Health Information Technology Advisory Committee
Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | May 10, 2022, 10:30 a.m. – 12:00 p.m. ET

Executive Summary
The focus of the Interoperability Standards Workgroup (IS WG) meeting was to work on Charge 2, which is due to the HITAC by June 16, 2022. The WG received presentations from subject matter experts on electronic case reporting (eCR) and from representatives of the HL7 Patient Empowerment Workgroup regarding the HIPAA Patient Right to Request Corrections to the medical record. WG members discussed the presentations and submitted questions.

There were no public comments submitted verbally, but there was a robust discussion held via the chat feature in Zoom Webinar.

Agenda
10:30 a.m.	Call to Order/Roll Call
10:35 a.m.	Co-Chair Remarks
10:40 a.m.	Electronic Case Reporting (eCR) Discussion
11:20 a.m.	HIPAA Right to Request Corrections
11:55 a.m.	Public Comment
12:00 p.m.	Adjourn

Call to Order
Michelle Murray, Acting Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:30 a.m. and welcomed members and the public to the meeting of the IS WG.

Roll Call
MEMBERS IN ATTENDANCE
Steven Lane, Sutter Health, Co-Chair
Arien Malec, Change Healthcare, Co-Chair
Kelly Aldrich, Vanderbilt University School of Nursing
Hans Buitendijk, Cerner
Jeff Ford, Department of Defense *(Attending on behalf of Thomas Cantilina)*
Christina Caraballo, HIMSS
Grace Cordovano, Enlightening Results
Steven (Ike) Eichner, Texas Department of State Health Services
Sanjeev Tandon, Centers of Disease Control and Prevention *(Attending on behalf of Adi Gundlapalli)*
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Jim Jirjis, HCA Healthcare
Kensaku (Ken) Kawamoto, University of Utah Health
John Kilbourne, Department of Veterans Health Affairs
David McCallie, Individual

Clem McDonald, National Library of Medicine
Mark Savage, Savage & Savage LLC
Michelle Schreiber, Centers for Medicare & Medicaid Services (CMS)

MEMBERS NOT IN ATTENDANCE

Hung S. Luu, Children's Health
Leslie (Les) Lenert, Medical University of South Carolina
Abby Sears, OCHIN
Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Michelle Murray, Acting Designated Federal Officer

Key Specific Points of Discussion

TOPIC: CO-CHAIR REMARKS

Steven Lane and Arien Malec, IS WG co-chairs, welcomed everyone. Steven reviewed the plan of work and agenda for the meeting, including presentations on the topics of electronic case reporting (eCR) and The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Patient Right to Request Corrections. He noted that this was the 17th meeting of the IS WG and thanked members for their hard work.

TOPIC: WORKGROUP WORK PLAN

Steven briefly reviewed the charges of the IS WG, which included:

- Overarching charge: Review and provide recommendations on the Draft United States Core Data for Interoperability Version 3 (USCDI v3) and other interoperability standards
- Specific charges:
  - Phase 1: Completed on April 13, 2022, following a presentation to the HITAC and approval by voice vote:
    - Evaluate draft Version 3 of the USCDI and provide HITAC with recommendations for:
      - 1a - New data classes and elements from Draft USCDI v3
      - 1b - Level 2 data classes and elements not included in Draft USCDI v3
  - Phase 2: Due June 16, 2022:
    - Identify opportunities to update the ONC Interoperability Standards Advisory (ISA) to address the HITAC priority uses of health IT, including related standards and implementation specifications.

TOPIC: ELECTRONIC CASE REPORTING DISCUSSION

Steven introduced the presenters, who included Craig Newman, Public Health Interoperability Expert, Altarum, ONC, Laura Conn, Health Scientist, CDC, and John Loonsk, Consulting Chief Medical Informatics Officer, Association of Public Health Laboratories (APHL), Adjunct Associate Professor, John Hopkins Schools of Medicine and Public Health. They discussed eCR in the context of opportunities to update the ISA.

Craig, co-chair of the HL7 Public Health Workgroup, introduced himself and presented on the topic of HL7 Standards Development. He began by reviewing the lifecycle of HL7 Standards, which includes the circular flow between the steps of content updates, balloting/publishing, implementation, and feedback. He explained that all of these steps happen within HL7 Work Groups. The eCR standard began this process in 2015, with the first balloting occurring in early 2016; since then, HL7 has been going through the lifecycle. He reminded WG members that change is expected over time for HL7 standards, and it occurs by design and through

learning via implementer feedback. He explained that the scope of a standard can expand over time and that HL7 uses a Jira based process to collect, track, and resolve comments. He described the types of feedback that are gathered, which were detailed in the presentation slides, and invited everyone to contribute feedback through HL7 Work Groups, Connectathons, Fast Healthcare Interoperability Resources (FHIR) Accelerators, and other methods, like associations, projects, and https://chat.fhir.org/. He highlighted the Helios FHIR Accelerator for Public Health data, which brings together a diverse team to tackle longstanding challenges and explore new opportunities offered by FHIR to advance interoperability. The key work of the Helios Accelerator was detailed in the presentation slides. He stated that tracking the maturity of standards supports and drives adoption, so the FHIR Maturity Model is a framework used to judge standards and implementation guides (IGs) on how much they have been tested and implemented in the real world. Discussions are underway regarding the adoption of similar frameworks for other products.

John introduced himself and presented on the topic of eCR interoperability standards and needs. He stated that there are about 12,200 facilities in production for eCR nationwide (mostly for COVID-19 reporting). He described how healthcare's use of eCR widened over the course of the pandemic and referenced his presentation slides. Similarly, public health agencies have expanded their capabilities to receive eCR. He discussed a slide depicting the eCR workflow and described the complexities and variations between different states' laws. He explained that public health agencies (PHAs) need data to support condition reporting, case ascertainment, investigation, classification, management, and further reporting. These eCR processes and outcomes were detailed in the presentation slides. He explained that eCR provides a single interface for healthcare organizations to provide electronic Initial Case Reports (eICR) in support of 132 reportable conditions and described how the structured and coded data enables the processing of eICRs to automate reporting and minimize provider burden.

John described how HL7 began the development of consensus-based eCR standards in 2015, noting that electronic health record (EHR) certification currently references no specific eCR standards. He explained that the single standard was built on Consolidated Clinical Document Architecture (C-CDA) templates as well as the CCDS and later United States Core Data for Interoperability (USCDI) to minimize the effort needed for construction. He shared the goals of the eCR specific standard and continued to discuss and define the standards that eCR has been advancing, which were detailed in the presentation slides. In response to Arien's question, he explained that for those implementers that onboard with this infrastructure, HL7 has unambiguously expressed which version of each standard from the full suite should be used. He shared HL7's recommendations to the IS WG around eCR interoperability and standards needs, and these were defined on the final slide in his presentation. The recommendations were identified to use eCR to reckon with the disconnect around supporting the 132 conditions public health agencies support and potential inappropriate data disclosures. Finally, he described the specific ways in which the ISA could be updated to support eCR, which were detailed in the appendix of the presentation

Steven thanked the presenters and invited WG members to submit feedback.

DISCUSSION:

- Arien shared several comments following Craig's presentation, which included:
  - The IS WG would like to make recommendations to include the latest versions of standards in the ISA and to include new information on the HL7 FHIR Accelerators. He invited Craig to share relevant feedback on how to HL7 and other Standards Developing Organizations (SDOs) can better align with the ISA. He requested feedback on eCR and other things that go through heavy production testing.
  - He discussed how HL7 Work Groups and the FHIR Maturity Model get feedback from pilots and production environments. He asked Craig to comment on how real-world implementers share feedback throughout the process to maturity.
  - The entry for eCR in the ISA currently points to STU 1.0, but the link references version 2.0, though the work the Centers for Disease Control and Prevention (CDC) is doing points at another version.
  - How can ONC reliably point implementers to the latest and most productive version of the

standard?

- Craig responded that the FHIR Accelerators produce standards that go through the HL7 process and referenced the Da Vinci Project's process for developing IGs. He encouraged the IS WG to coordinate with the accelerators to align with the ISA, noting that the standards HL7 produces are similar across the board. He explained that there are usually multiple versions, which can be difficult for implementers, so there is a role for the ISA to work with the accelerator project leads to indicate what is ready and recommended for use. He stated that there is variation in what is used by the community, which creates considerations for the WG. Arien commented that there is a risk that the ISA points implementers to older/less useful versions of standards simply because they were the ones that went through the formal HL7 balloting process, and he discussed examples.

- Arien thanked the presenters, noting that the work they described was originally triggered by Zika and the need for a more flexible way of responding to emergent crises. He discussed how larger EHR vendors have partnered with HL7 since the beginning of the COVID-19 pandemic to drive eCR into products. He asked how the work that connects EHRs with states tracks the work HL7 Work Groups do to coordinate updates to IGs and what policy recommendations they would make to ONC to ensure that the ISA is a better tool for enabling implementers.
  - John recognized the roles the Council of State and Territorial Epidemiologists (CSTE), the CDC, The Association of Public Health Laboratories (APHL), and others played as part of the eCR team, which has driven the standards development process through the HL7 Public Health Work Group. eCR is not a use case in the Helios Public Health Accelerator because most of the standards are mature, but the identification and communication of them in ISA has been a challenge. He described challenges for EHR vendors and public health and stated that incorporating these standards in EHR certifications would be very helpful. He suggested that WG members could direct additional questions to Laura Conn by using the public chat in Zoom.
- Hans reviewed the questions he shared with Laura in the public chat and asked about considerations/challenges during the shift from the C-CDA to the FHIR-based standards. Also, he recognized that the HITAC is interested in recommendations beyond updates to the ISA, specifically around public health topics. He inquired about barriers and opportunities related to the use of FHIR payloads for eCR. How can they take advantage of existing networks to help with this transition when they are still working on getting fully on FHIR?
  - Arien responded that the limit for eCR for the FHIR-based workflow is that most of the major EHR vendors have gone forward with the CDA version of eCR. The issue is more on the provider side than for public health to view/accept. Hans noted that he was trying to better understand challenges on the public health side, and Arien discussed how public health consumes and publishes the data (through bespoke/custom integration engines).
  - Steven stated that the FHIR app is a means to assemble the document and is not a full end-to-end option at the public health level. Hans responded that he had also heard about an end-to-end option using FHIR and would like to know more about it. Ike added that, currently, FHIR interfaces between eCR Now (on the backend) or via built-in technology on the EHR side. It is not standardized as a FHIR interface, so substantial investments would be needed by public health.

TOPIC: HIPAA RIGHT TO REQUEST CORRECTIONS

Steven introduced Grace Cordovano, IS WG Member, Enlightening Results, Debi Willis, Founder and CEO, PatientLink Enterprises, Inc., and Dave deBronkart, Founding Co-Chair, HL7 Patient Empowerment Workgroup. Grace introduced herself and the other presenters, who are the leads of the effort, and she thanked the IS WG for the opportunity to present on behalf of the HL7 Patient Empowerment Workgroup that is leading the charge on patient requests for medical record corrections.

Grace began by describing the scope of the problem, noting the staggering volume and impact of errors in patient records, and she shared related statistics and citations in the presentation slides. She explained that

their group's goal is to empower patients to help identify and correct errors in the medical record in this new era of shared accountability and provided an overview of the common types of errors found in patient records, which were listed in her presentation. She described the results of a recent OpenNotes study on the frequency and types of patient-reported errors in EHR Ambulatory Care notes, in which 1 in 5 patients reported finding a mistake in their note, and 40% of these were perceived as serious or very serious. She suggested that there is an opportunity to focus on this volume of errors and that patient engagement includes their requests for records and to update them. She emphasized the need to develop efficient mechanisms to receive and respond to reports of errors.

Grace stated that errors in the patient record have a greater impact on the most vulnerable, specifically minorities and those with poorer health, and contribute to inequity in healthcare. She described common barriers patients face to reporting errors in the medical record and discussed how missing information can lead to the unnecessary repeating of tests, delays in care, increased costs, and overburdened healthcare facilities. Because the problem is widespread and increasingly visible, there is an urgent need for a standardized process for patients to request corrections. She shared several suggestions for reporting options.

Grace explained that there are data integrity issues in the use of EHR data by research organizations, including public health, and emphasized that the use of poor quality data leads to poor quality research. She provided an overview of the reach of the work the HL7 Patient Empowerment Work Group has done on the issue of patient requests for medical record corrections, which was detailed in the presentation slides.

Grace highlighted the various policy levers that are applicable in ensuring the patient's right to correct their medical record. These included the ONC Correction Principle (2008), the HIPAA Privacy Rule, the initial charge and recommendations of the Health IT Policy Committee (2011) to ONC, and the 2015 Edition Health IT Certification Criterion. She described the current state and compared the current ability to access data versus the ability correct errors and noted deficiencies in the process. She provided an overview of the HL7 Patient Empowerment Work Group's Patient Request for Corrections Project and shared their structural, granular, and global recommendations for the ISA, which were detailed in the presentation slides. Then, she invited Debi and Dave to field questions from the IS WG and shared contact information.

DISCUSSION:

- David asked if the recommendations that Grace presented address the workflow questions around how this process will work in the real world. He asked for clarification on how they determined what FHIR API to use (mentioned in the recommendations) before figuring out the implications of the workflow. They could end up with an API that nobody uses.
    - Debi responded that the IG is not telling healthcare systems how to make corrections, noting that these requests come in from a variety of methods, so HL7 has been building a communications channel that is a standard way to use FHIR to share patient requests with the healthcare system. Then, the healthcare system will use its own workflows; HL7's contribution is a better way to share, respond to, and document patient requests for corrections.
    - In response to David's further inquiries about the mechanics of the FHIR API, Debi responded that patients should not be able to directly edit charts but that current HL7 resources would be used to communicate requests. She described the potential process and stated that communications will be labeled as a request for correction (for filtering/sorting purposes). Dave deBronkart commented that there are appropriate limits to patients being allowed to make edits to their records (e.g., patients denying that they have COVID-19 right up until death); rather, the use of the FHIR API brings greater organization to the process. He noted that a new ecosystem will likely spring up to support the process.
    - Arien commented that unstructured secure messaging has been used for years and that it has been ad hoc/disorganized. The old method often does not lead to corrections to the patient record, so the minimum request for the ISA is to track the HIPAA Right to Request

Corrections as a use case. Another recommendation could be to track the standards that are going through the accelerators as implementation guidance to be tracked under the use case. He asked if the Patient Empowerment Work Group has an approach to real-world testing with EHRs and production use prior to standardization. Debi responded that HL7 would be amenable if a vendor were to step up and help.

- Steven encouraged Grace and other IS WG members to use learnings and recommendations from the presentations to formulate draft WG recommendations to the HITAC.
- Christina asked about the recommendation around structural change to specialty care use cases. Grace described how the ISA website displays specialty care as a separate item and suggested that it be updated to include use cases. Arien noted that there is a recommendation in the WG's working spreadsheet document (will be reviewed at a future meeting) that recommends a view that tracks use cases and related standards/IGs across the ISA website.

Action Items and Next Steps

Homework for the May 17. 2022, IS WG Meeting:

- Review the ISA Topics / recommendations spreadsheet. Refine the entries and edit recommendations based on presentations given at the WG meetings. If entering new content, please label with your name. Please document policy levers at ONC's disposal or where ONC might partner with other agencies.
- Write specific recommendations in a format that emphasizes action that can be taken by ONC, i.e., "we recommend ONC…"
- Update your entries in the Rankings spreadsheet (1=High, 2=Medium, 3=Lower) as needed to help prioritize the WG's discussion.
- Focus your work on items ranked as higher priority so that the WG can address those first.
- WG ISA Topics Worksheet: Observations, Recommendations, and Policy Levers
  - Note that a new column has been added to the Topics Worksheet identifying the topics that ONC has specifically asked the WG to address.

Public Comment

QUESTIONS AND COMMENTS RECEIVED VERBALLY

There were no public comments received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Rita Torkzadeh: How does HL7 track maturity/adoption of standards across work groups?

Steven Lane: ISA page re Case Reporting to Public Health Agencies: https://www.healthit.gov/isa/case-reporting-public-health-agencies

Grace Cordovano: Is there a link that summarizes the currently supported 132 conditions?

Steven Lane: https://www.rckms.org/wp-content/uploads/2022/02/Conditions-available-in-RCKMS-February-2022.pdf

Steven Lane: Laura, what is the page where the latest version of the reportable disease list can reliably be found?

Arien Malec: One of the goals of eCR is to be trigger based so that in emergent situations like Zika (and Covid) we can have a more real-time adaptive case reporting system.

Steven Lane: The Reportability Response provides a great example of bidirectional exchange between provides and public health.

David McCallie: I'm confused about the desired pace for crossing over from CDA based reporting to FHIR based reporting?

Grace Cordovano: Thank you, John, for an excellent presentation on eCR interoperability and standards needs. This was so helpful!

Laura Conn: @David - eCR infrastructure is ready for either CDA or FHIR eICRs - currently EHRs are only sending CDA but as they move to FHIR implementation we will be ready. eCR is agnostic to CDA or FHIR and supports both.

David McCallie: @Laura - thank you.

Hans Buitendijk: @John/Laura: What are perspectives from public health jurisdiction to begin a shift from CDA Based or FHIR based eICR?

Hans Buitendijk: @John/Laura: With suggestions that eCR would be better suited to convey data that is currently being added to ELR, what are key barriers to address to expand on eCR as a vehicle to submit additional data?

Arien Malec: @Hans -- I see your hand is up -- can you drop your comments in the chat?

Arien Malec: @Hans -- what I've heard is that PH agencies that were eCR connected got eCR reports before lab reports.

Hans Buitendijk: @Arien: And eCRs can more easily contain more information applicable to the condition/tests from the ordering provider that has a larger data set available than a lab. That would indicate it would be helpful. Curious about any challenges that would have to be addressed to move that direction and that we may need to further highlight in our recommendations.

Steven (Ike) Eichner: PHAs are working through the CSTE and with APHL on eCR. It is critical that EHR vendors work to implement the standards expected by public health for eCR or information cannot be successfully exchanged. There needs to be greater clarity in regulation and other materials

Laura Conn: @Hans - related to the Ask on Order Entry questions that were requested during COVID, those types of data are included in the eICR standard so if eCR was widely implemented public health would have had that data (and more) to pair with the ELR when it arrived. The newest version eICR CDA 3.0 and FHIR 2.0 include a section where "additional data" (like those not yet known but need to be shared in the next PH emergency) could be populated.

Laura Conn: Re to transitioning eCR to FHIR - we also need the Health Information Networks (Carequaility, *[sic]* eHealth Exchange, Direct and CommonWell) to support FHIR eCR standards for policy and at times transport

Steven Lane: Thank you to both groups of presenters today for providing very specific recommendations that our WG can consider to send on to HITAC next month.

Mark Savage: +100 @Steven

Arien Malec: Indeed.

Mark Savage: Different providers use different approaches, so wise not to dictate one workflow, I think.

David McCallie: @Mark - yes, but some expectations about the back and forth between patient and the system is reasonable to expect

Hans Buitendijk: @Laura: Thank you! On the second question/topic, If eICR were to shift from CDA to FHIR, it would seem to still work under the current CQ legal framework as no data needs to actually need to flow throw the networks. As long as APHL/AIMS and/or jurisdictions could handle FHIR formatted eICR and at some point FHIR endpoints. Would APHL/AIMS and jurisdicatins *[sic]* be ready to receive FHIR based eICR payload in Direct or XDR, or using a FHIR endpoint? If not, what are barriers/challenges to consider?

Steven Lane: Members of the public are able and welcome to raise your hand in Zoom at any time so as to get in queue prior to our Public Comment period at 5 minutes before the hour. (If there are a number of raised public hands we have the option of going to public comment early to accommodate.

Mark Savage: Thank you so much Grace, Dave, Debi and team! So clear that this is an extremely high priority need and use.

Debi Willis: Thank you!

Steven Lane: ON this page https://www.healthit.gov/isa/isa-document-table-contents hover over the ISA Content header text there is a drop down menu.

Dave deBronkart: Grace's super-informed ONC knowledge is a blessing for our IG work - she puts it in a context that's useful to this group. So grateful!

Hans Buitendijk: @Ike: Thank you!

Rita Torkzadeh: For eCR, has non-CDA FHIR questionnaire resource or other standards been considered/used for reporting conditions?

Hans Buitendijk: That would imply that it is premature from a PH perspective to contemplate shift from CDA-based payload to FHIR, or adding/shifting transport to include FHIR based RESTful services.

Arien Malec: To be fair, PH don't routinely accept the CDA natively either.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources

IS WG Webpage
IS WG – May 10, 2022 Meeting Webpage
IS WG – May 10, 2022 Meeting Agenda
IS WG – May 10, 2022 Meeting Slides
HITAC Calendar Webpage

Meeting Schedule and Adjournment

Steven and Arien thanked the presenters and everyone for their participation, summarized key achievements from the current meeting, and shared a list of upcoming IS WG meetings.

The next meeting of the IS WG will be held on May 17, 2022.

The meeting was adjourned at 11:58 p.m. E.T.