Health Information Technology Advisory Committee
Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | May 31, 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 reviewed draft recommendations to the HITAC, and WG members provided feedback. 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.	Review of Recommendations (Workgroup Prioritized ISA Topics, Non-prioritized ISA Topics, Additional Non-ISA Recommendations)
11:55 a.m.	Public Comment
12:00 p.m.	Adjourn

Call to Order

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:31 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
Thomas Cantilina, Department of Defense
Christina Caraballo, HIMSS
Grace Cordovano, Enlightening Results
Steven (Ike) Eichner, Texas Department of State Health Services
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)
Abby Sears, OCHIN
Ram Sriram, National Institute of Standards and Technology

MEMBERS NOT IN ATTENDANCE

Adi Gundlapalli, Centers of Disease Control and Prevention
Leslie (Les) Lenert, Medical University of South Carolina
Hung S. Luu, Children's Health

ONC STAFF

Mike Berry, Designated Federal Officer
Andrew Hayden, Standards Advisory Lead, Standards Division

Key Specific Points of Discussion

TOPIC: CO-CHAIR REMARKS

Steven Lane and Arien Malec, IS WG co-chairs, welcomed everyone. Steven reviewed the WG's plan of work and agenda for the meeting. He explained that the IS WG's Phase 1 Recommendations to the HITAC were transmitted to the National Coordinator for Health IT and have now been received and approved in their entirety. Arien reminded WG members that the draft recommendations must be finalized prior to the WG's presentation to the HITAC at its June 16 meeting. Finally, Steven welcomed members of the public and invited them to submit commentary during the public comment period.

TOPIC: WORKGROUP WORK PLAN

The charges of the IS WG 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:
  - o 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
  - o 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: REVIEW OF RECOMMENDATIONS

Arien explained that the IS WG discussed the set of recommendations related to Results at the previous meeting and would now discuss the recommendations related to Orders. The co-chairs displayed the IS WG's working document containing the WG's recommendations and invited IS WG members to describe the draft recommendations they submitted, including related observations, recommendations, and policy levers. The ISA recommendation topics included:

- Workgroup Prioritized ISA Topics:
  - o Lab Orders/Results: Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care (SHIELD)/LOINC In Vitro Diagnostic (LIVD); Presenter: Hung Lu, et al
  - o Social Determinants of Health (SDOH) Standards: Centers for Disease Control and Prevention (CDC) Race/Ethnicity vocabulary subset; Presenter: Mark Savage
  - o Communications/ referrals between providers and community based social care providers; Presenter: Steven Lane
  - o Fast Healthcare Interoperability Resources (FHIR) Endpoint Standards; Presenter: David

McCallie

- Non-prioritized ISA Topics:
  o Enabling consumers to download Digital Imaging and Communications in Medicine (DICOM) images; Presenter: David McCallie
  o Enabling consumers to download genomic variants data; Presenter: David McCallie
- Additional Non-ISA Recommendations: (note: the WG has determined that these are scope-adjacent recommendations that will be presented to the HITAC_
  o Usage of standard codes in laboratory output; Presenter: Clem McDonald
  o Public Health Data Systems Certification; Presenter: Steven Lane, et al

DISCUSSION:

- Hans discussed the recommendations that he and Hung Luu submitted around Lab Orders/Results: SHIELD/LIVD (Orders) and shared background information. These recommendations included #33a, #33b, #33c, and #33d.
  o Hans explained that #33a recommended that ONC, in conjunction with other Federal partners, SDOs and industry partners, create and support a policy framework that encourages, incentivizes, requires, or otherwise enables bilateral closed loop order to result communication and multi-lateral distribution of results (especially including Public Health) using standards and comprehensive implementation guidance. He stated that the lab results interface (LRI) and laboratory order interface (LOI) specifications are fit for purpose and mapped to multiple needs, including electronic laboratory reporting (ELR) for public health. He added that while the associated Meaningful Use measures were "topped out," there is no broad scale deployment of tightly constrained implementation guides (IGs) that allows full communication of orders and results end-to-end including public health.
    - Ike suggested clarifying the terms "closed loop" and "bi- or multilateral," because the purposes and processes are slightly different. Arien explained that the intent of the recommendation is to go from Order to Result, where that Result is returned to the provider and then optionally sent by the provided to other key downstream actors who need the information, especially public health. WG members discussed wordsmithing options, and Arien offered to post updated text to the public chat.
    - The WG reviewed Arien's updated text and Hans' suggested additions.
    - WG members agreed to approve the recommendation.
  o Hans explained that #33b recommended that ONC, in conjunction with other Federal partners, SDOs and industry partners, create and support an ongoing consensus development process to prioritize the most common/important orderable tests and panels of each order type, including the orders that link to prioritized results. He shared examples and clarifying sub-recommendations, noting that radiology orders are not covered under LRI, and they will be addressed in the implementation of the interpretation of USCDI Version 2 (USCDI v2).
    - Steven amended the recommendation to reflect the need to support the most common orders and results at a national level through the prioritization schema.
    - David stated that incentives to use the standardized order catalog should be clarified. Steven explained that a previous task force discussed the challenge of mapping and allowing Orders and Results to move effectively downstream; they determined that a starting point would be to identify the top Orders and ensure that mapping was done. The purpose of this recommendation is to identify those top Orders and to create a standard catalog of orderables. David agreed, noting his longtime support, but asked who would be responsible for making this work happen and how incentives would be used to promote compliance. Arien explained that ONC asked the WG to use care when articulating specific incentives. He suggested that ONC work on a policy

framework that includes submission of self-developed tests for assignment of standard codes, while ensuring harmonization of multiple existing codes. These questions were addressed in recommendations #33c and #33d.

- WG members discussed the intended goal for this recommendation and the most appropriate way to articulate it to ONC. Arien posted updated text to the public chat. WG members agreed to approve the recommendation.

o Steven explained that #33c recommended that ONC, in conjunction with other Federal partners, SDOs and industry partners, encourage/incentive laboratories to submit their self-developed test specifications to LOINC for assignment of standard codes.

- David commented that the IVD developers submit their test to the Food and Drug Administration (FDA) and then, indirectly, to SHIELD. Is LOINC the correct target for the recommendation? In response to comments from Hans and Ike, Arien commented on a previous recommendation that refers to the IVD mapping process; this recommendation is to ensure that self-developed tests have an orderable code that is mapped in LOINC. David and Hans suggested clarifying this recommendation, and Arien discussed the applicable regulatory schemes.
- Hans stated that not all test codes are orderables, which is a sub-set, and asked if using the term was restrictive. Arien updated the wording.
- WG members shared feedback on the wording, Arien posted updated text to the public chat,and WG members agreed to approve the recommendation.

o Hans explained that #33c recommended that ONC, in conjunction with other Federal partners, SDOs and industry partners support and assure the standardization of the multiple existing code sets for orderable tests to LOINC and develop cross maps for administrative purposes. He stated that, currently multiple terminologies such as SNOMED-CT, Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) billing codes, Proprietary Laboratory Analyses (PLA) codes, and LOINC codes are variably used for orderables. These code sets require harmonization amongst one another or, preferably, mapping to LOINC codes to support consistent interoperability.

- John suggested that the purpose of this recommendation should be more focused and commented that "harmonize" could be too vague of a term.
- WG members discussed the intent to use LOINC for the orderables catalog and discussed updates to the wording of the recommendation. Hans suggested that both cross-mapping and alignment on a single set for orderables would be necessary. David commented on the need to incentivize the use of LOINC.
- Arien updated the recommendation text to replace "harmonization" with "standardization" and to reflect the need for cross-mapping. WG members agreed to approve the recommendation.

- Hans explained that #34 recommended that ONC, in conjunction with other Federal partners, SDOs and industry partners encourage the development of and eventually require the use of standard "patient friendly" Order and Result display names (aka "Consumer Names") for patients based on LOINC standards, when sufficiently mature.

o WG members discussed whether this work is already in progress, and they determined that it does not seem to be at this time.

o Ike suggested some simple wordsmithing suggestions and shared updated text.

o David and Steven discussed complications around creating "patient friendly names" for tests, noting that third-party vendors have tried to provide some clarification. Hans discussed the use of an Info Button as part of certification, but Arien commented that the WG should not work outside of its scope. He suggested adding "names or explanatory content" to the wording of the recommendation, and WG members discussed wording options.

o WG members discussed how to best update the wording to include David's feedback, and

the co-chairs requested more time to determine how best to include this suggestion. They added "as well as the ability to reference patient-facing explanations" to the recommendation. WG members agreed to approve the recommendation.

- Hans discussed recommendation #35 that he and Hung submitted, which recommended that ONC, in conjunction with other Federal partners, revisit existing requirements for ELR, given broader adoption of electronic case reporting (eCR). Arien explained that there may be overlap, and eCR should be prioritized as the case reporting function, while ELR is focused on providing relevant result data.
  - o Arien commented that feedback from public health has stated that they receive case reports faster using eCR.
  - o Ike commented that wording should be updated to change "performance" to "resulting."
  - o WG members agreed to approve the recommendation.
- Mark Savage discussed updates that were made to the recommendation (#7) he submitted around SDOH Standards and reporting for the CDC Race/Ethnicity vocabulary subset. He shared several observations and added recommendations developed by the Gravity Project as part of the SDOH Clinical Care IG STU2 and added notes for how to update the ISA. Also, he explained that the Gravity Project is testing the transmission of other characteristics beyond race and ethnicity.
  - o Arien asked for clarification around which ISA IGs are referenced in the recommendation, and Mark explained that the approach is being laid out now, in the STU2 IG (a FHIR IG currently in the balloting stage). Arien suggested that this FHIR IGs should be named specifically in the recommendation.
  - o Arien and Hans discussed how to update IGs to versions of the USCDI, and Hans commented that sexual orientation and gender identity (SOGI) data is being addressed in current updates. He suggested keeping them separate, due to the status of work on standards.
  - o Abby asked for clarification on why they are looking for information on the source and method of data collection and explained that this work requires extra effort. She questioned how accurate the results would be if they can be obtained. Mark explained that there will be a significant number of instances where the origin/method of collection for information in the EHR is unclear; is it self-reported, a clinical observation, or from a batch file? Abby asked why this matters, and Mark explained that mis-categorizations can have health implications. Also, patients should have the ability to correct errors in medical records. Abby reiterated her concerns around the burden of collecting this information.
  - o The text was updated to state that standards for reference in ISA include the FHIR SDOH Clinical Care IG STU2 (draft specification currently in ballot), HL7 C-CDA, and HL7 v2 as available. The WG agreed to accept the recommendation.
- Steven reviewed recommendation #10 and explained that, while it has been discussed by other task forces and workgroups, it is not an ISA-specific recommendation. This recommendation was that ONC, in coordination with other Federal partners, public health organizations, SDOs and industry stakeholders, explore the development of a certification program and associated funding to facilitate compliance for public health information systems to establish minimum technical and functional standards in support of bidirectional health data interoperability with exchange partners including providers and individuals.
  - o Ike added additional observations to this item during offline work.
  - o Arien suggested that the IS WG recommend that the ISA be updated to include the definitive set of public health standards, applicable both to reporting systems (EHRs) and public health data systems, that could be used in policy and programmatics. Ike agreed but commented that this could be done at the national level, not the state level. He explained that providers often make localized changes to their systems that result in standardized messages that are not semantically/syntactically accurate, and this affects public health certification indirectly.

- o Steven added a recommendation that ONC update the ISA to identify the minimum data elements, standards, and IGs to support data exchange between public health and other stakeholders, including providers and individuals.
- o David commented that the certification program would be complicated and expensive and asked what problem was going to be solved through its use. Arien explained that this issue was first raised during Meaningful Use Stage 2, and EHRs are adopting common standards for public health without states having the means to accept the data. WG members discussed the intent of the recommendation and how it could be effectively implemented. Hans asked about the use cases that are missing. Arien asked if the ISA can show the latest, best, and most comprehensive set of public health standards and IGs that are the most reasonable to adopt to achieve public health data interoperability. Hans stated that most are updated and shared a link in the public chat. Hans commented that many public health data systems are more segregated by background systems, due to their use of highly customized solutions.
- o David asked if certification of APIs/interfaces should be addressed. Ike agreed and suggested that the transmission of messages should also be addressed.
- o Steven commented that this is a non-prioritized item and asked the WG to determine whether to put it in the parking lot to focus on other, ISA-related priority topics.
- o Ike commented that the WG could recommend investigating better ways to look at data quality issues in production environments and potential solutions. Steven responded that many others are already looking at these challenges and opportunities.
- o Abby commented that the lack of standardization and certification process, including mapping issues, is creating problems. She emphasized the importance of this work but noted that, if it has been addressed elsewhere, this item could be omitted. Related work is already underway.
- o Arien explained that recommendation #18, which was already accepted by the WG and focused on expanding the Use Case section in the ISA, included a bullet that mentioned the use case of Disaster Preparedness and Pandemic Response. He suggested adding Public Health to this list.
- o Mark suggested a recommendation to explore the development of a certification program would add structure across the ecosystem. Steven agreed with this suggestion. Ike commented that funding must be attached to certification.
- o Steven responded that this recommendation would be discussed at the next meeting of the WG.
- Steven discussed recommendation #21, which recommended that ONC update the use case of bidirectional communications and closed-loop referrals between community-based social service providers and other healthcare stakeholders, including individuals/patients, clinicians, payers, and public health. The IS WG ranked this item as a high priority.
  - o David and Steven discussed the intent of the recommendation, and Hans commented that most of these items are already in the ISA. He asked what is missing that needs to be added.
  - o Ike suggested that the recommendation should start with the referral and healthcare provider and that it should be worded in the way it is usually interpreted. As it is worded in the recommendation, the referral would start with the social service provider. Steven commented that the process could begin either way.
  - o Arien and Hans suggested changing the text to "referral to extra-clinical services" to "referral to community-based organizations and other extra-clinical services" in the ISA and to mention that need to track Gravity Project standards and IGs in this area.
  - o The text was updated, and the WG agreed to accept the recommendation.
- David discussed recommendation #24, which recommended that ONC track in the ISA the use case and emerging standards related to identifying FHIR endpoints to facilitate API access

supporting consumer access and other services. He explained that he surveyed colleagues and arrived at this request, as the ISA did not appear to mention related work that is underway.

- o Hans explained that the FAST FHIR accelerator includes directories of key elements and that there is certification (with a deadline in 2022) that requires the listing of endpoints identifying certain APIs.
- o Hans commented that there is the need for vendors to publish endpoints and discussed challenges related to endpoint directories/libraries.
- o The WG agreed to drop the recommendation, as this has been covered elsewhere.

- David discussed the two recommendations (#22 and #23) he submitted that were designated as non-prioritized updates to the ISA. They included enabling consumers to download Digital Imaging and Communications in Medicine (DICOM) images and enabling consumers to download genomic variants data. He described the need for these recommendations, including related work done by the Sync for Science program; a summary of this work is located at https://github.com/sync-for-science/imaging. David stated that the problem is that the consumer has a right to access information that is not in the EHR, so there should be a way to transfer authorization to the managing system.
  - o Hans suggested that wording should be added to reflect viewing, downloading, and sharing DICOM.
  - o David explained that an HL7 Genomics Workgroup has been developing FHIR extensions to handle variants of clinical significance (VCS), so they could have feedback on recommendation #23. However, he was unable to find a source/link online.
  - o The WG updated the language and agreed to accept the recommendations.

- Steven presented Clem's submission, recommendation #25, which recommended that ONC, in coordination with other Federal partners, SDOs and industry stakeholders, develop and support/incentivize the implementation of a methodology to assess and monitor the actual delivery of standard codes in real world laboratory messages. This recommendation was discussed at great length by the WG at previous meetings.
  - o WG members discussed the wording of the recommendation and Clem's intent. David discussed a recent study on the accuracy of mapping of data.
  - o The WG agreed to accept the recommendation and to add it in with the other recommendations related to labs.

Action Items and Next Steps

Homework for the June 7, 2022, IS WG Meeting:

- Review the ISA Topics / recommendations spreadsheet and focus only on items that have been accepted by the WG (turned purple).
- Pivot to focus work on the transmittal recommendations document and prepare for the presentation to the HITAC at its meeting the June 16, 2022.

Public Comment

QUESTIONS AND COMMENTS RECEIVED VERBALLY

There were no public comments received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Welcome to the Interoperability Standards Workgroup. We will be starting soon.

Christina Caraballo: Christina is here too. Good morning, Mike and all!

Wendy Noboa: IS WG recommendations Final Report Phase 1:
https://www.healthit.gov/sites/default/files/page/2022-05/2022-04-13_IS%20WG_Phase%201_Draft%20USCDI%20Version%203_Transmittal%20Letter_508.pdf

Arien Malec: "enables bilateral closed loop order to result communication and multilateral distribution (especially including Public Health)"

Jim Jirjis: Jim Jirjis Joining late

Arien Malec: "to priorize *[sic]* and encourage or incent the adoption of the most common"

Arien Malec: https://www.grammar.com/incentivize-incent#:~:text=Both%20mean%20%E2%80%9Cto%20motivate%20or,one%20redeeming%20feature%3A%20it%27s%20shorter.

Sylvia Trujillo: Clarification: CMS under CLIA regulates Laboratory Developed Tests (LDTs) (only performed by that lab) and FDA regulates IVDs (kits, mass produced, performed in many labs). If a lab modifies an IVD, it becomes an LDT.

David McCallie: Cross-map as the goal?

Grace Cordovano: Thank you Hans

Grace Cordovano: If there was any supporting info or references that would be helpful.

John Kilbourne: "friendly naming" may result in one-to-many names, or multiple tests having the same "friendly name"

Steven Lane: https://loinc.org/consumer-names/

Mark Savage: Glad we're keeping "Consumer Names" or "Common Names", though, because that is a common issue--different stakeholders often using distinct names.

Steven Lane: Per LOINC: " LOINC's Consumer Names have an Alpha status. We do not have a schedule for promoting Consumer Names to a production status."

Hans Buitendijk: Clarification on referencing HL7 FHIR, HL7 C-CDA, and HL7 ADT would be to use HL7 v2 instead of HL7 ADT as we are finding that the data may need to be included in non-ADT messages as well where ADT feeds are not in place, or eCR is not in place / not covering the scenario at hand.

Arien Malec: That was my point that this is part of generally mapping USCDI V2/V3 to a broad range of standards.

Kelly Aldrich: Excellent points Abby

Hans Buitendijk: @Arien: That raises and an interesting, but essential question in that only HL7 FHIR and HL7 C-CDA are referenced as standards supporting USCDI. As we get into USCD+ and as we are going beyond view-only access to data into workflow support more widely (already for some, but many more to come), that all standards (view, workflow, etc.) that touch USCDI(+) data are consistent with USCDI(+).

Arien Malec: @hans -- agreed - will see implications for NCPDP, ADT/LRI/LOI v2 specs, etc.

Arien Malec: @hans -- is there a recommendation here? Feels like one...

Andrew Hayden: ISA Public Health section: https://www.healthit.gov/isa/isa-document-table-contents

Hans Buitendijk: https://www.healthit.gov/isa/section/public-health-reporting

Andrew Hayden: Thanks, Hans.

Hans Buitendijk: For vocabulary in Public Health: https://www.healthit.gov/isa/section/public-health-emergency-preparedness-and-response

Arien Malec: Obviously having some issues somewhere in the chain.

Hans Buitendijk: BSeR is here: https://www.healthit.gov/isa/referral-extra-clinical-services-request-updates-outcome

Hans Buitendijk: Agreed that "extra-clinical" services could be more clear to be community and social services.

Hans Buitendijk: services.

Mark Savage: Note FAST conclusion that patients, too, will have FHIR endpoints in the ecosystem.

Mark Savage: Patients and patient applications and equipment.

David McCallie: @Mark - interesting. Sounds like a security and privacy nightmare?

Mark Savage: Nothing that the ISWG cannot handle. :-)

Hans Buitendijk: @David: I'm very hopeful that the personal devices and consumer app community would help simplify any potential consumer FHIR endpoint proliferation, plus associated privacy/security challenges.

Arien Malec: incent >> incentivize. AMA.

Hans Buitendijk: @David: The FHIR extensions you are interested in may be here: http://hl7.org/fhir/uv/genomics-reporting/STU2/artifacts.html

Christina Caraballo: The bullets are pulled from HITAC recs.; consider adding to b. right below

Abby Sears: that is fair

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL
There were no public comments received via email.

Resources
IS WG Webpage
IS WG – May 31, 2022 Meeting Webpage
IS WG – May 31, 2022 Meeting Agenda
IS WG – May 31, 2022 Meeting Slides
HITAC Calendar Webpage

Meeting Schedule and Adjournment
Steven and Arien thanked 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 June 7, 2022. The meeting was adjourned at 12:02 p.m. E.T.