Health Information Technology Advisory Committee
Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | May 3, 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 recommendations related to the lab topics discussed at a previous meeting, and WG members discussed the list of suggested ISA priority topics.

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.  Lab Recommendations
11:10 a.m.  ISA Priority Topics Discussion
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 10:30 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
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
Sanjeev Tandon, Centers of Disease Control and Prevention (Attending on behalf of Adi Gundlapalli)
John Kilbourne, Department of Veterans Health Affairs
Hung S. Luu, Children’s Health
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
MEMBERS NOT IN ATTENDANCE
Thomas Cantilina, Department of Defense
Jim Jirjis, HCA Healthcare
Kensaku (Ken) Kawamoto, University of Utah Health
Leslie (Les) Lenert, Medical University of South Carolina

ONC STAFF
Mike Berry, Designated Federal Officer
Andrew Hayden

Key Specific Points of Discussion

TOPIC: CO-CHAIR REMARKS
Steven Lane and Arien Malec, IS WG co-chairs, welcomed everyone. Steven introduced Dr. John Kilbourne, who is a new member of the WG and serves on behalf of the Department of Veterans Health Affairs (VA). John introduced himself and explained that he trained as a family practice doctor and that his areas of focus at the VA are terminology and informatics.

Arien described the plan of work and agenda for the meeting. He commended WG members who have been adding information to the WG’s working Google spreadsheets. Steven added that Christina and Grace have offered specific recommendations regarding the structure and organization of the Interoperability Standards Advisory (ISA), similar to how the predecessor USCDI Taskforce has made recommendations regarding the USCDI in the past. He stated that there may be opportunities to improve on the formatting and tools available on the website to make it more understandable, especially for members of the public. WG co-chairs and ONC will review recommendations related to the structure of the ISA.

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.

Steven explained that ONC provided a list of the HITAC Priority Uses of Health IT, which were included in the presentation deck on slide #6, and he added that updates to the ISA can be structural or directional as well as related to its content. Mike noted that ONC would share additional information regarding high-priority uses with the co-chairs.
TOPIC: LAB RECOMMENDATIONS

Previously, the IS WG was asked to prioritize the enumerated ISA topics by ranking them in order of importance. The Laboratory-related topics were given a high priority by WG members.

Several WG members worked offline to add information from the SHIELD/LIVD project and presentation to prior Interoperability Standards Priority Task Force 2018-2019 (ISP TF 2018-2019) Recommendations related to laboratory orders and results. Arien explained that he used the information from the recommendations to create draft recommendations text and reviewed updates to the following ISP TF 2018-2019 recommendations, which the WG reviewed and discussed at its previous meeting:

- ISP TF 2018 Recommendation 05 – Orders & Results: Consistent encoding of tests and their result values
- Other ISP TF 2018 Recommendations

Arien invited WG members to submit feedback on the updated recommendations.

DISCUSSION:

- Steven explained that Clem’s feedback on ISP TF 2018 Recommendation 05 was taken into consideration when the co-chairs updated the text.
  - John asked if the WG should call out interpretation codes as an additional category of codes in this recommendation or if they are part of qualitative results. Arien responded that the text referred to the flags that often accompany Results and that the content of these fields has likely been standardized. He explained that there is a set of informal conventions that govern the interpretation flags that govern the Test Result. This is not in SNOMED. Steven asked if this should be called out or if there is a published standard; Clem stated that there is a published standard (HL0078) that has been in HL7 for 20 years. Hans shared the links in the public chat and explained that the list of possible flags for Test Results includes more choices than high/low. Hung suggested using the wording “abnormal flags” to avoid confusion, and Arien stated that he is using the term from USCDI Version 1. The WG discussed wording and updated the text.
  - Arien explained that the ISP TF 2018-2019 made specific policy recommendations for how ONC’s Federal partners could create policies to encourage the support of content standards for Orders & Results. Clem commented that many labs do not send LOINC or SNOMED codes to clients, so a push from Federal partners, like the Centers for Medicaid and Medicare (CMS), would be helpful. WG members discussed the reasons why labs have not mapped their local codes to standards. Hung suggested not defining the strategy further than the original recommendation, and WG members discussed the accuracy of lab data shared following Meaningful Use. Steven commented that the recommendations are more general and meant to carry those made by prior TFs forward (with appropriate modifications/amendments).
  - Ike commented that there should be alignment between the WG’s recommendations and language around electronic case reporting (eCR) to ensure consistency around LOINC codes for lab reports utilized in eCR. He discussed how mis-mapping of codes occurs when laboratories are on-boarded for electronic lab reporting (eLR) for public health. Vendors must work on validating their mapping at the local level. Arien noted that the WG has recommendations specific to mapping later in the document.
  - Arien suggested that some of the highlighted text be used as a preamble or in an appendix. Clem shared a comment in the chat clarifying recommendations about SNOMED testing and LOINC string codes.
  - Arien shared the recommendation that was updated following the SHIELD project that ONC, in collaboration with Federal partners, create sustainable mechanisms that lead to in-vitro diagnostic (IVD) Test devices and laboratory information systems (LISs) to automate mapping and translations to enable test resulting following standards. He stated that the recommendation was meant to be non-specific in terms of how it should be completed and
that use case information was included as an example.

- Arien shared the recommendation that ONC collaborate with other Federal partners, standards development organizations (SDOs), and industry stakeholders to assure that there is a well-managed and appropriately resourced process to develop and deliver additional LOINC codes when needed for new tests or needed variations of existing tests. Hans shared an example of how to make mapping data available electronically for LISs. Also, he suggested that the work the Centers for Disease Prevention and Control (CDC) has done on mapping COVID-19 tests should be made generally available. Arien agreed, noting that the amount of manual mapping required is creating a burden on the U.S. healthcare system and impacting the usability and quality of data. This is a good opportunity to look at how the WG’s set of recommendations calls out the standards in the ISA that are mature and ready to be advanced. The WG’s recommendations will direct ONC to work on the related policy levers.

- In response to a question from Clem, Arien explained that the inclusion of the wording “formal support” means that there is a well-managed and appropriately researched process that includes funding, the necessary talent, people, etc.

- Arien explained that he included text that Hans and Ricky created as a recommendation around the need to map internally generated codes to standard vocabularies through user-supported mechanisms. He asked WG members to provide feedback on how this could be turned into a recommendation to ONC, and John suggested that the recommendation could be toned down to suggest that ONC could make this process easier. He discussed the complexities around mapping these codes based on his personal experiences. Hans suggested updating the wording from “mechanisms” to “tools/education and guidance.” WG members discussed current state challenges, and Clem suggested that commercial labs could publish their codes and mapping table for others to review, noting that they are not currently obliged by statute or regulation to do so. Arien noted his agreement with the suggestion and summarized other suggestions from the public comments in Zoom. The WG’s general consensus was to focus on recommendations for education and guidance and to support/encourage transparency of resulting mapping. Hung agreed with the need for transparency but added that the mapping should be made more easily accessible. Clem stated that all medical record systems have mapping, but not all of it can be exposed for review. Arien stated that the WG has made recommendations previously that systems be easier to use as part of the certification process, noting that this is hard to enforce.

- Arien reviewed the recommendation that ONC collaborate with other Federal partners, standards development organizations (SDOs), and industry stakeholders to create and support mechanisms to support and ensure proper and consistent LOINC, SNOMED-CT, and universal device identifier (UDI) encoding across result sources by resulting organizations. He stated that the SHIELD Project suggested funding their proposed Laboratory Interoperability Data Repository (IDR) as an example. Clem commented that not all tests are approved by the Food and Drug Administration (FDA), so the focus should be on whoever is producing the tests upstream. Arien stated that previous TF recommendations mentioned the term “resulting organizations” and that it has been clearly defined in the past.

- The WG will continue to discuss other ISP TF 2018-19 Recommendations at a future meeting. Arien asked WG members to review these recommendations and to provide feedback on how to best turn them into text describing actionable recommendations for ONC to get to the desired state.

**TOPIC: ISA PRIORITY TOPICS DISCUSSION**

Steven thanked WG members who have shared their rankings on ISA priority topics and briefly shared that table. Then, he explained that these results were used to guide the WG’s ISA Topics Worksheet, which allows WG members to share background/supporting references, observations, and recommendations on the topics.
The list included:

- High Priority:
  - Lab Orders/Results: Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care (SHIELD)/LOINC In-Vitro Diagnostic (LIVD) test code mapping tool
  - Social Determinants of Health (SDOH) Standards: Centers for Disease Control and Prevention (CDC) Race/Ethnicity vocabulary subsets
  - Lab Orders/Results: laboratory information system (LIS) to electronic health record (EHR)/public health (PH) systems
  - SDOH Standards: Gravity Project Standards

- Medium Priority:
  - CDC: Electronic Case Reporting (eCR) Standards
  - Care Plans/Chronic Dx Management

- Additional Priorities:
  - HIPAA right to request corrections to one’s medical records
  - CDC: PH Data Systems Certification
  - Portal Data Aggregation Across Multiple Portals
  - Data Exchange Formats for Price Transparency
  - Data Sharing Between Federal & Commercial Entities
  - Occupation and Location of Work

- New:
  - Vulcan - HL7 FHIR Accelerator supporting clinical and translational research IGs
  - Helios - HL7 FHIR Accelerator supporting public health IGs
  - CodeX - HL7 FHIR Accelerator supporting oncology IGs
  - CARIN work to streamline digital identity and consumer auth/auth to portals
  - Coalition for Content Provenance and Authenticity - C2PA - New provenance standard from Adobe et al
  - TEFCA standards for consumer access to qualified health information networks (QHINs), RLS
  - Expand ISA to incorporate information in USCDI Submission Form • ISA Federally Required section: note specific federal requirements
  - Add data classes/elements in USCDI to ISA
  - Communications and referrals between providers and community based social care provider

DISCUSSION:

- Mark discussed the observations and recommendations he included for the SDOH /Gravity Project Standards topic. He stated that a use case structure is missing from the ISA and could be useful in connecting concepts across the ISA. He suggested that “Specialty Care and Settings,” which currently includes SDOH, be renamed to be called “Priority Use Cases.” He suggested that the WG recommend that ONC review and consider incorporating the recommendations from the Gravity Project. Mark will work on turning his entries into specific recommendations to the HITAC and ONC.

- Hans asked Mark to point to specific implementation guides (IGs) and value sets, and Mark responded that the Gravity Project defined these in the recommendations they presented to the WG. Mark added that the ISA does not automatically incorporate USCDI Version 2, so this must be included as a specific recommendation. Hans asked if the WG could recommend that ONC work with standards organizations to routinely include the newest version of USCDI data elements and associated standards into the ISA. Mark agreed,
adding that this idea has already garnered support.

- Clem voiced his support for Mark’s suggestions but noted that the SDOH items specifically state that LOINC should be used to codify answer codes. He discussed how the words in a survey instrument answer list are very specific and described differences between the uses of different answer codes. Mark commented that he did not know how this process works or about the current data elements in USCDI Version 2.
• Steven summarized the observations and recommendations he entered under the ISA Topic of CDC: eCR Standards, noting that the standards are identified in the ISA but are out-of-date. Also, CMS has not specified the use of a particular technical standard for eCR. Also, while the eCR Now standard is widely deployed, there is no required standard leading some EHR vendors to develop custom solutions, making it difficult for public health jurisdictions to support standardized data flows.
  o Ike commented that most of the public health ecosystem is orienting towards implementing the eCR Now standard and the associated information flow through the Association of Public Health Laboratories (APHL), so the disconnect is more on the provider side and implementations. Steven responded that the APHL would present its recommendations on updating the ISA to the WG at its next meeting. He discussed proposed policy levers. Ike commented that the APHL has a proposed public rule out for comment now and that comments are due in June 2022. He stated that there is an opportunity to get feedback in the current cycle of rulemaking if the IS WG accelerates feedback to the HITAC.
  o Hans asked if the WG should be more specific regarding the version of the eCR standard that is referenced in the ISA. Also, he asked the WG to consider how they could organize a recommendation sooner rather than later so it can be used in the HIT certification program.
  o Steven explained that the APHL team would present on the updated standard, which the WG could consider as a specific recommendation.

• Steven explained that there were high-priority recommendations on items related to labs, as previously discussed, and informed WG members that the recommendations listed in the working Google document would become the specific recommendations to the HITAC.

• The Care Plan/Chronic Disease Management topic was designated as a medium priority use case. Mark discussed the work he has done in this space in the HL7 Fast Healthcare Interoperability Resources (FHIR) Ecosystem Use Case Tiger Team and added that he, Abby, and Grace would create a set of draft recommendations related to this topic during offline work.
  o Arien explained that the WG should craft its recommendations in a specific format in order to more easily transform them into actionable recommendations text. He provided examples and invited WG members to follow the format of (for example): “We recommend that ONC update the ISA to track the priority use case [specific example here] and list the standards and certification criteria tracked to the [example] inclusive of [specific elements].” Mark inquired about the level of detail to include following that structure, and Arien suggested following the structure of the ISA (“tracking use case X, prioritized by use case Y”) unless making structural changes to the ISA.
  o David suggested that a fully-formed example would be helpful for others who are creating their own draft recommendations.

• David reviewed a series of recommendations he added to the spreadsheet regarding support for the Vulcan, Helios, and CodeX HL7 FHIR Accelerator Programs. He explained how he created his recommendations by looking at which listings in the HL7 FHIR Accelerator projects were active and underway to see which mentioned the ISA and that he did not find any specific references to work on IGs that align well with the WG’s priorities. He will create draft recommendations related to these use cases.
  o Arien suggested that the Helios project needs could likely go under an existing use case related to public health. He suggested that the Vulcan project is about supporting clinical research, so a recommendation could be added for a new prioritized use case under the Research tab. He suggested that WG members could recommend that the Vulcan IG is listed as an emerging specification under Research in the ISA. The formatting he suggested was, “The WG recommends that the ISA track the use case of collecting data for translational and clinical research inside electronic health records (EHRs), and the WG recommends that ONC include the appropriate implementation guides and standards tracked by the Vulcan project.”
David stated that the ISA should be a space for people to catalog, discover, and track work that is underway, and not that inclusion implies that a standard will be implemented or required. Arien agreed.

In the public chat in Zoom, Andrew Hayden shared the two sections in the ISA that are related to research.

WG members discussed the structural recommendations that could be made to the ISA to make it easier to explore and cross-reference.

Christina and Arien suggested that the WG make an overarching recommendation that ONC work with the leads in HL7 and other SDOs to automatically track established accelerators in the ISA. David suggested that the ISA have a submission process (like what is used for the USCDI update process) where an entity can submit their ideas for consideration. Arien supported this suggestion and shared several examples.

Ike commented that there is an existing way to submit materials for the ISA. He suggested that the WG consider common backend applications that support interface standards and consider making a recommendation around identifying these mechanisms across the ISA. This could help resolve linguistic differences and harmonize language.

Hans commented that a clearly defined process exists for SDOs to submit items for inclusion in the ISA and suggested that a fast-track be put in place to improve this workflow. He offered to add this recommendation as a new row in the working Google document during offline work.

The co-chairs noted that they were tracking the specific recommendations submitted by WG members. Arien suggested that the WG track the specific programs under the standard or IG that is required.

- David stated that some major content vendors (e.g., Adobe, Apple) are collaborating on a new standard (C2PA) targeted at ensuring that news stories can be mapped back to a specific news source to ensure trustworthiness. He discussed his recommendation that ONC add this standard to the appropriate ISA section regarding provenance information to ensure trustworthiness and to digital authentication based on the ways in which commercial standards are being deployed across consumer devices and browsers.
  - Clem suggested that this information be shared with HL7 and FHIR activists, and David noted that he included a link in the WG’s shared spreadsheet. Hans offered to share this information with relevant parties.
  - Steven explained that a new column was added to the spreadsheet as a result of Grace’s suggestion that links to additional background information or should be included.
  - The WG agreed to finalize David’s recommendation.

**Action Items and Next Steps**

Homework for the May 10, 2022, IS WG meeting includes:
• Review the second (new) tab “Full Topic List” in the Google sheet and, under your name, prioritize each topic as High/Medium/Low. The WG leads will utilize this ranking to inform the order in which topics will be discussed and recommendations developed.
• Thank you to all WG members who added topics to the worksheet document prior to our deadline for contributions. Please continue to add your observations, recommendations, and policy levers in the WG’s Google Sheet.
• Hans, Hung, and Riki Merrick have reviewed the lab-related recommendations pulled from the 2018/2019 ISP Task Force reports and provided redline comments in this Google document. WG members are invited to please continue to review and add comments.
• Please continue to add any new topics and document your observations, recommendations, and policy levers in the Google Sheet.

Public Comment

QUESTIONS AND COMMENTS RECEIVED VERBALLY
There were no public comments received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT
Christina Caraballo: Christina is here too. :)

Hans Buitendijk: HL0078


Abby Sears: From OCHIN’s perspective, we would like to see the requirements for everyone to be the exact same across the following elements:
• Unit of Measure
• Results Status with date and time stamps
• Laboratory Test Performed Date
• Specimen Source Site
• Test Kit Unique Identifier

David McCallie: lots of vendors have tools to help with mapping.

David McCallie: the incentives are more important that the tools, probably

David McCallie: maybe penalties even more useful

Hung S. Luu: “Education and tooling”

David McCallie: +! for transparency as a driver

David McCallie: +1

Hans Buitendijk: And whether the tools are from vendors, a “NLM Library” lookup that can aid in the mapping process, they are all valid to improve on the quality of mapping, particularly considering that mapping cannot yet be fully automated based on context.

David McCallie: hard core - just don’t pay for a non-mapped test?
Hans Buitendijk: We should stay with the principle though that the mapping should happen at the source that has the best knowledge to get it right.

John Kilbourne: If we’re asking to have mapping tables published, we may want to use the phrase “versioned mapping tables”

Hans Buitendijk: @John +1

David McCallie: Less nuclear - take 5% off the payment if the results are not appropriately mapped, by said date.

Hans Buitendijk: Sounds good.

Clem McDonald: Be aware that at lest half of all tests are laboratory developed test so LIVD will not help them. The big referral labs are the source for their lab developed tests.

Clem McDonald: The open source community says that 1000 eyes see (and fix) all problems. Since we worry about potential mapping errors the same principle should apply. Transparency fixes lots of problems. The big referral [sic] labs do it, and many hospital systems are multibillion dollar organizations. Why shouldn’t they also publish their mapping table.

Steven Lane: +1 to transparency and a requirement to publish mapping data, ideally with FHIR support to allow for automation.

Hung S. Luu: LOINC codes have no computable relationship and hierarchy and will require additional mapping to another ontology with a hierarchy for aggregation. Something to consider.

Clem McDonald: Dave Mcallie has a number of pertinent responses. He is savvy [sic] and thoughtful.

David McCallie: Perhaps Arien could provide a template for us to use?

Arien Malec: Here’s the general structure: https://www.healthit.gov/isa/isa-structure

Arien Malec: A worked example: https://www.healthit.gov/isa/referral-a-specialist-request-status-updates-outcome

Steven Lane: https://www.healthit.gov/isa/section/research-0

Andrew Hayden: There are two Research sections in the ISA.

Andrew Hayden: I’ll put them in the chat...

Clem McDonald: Not true that LOINC does not have a hierarchy. It will soon be avaliable [sic] on Search LOINC the pretty new LOINC browsers. (https://loinc.org/search/) LOINCs hierarchy It is not as good in all areas as SNOMED but pretty good in the lab space. LOINC parts are internally connecte [sic] to some ontologies, Eg the NCBI ontology for organisms which is based purely on DNA/RNA related nesses [sic] and the big chemistry ontology. These are not exposed very well yet. LOINCs bad. but they will be

Andrew Hayden: 1: Vocab section - https://www.healthit.gov/isa/section/research

Andrew Hayden: 2: Content and Structure section - https://www.healthit.gov/isa/section/research-0

Andrew Hayden: Clinical trials in second link...
Hung S. Luu: The hierarchy depends on the mapping to the other ontologies such as the NCBI ontology then and is not inherent to the LOINC structure itself, correct?

Mark Savage: I like to list by high-level names at least for clarity and certainty.

Mark Savage: “list accelerators

Clem McDonald: Regarding computability that is one of SNOMEDs bragging points. But I understand that 70% of their codes are primatives [sic] and not computable and computability is not now a property of other widely used health coding systems such as ICD- (all of them), CPT, Z-codes,

Hans Buitendijk: Agreed that SDOs should initiate submissions to ISA proactively as their materials are being published, or worked on.

Arien Malec: This is the ISA overall process: https://www.healthit.gov/isa/isa-timeline-and-comment-process

David McCallie: “If you have seen one ontology, you have seen one ontology” - which is to say that almost all ontologies are use-case specific. But there are common use-cases that could benefit from “standardized” ontologies

Arien Malec: It’s not quite as simple as submitting to the ISA — you can submit comments…

Arien Malec: But this implies that you have an ISA page to which to submit comments.

Andrew Hayden: ISA Comment Submission Page: https://www.healthit.gov/isa/about-isa

Hans Buitendijk: Just need to be registered.

Andrew Hayden: Sorry, my audio is not working properly...

Clem McDonald: The LOINC hierarchy is based on the Class of a term and then on the hierarchy of the parts. https://loinc.org/search/ These other Ontology [sic] codes are linked to the parts. but don't think they are exposed

Andrew Hayden: Here’s a blog on the submission process. Hans is correct, users must register and login before submitting a comment. Blog: https://www.healthit.gov/buzz-blog/interoperability/opportunity-trifecta-isa-swap-and-draft-uscdi-version-3-feedback-period-now-open

Andrew Hayden: And yes, feedback/comments are accepted year-round.

Abby Sears: Thank you Grace.

Grace Cordovano: Yes!)

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

Resources
IS WG Webpage
IS WG – May 3, 2022 Meeting Webpage
IS WG – May 3, 2022 Meeting Agenda
IS WG – May 3, 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 May 10, 2022.

The meeting was adjourned at 12:00 p.m. E.T.