repositories of the data owners. This privacy preserving approach will be tested through pathfinder use cases of the FAIR4Health project.

Addressing the FAIRification challenge within the boundaries of the data owner, an HL7 FHIR repository is located at the core of the architecture as the data repository. The project has decided to use onFHIR.io [18], as the FHIR repository. onFHIR.io is very competitive in terms of FHIR conformance, scalability and performance. The FHIR repository utilizes FHIR profiles [19] to dictate a common data model following the FAIRification workflow of the FAIR4Health project. Versioning and provenance are also designed on top of FHIR, using its own standard versioning and provenance machinery with additional specifications. A set of tools and components surround the FHIR repository, designed to transform the raw data into FAIR data. These components are expected to operate in the same order as in the designated FAIRification workflow, and they are expected to work interoperably with the FHIR profiles exposed by the FHIR repository. The first tool is the Data Curation and Validation Tool, which is expected to be used by the data owners after the raw data analysis step. The objective is to increase the quality of the data set for research purposes. Data fields, types and values are characterized; and clinical concepts such as data elements for diagnostics, medications, lab results, etc. are extracted. The curated data needs to be validated

⁴ Usually technical requirements, e.g. “it has a globally unique and persistent identifier”;

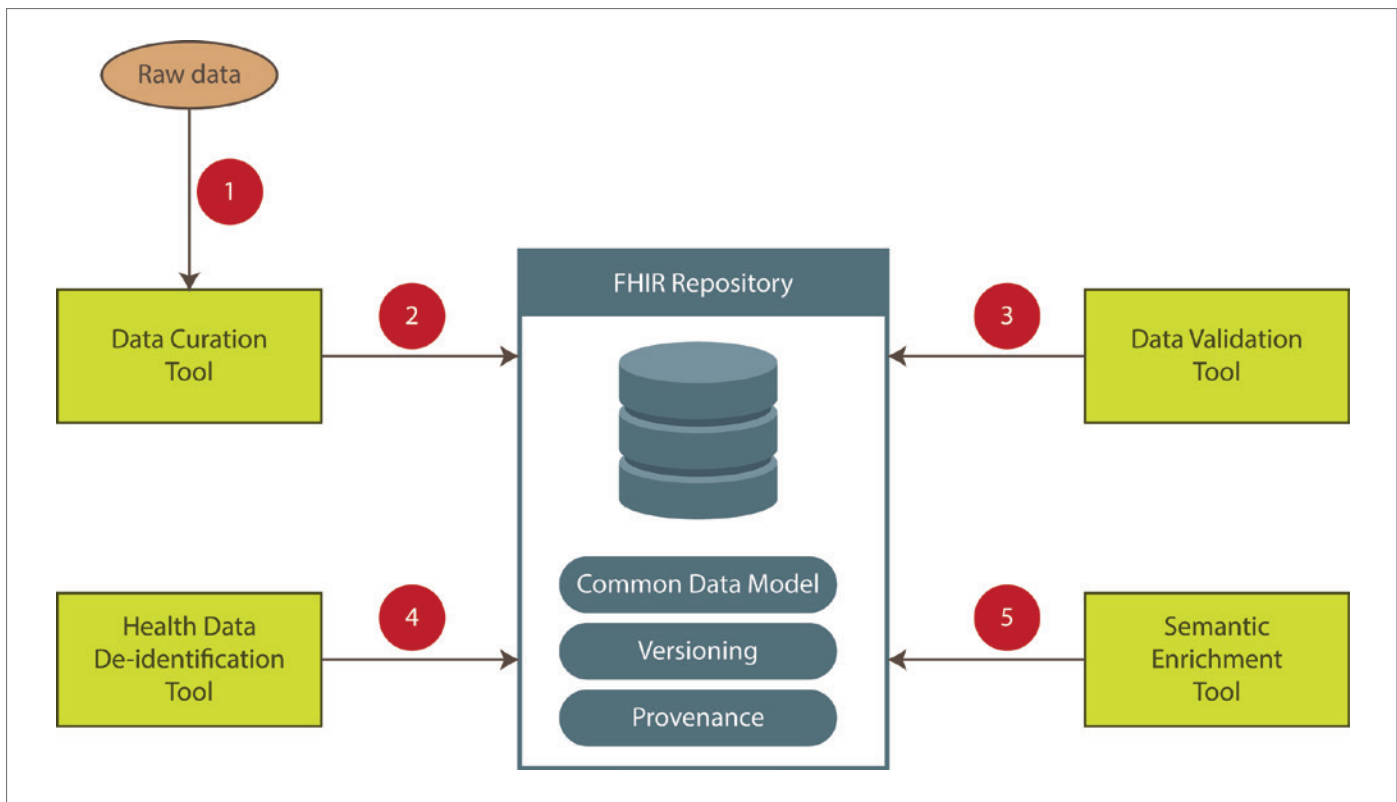


Figure 2. The FAIR4Health architecture implementing the FAIRification workflow

against the semantic model exposed by the FHIR repository using quantitative measures. The FAIR4Health project developed this tool as an open source project maintained on Github [20].

After utilization of the Data Curation and Validation Tool, the next step is to apply privacy related measures to the sensitive health data. To address this challenge, the Data Privacy Tool [21] is under development, so the curated data set can be de-identified through several de-identification methods and algorithms. The Data Privacy Tool is designed to work on an HL7 FHIR API so it can be added on top of any standard FHIR repository as a data de-identification, anonymization and related actions toolset. The component is expected to do the following: access FHIR resources; present metadata to the user; guide the user about the

configuration; and then output the processed FHIR resources. The resulting FHIR resources are to be de-identified/anonymized based on the configurations that the data owner provides, then written back to the FHIR repository as versioned resource instances and labeled with security flags. This process follows the guidelines published by the Security and Privacy Module of HL7 FHIR R4 [22].

Privacy Preserving Data Mining on Top of the Distributed FHIR Repositories

Once the healthcare and health research data have been FAIRified and are ready to be consumed, it is time to show how they can be used for large scale research purposes or simply for data sharing between different data sources. The key point is to perform data mining algorithms and reply prediction,

and/or correlation related questions using all available FAIRified data sets residing at distributed FHIR repositories from different sources. For this purpose, the FAIR4Health project has designed an architecture which deploys FAIR4Health agents on top of the FHIR repositories and a cloud-based FAIR4Health platform to interact with health researchers and data scientists, as well as handle the orchestration between the registered agents. The system enables its users to perform data mining algorithms, specifically statistical/machine ones in a distributed manner. No data leaves the FHIR repositories residing within the data source boundaries. Metadata containing statistical information about the available data in the repository, and some vector of floating points corresponding to function coefficients, leave the data source

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Improving Health Research Through FAIR Data

boundaries to fuse the distributed data mining orchestrated by the cloud-based platform.

Following an authenticated, access-controlled, encrypted and audited communication between the platform and agents, a health data scientist can execute data mining algorithms such as different kinds of regressions or clustering algorithms by using the graphical user interfaces provided by the FAIR4Health platform. The platform executes the algorithms on each FAIRified data set by interacting with the associated agent. The responses are generally a vector of floating points to be collected by the platform and then sent to the next agent so the model training can continue on top of the previous agent's

results. In a very general sense, this approach opens the door for privacy-preserved distributed data mining using the FAIR4Health agents deployed on top of the FHIR repositories, which maintain the FAIRified data sets.

Next Steps

FAIR4Health is still an ongoing project and is expected to be finalized in November 2021. To demonstrate the potential impact of the solution implemented in the project on FAIRifying health data in terms of health research and health outcomes, two pilot case studies will be performed in four different countries, i.e., Spain, Switzerland, Italy and Serbia. The first pilot case study focuses on the discovery of disease onset triggers

and disease association patterns in comorbid patients. The second pilot case study covers a prediction service for 30-days readmission risk in complex disease patients.

In these pilot studies, the raw data residing at different silos will first go through the FAIRification process and will be transformed into HL7 FHIR resources to become FAIR data. Afterward, the statistical/machine learning algorithms will be run on FAIRified data sets in a distributed manner in order to show that the data coming from countries in different formats can be used together to achieve the specific objectives of the two case studies. This will prove that they are findable, accessible, interoperable and reusable. ■

Acknowledgements

The FAIR4Health project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 824666.

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HL7 Policy Spotlight

New Federal Interoperability and Patient Access Final Rules



By Ticia Gerber, MHS/HP,
Senior HL7 Policy Advisor

Overview

Final interoperability, patient access and information blocking rules related to implementing provisions in the *21st Century Cures Act* (Public Law 114-155) were released by the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) on May 1, 2020. HL7 and its standards, such as Fast Healthcare Interoperability Resources (FHIR®), are centrally embedded. Through these rules, CMS and ONC seek to the following:

- Improve the interoperability of electronic health information, primarily through standards-based APIs
- Enhance care coordination
- Foster innovation that promotes patient access to and control over their health information
- Put forward a framework for implementing the information blocking provisions of the *21st Century Cures Act*

The rules contribute to the overall federal government effort to support value-based healthcare and to give Americans access to their medical information through the MyHealthEData initiative.

Final rule text is available at the following locations:

CMS Final Rule

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and

Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally Facilitated Exchanges and Health Care Providers

<https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and>

Particularly in light of COVID-19, accompanying these final rules was an announcement of enforcement discretion by both CMS and ONC, delaying some compliance dates and timeframes. Updated implementation and enforcement schedules can be found at:

ONC Updated Schedule for Final Rule Enforcement

https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf

CMS Enforcement Discretion Announcement (Consolidated with enforcement details):

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>

The final CMS and ONC rules collectively exceed 1,700 pages and address a large diversity of topics. Some issues particularly key to HL7 are explored below.

HL7 FHIR, APIs and Conditions of Participation

HL7 and its standards, including FHIR, are foundational to the final CMS and ONC rules, as they are to today's healthcare experience. The

21st Century Cures Act (Section 4002) requires the U.S. Health and Human Services (HHS) Secretary to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program. The Conditions and Maintenance of Certification express initial requirements and ongoing requirements for health IT developers and their certified health IT module(s). Following the final rules, there are seven conditions of certification with accompanying Maintenance of Certification Requirements:

1. Information blocking
2. Assurances
3. Communications
4. Application programming interfaces (APIs)
5. Real world testing
6. Attestations
7. (Future) Electronic Health Record (EHR) Reporting Criteria Submission

Regarding this topic, ONC's *21st Century Cures Act* final rule made several changes to the existing 2015 Edition Health IT Certification Criteria. The final rule introduced a small number of new certification criteria, revised several existing certification criteria, and removed several certification criteria. The final rule also introduced a new Privacy and Security Attestation Criteria under certification. A certified health IT module must now include export capabilities for:

- A single patient electronic health

Continued from page 24

New Federal Interoperability and Patient Access Final Rules

information (EHI) export to support patient access; and

- Patient population EHI export to support transitions between health IT systems

One of the new criteria added, § 170.315(g)(10) Standardized API for Patient and Population Services, requires the use of the HL7 FHIR Release 4 standard and several implementation guides. Two types of API-enabled services are required —(1) services for which a single patient’s data is the focus, and (2) services for which multiple patients’ data are the focus. The scope of patients’ electronic health information that must be accessible via certified API technology is limited to the data specified in the United States Core Data for Interoperability standard (USCDI).

Overall, on this point, ONC’s final rule establishes secure, standards-based API requirements to support a patient’s access and control of their electronic health information. APIs are the foundation of smartphone applications (apps). As a result, patients will be able to securely and easily obtain and use their electronic health information from their provider’s medical record for free, using the smartphone app of their choice. CMS, in partnership with ONC, has also identified HL7 FHIR Release 4.0.1 in the final rules as the foundational standard to support data exchange via secure APIs.

In conjunction with ONC, the CMS Interoperability and Patient Access final rule requires health plans in Medicare Advantage,

Medicaid, CHIP, and through the federal exchanges to share claims data electronically with patients. Medicare Advantage, Medicaid, CHIP, and plans on the federal exchanges will be required to share claims and other health information with patients in a safe, secure, understandable, user-friendly electronic format through the Patient Access API. HHS states that “this Patient Access API will allow patients to access their data through any third party application they choose to connect to the API and could also be used to integrate a health plan’s information to a patient’s electronic health record (EHR).”

In addition, the CMS final rule establishes a new Condition of Participation (CoP) for all Medicare and Medicaid participating hospitals, requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged or transferred.

In order to advance interoperability, the 2015 Edition Cures Update also established that the data required by the United States Core Data for Interoperability (USCDI) standard be met instead of the Common Clinical Data Set. The USCDI standard establishes a set of data classes and constituent data elements required to be exchanged in support of interoperability nationwide.

Regarding provisions in the final rules, the ONC and

CMS enforcement discretion announcements mean that:

ONC will exercise its discretion in enforcing all new requirements that have compliance dates and timeframes until three months after each initial compliance date or timeline identified in the ONC Cures Act Final Rule.” ONC highlights to please see, and that this is in relation to Certification Timelines.

CMS is extending the implementation timeline for the admission, discharge, and transfer (ADT) notification Conditions of Participation. CoPs at 42 CFR Parts 482 and 485 will now be effective 12 months after the final rule was published in the Federal Register.

CMS also finalized the Patient Access API and Provider Directory API policies for Medicare Advantage (MA), Medicaid, and the Children’s Health Insurance Program (CHIP) effective January 1, 2021. CMS will not enforce the new requirements under 42 CFR Parts 422, 431, 438, and 457 until July 1, 2021.

CMS finalized the Patient Access API for Qualified Health Plan (QHP) issuers on the individual market Federally-Facilitated Exchanges (FEEs) beginning with plan years beginning on or after January 1, 2021. CMS will not enforce the new requirements under 45 CFR Part 156 until July 1, 2021.

CMS notes that other policies contained in the final rule will be implemented and enforced on schedule.

Information Blocking

Section 4004 of the 21st Century Cures Act defines “information blocking” and authorizes the HHS Secretary to identify, through rulemaking, reasonable and necessary activities that do not constitute information blocking. It also prescribes penalties for information blocking. Actors must comply with information blocking provisions six months after publication of the final rules. Being subject to the information blocking provisions involves:

- Being an actor regulated by the information blocking provision [healthcare providers, health IT developers of certified IT, health information exchanges (HIE), and health information networks (HIN)]
- Electronic health information as defined in the final rule (EHI)
- A practice likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI
- Requisite knowledge by the actor
- Not being covered by an exception

Publication of “FHIR service base URLs” (sometimes also referred to as “FHIR endpoints”) comes into play in the information blocking interference section. HHS notes that a FHIR service base URL cannot be withheld by an actor as it (just like many other technical interfaces) is necessary to enable the access, exchange and use of EHI.

The Department of Health and Human Service’s Office of the Inspector General (OIG) published a proposed rule related to information blocking on April 24 entitled “Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General’s Civil Money Penalty Rules.” It can be accessed at: <https://www.federalregister.gov/documents/2020/04/24/2020-08451/grants-contracts-and-other-agreements-fraud-and-abuse-information-blocking-office-of-inspector>

Standards Version Advancement Process

The Standards Version Advancement Process (SVAP) is an important element of the final rules. ONC describes the Standards Version Advancement Process (SVAP) in the final rules as follows:

“The Standards Version Advancement Process allows developers to choose among the versions of standards and implementation specifications listed in regulation or National Coordinator (NC)-approved newer version updates for any or all standards applicable to criteria subject to real world testing requirements. This flexibility to choose among NC-approved versions of standards and implementation specifications will be available both when developers seek initial certification or to maintain certification of a Health IT Module.”

Conclusion

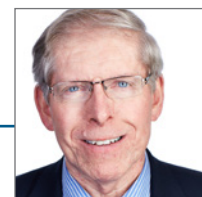
HL7 works with both ONC and CMS on shared healthcare interoperability goals and believes the use of HL7 FHIR Release 4 and other key HL7 standards strongly supports the final rules’ expansion of seamless data exchange and patient access to their healthcare data to make better and more informed decisions, among other advancements. HL7 is committed to creating helpful policy resources for our members and the implementation community on this topic. Please look out for these tools in the months ahead. ■

Benefactors



Promoting the Viewpoint of Patients and their Caregivers

HL7 Patient Empowerment Work Group Launches



By Dave deBronkart,
Founding Co-Chair, HL7
Patient Empowerment
Work Group

“In the past decade the culture of medicine has begun to recognize that healthcare value is measured by the person getting care: the consumer, the patient, and the family. The recipients of care inevitably have a different perspective than those creating and working in the healthcare system, and that perspective needs to be included by direct participation of patients and caregivers in the standards process.”

So begins the recently approved charter of HL7’s new Patient Empowerment Work Group (PEWG), authorized by the board at the 33rd Annual Plenary & Working Group Meeting in September 2019 in Atlanta. It couldn’t be more timely, given the new Final Rules announced Monday, March 9 by the Office of the National Coordinator for Health Information (ONC) and the Centers for Medicare and Medicaid Services (CMS), which promise to make real what I myself have long called for: a “[health data spigot](#)” for all my medical information.

The opening paragraph points tacitly to a fundamental change: for two centuries all improvement in healthcare arose brilliantly out of better biology, to the point where we now have an unprecedented number of elders, aka “people who didn’t die young.” I’m one – kidney cancer almost killed me at 57, but we beat it, so I’m alive.

Today, though, the greatest improvements often require empowering the consumer – “the ultimate stakeholder” – because among a range of possible treatments, the best choice

sometimes depends on patient preference. After all, the whole point of healthcare is to help the patient and family have the life they want. This has been reflected in medical trends since the 1980s: shared decision making, preference-sensitive decisions, patient experience, patient-centered care.

We in the PEWG are passionate about data liberation. Many of us have personal stories where data access – or lack of it – were pivotal in the outcome. A dozen such stories are in [this virtual talk I gave](#) at HealthDevJam after HIMSS was cancelled. The stories leave no doubt: patient data access can make a clinical difference.

An Outgrowth of FHIR DevDays

Having been involved in standards work outside healthcare, I’ve been amazed at how rapidly HL7 has responded to this sprout of an idea.

I first touched HL7 Fast Healthcare Interoperability Resources (FHIR) at DevDays Boston in 2018. Both HL7 FHIR Product Director Grahame Grieve and Bostonian Keith Boone had



Wayne Kubick, Grahame Grieve, W. Ed Hammond and Dave deBronkart at “the conception” of the Patient Empowerment Work Group, June 2019 social evening at DevDays US, Seattle.

separately told me about the standard years earlier. After 2018 DevDays in Amsterdam, next came DevDays Seattle in 2019, and as we dug deeper into “How is the patient point of view represented in HL7,” it became clear that as important as HL7 believes patients to be, there wasn’t a consensus concept of what “patient” is, which is ironic for an international health IT standards developing organization.

Before that meeting was over, an august group of luminaries (see photo) had decided a patient work group was necessary. In Atlanta, the HL7 Board of Directors approved the idea. We began meeting informally, and in November the HL7 Technical Steering Committee (TSC) approved the group; a mere five months after Seattle! Who ever heard of a standards group moving so fast? The founding PEWG co-chairs are Virginia Lorenzi, Debi Willis and me; we also get frequent advice from Lloyd McKenzie. Our charter and mission are located on the group's Confluence home page. The charter states the

group “promotes and amplifies the viewpoint of patients and their caregivers in HL7’s standards work, in support of the HL7 mission.” We know this work will touch on many aspects of HL7’s work, and we very much hope to grow a vibrant and useful community of people who can help weave “patientness” into everything the organization does.

It’s important work: every one of the patient stories in that video is a real use case where data mobility (or its lack) made an identifiable difference. In addition, as we “elders” get older (and as you do, too), if we don’t die first we will crush the system – so really, we’d better “Let Patients Help” (the

title of my book) where possible, so the system can be kept open for those who *need* the professional help. And that will require data and tools. If this opportunity inspires you, please join us. ■

(Note: see that line about keeping people out of the system so it can serve those who need professional help? It was written weeks before the coronavirus began overwhelming health systems around the world. This is no joke: going forward, we need to empower patients to do what they can, so the professionals can do what only they can. The well-being of care professionals depends on it.)

Improving Readability and Ease-of-Use

Governance Operations Manual (GOM) Update Project

The Governance Operations Committee (GOC) has received concerns from the Technical Steering Committee (TSC) and members about the readability and content of the Governance Operations Manual (GOM). The GOC is responsible for the ongoing maintenance of the GOM and has started a project to address these comments and to improve the GOM.

The first phase of the project includes the restructuring of the GOM to reorganize content and make it easier to find, using a new table of contents approved by the HL7 Executive Committee. This

restructuring has been applied to the latest version of the GOM (last updated on January 15, 2020). A cross-reference will be available to allow for a quick reference between the old and new version. This phase is complete and the updated GOM has been submitted to the HL7 Executive Committee for approval.

Once the approval has been received, the next phase of the project will get underway. This phase is more extensive and includes the following:

- Additional formatting changes
- Rewording of content to make it easier to understand

- Addition of new content (will undergo peer review by members)
- Removal of content (will undergo peer review by members)
- Some additional reorganization

It is expected that this work will be completed by the September 2020 WGM.

If you have questions, concerns or suggestions for changes, please email the GOC list, any member of the GOC, or the Director of Membership and Administrative Services. ■



By Melva Peters,
Chair, Governance and
Operations Committee

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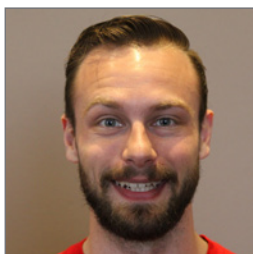
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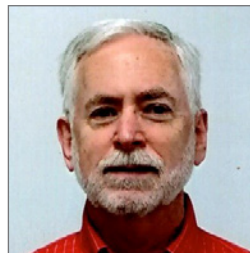
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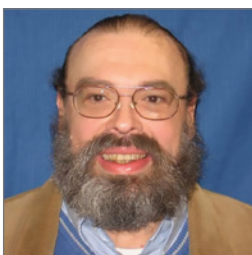
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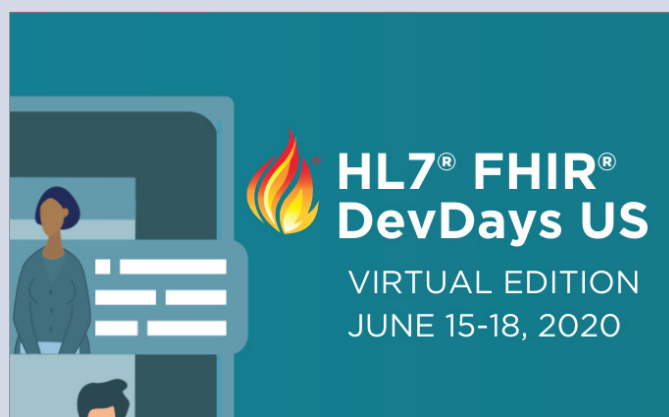
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