Health Information Technology Advisory Committee
Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | June 7, 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 a draft of the IS WG Recommendations Report 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 Draft Report
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
Sanjeev Tandon, Centers of Disease Control and Prevention *(standing in for Adi Gundlapalli)*
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Hung S. Luu, Children's Health
Jim Jirjis, HCA Healthcare
John Kilbourne, Department of Veterans Health Affairs
David McCallie, Individual
Mark Savage, Savage & Savage LLC
Michelle Schreiber, Centers for Medicare & Medicaid Services (CMS)
Ram Sriram, National Institute of Standards and Technology

MEMBERS NOT IN ATTENDANCE
Thomas Cantilina, Department of Defense
Kensaku (Ken) Kawamoto, University of Utah Health
Leslie (Les) Lenert, Medical University of South Carolina
Clem McDonald, National Library of Medicine
Abby Sears, OCHIN

ONC STAFF
Mike Berry, Designated Federal Officer
Andrew Hayden, Standards Advisory Lead, Standards Division
Chris Muir, Director, Standards Division

Key Specific Points of Discussion

TOPIC: CO-CHAIR REMARKS
Steven Lane and Arien Malec, IS WG co-chairs, welcomed everyone. Steven welcomed members of the public and invited them to submit commentary during the public comment period or by entering comments into the public record via the chat in Zoom. Then, he reviewed the WG's plan of work and agenda for the meeting. Arien asked WG members to focus on preparing the WG's transmittal letter in advance of their presentation to the HITAC at its June 16, 2022, meeting. He requested that the WG not make major additions to the transmittal, as a lot of work was done to craft it. The co-chairs noted that Ram Sriram drafted one final recommendation and that the WG would review it at the meeting. Finally, Steven explained that a final meeting of the IS WG is scheduled for June 14 and that the WG would have one final opportunity to review their documents, if necessary.

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:
  - 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: REVIEW OF DRAFT REPORT
Steven thanked Arien for his collaborative work on the draft report, and Arien provided an overview of the draft IS WG Report to the HITAC. He described the sections, which included background information (ONC Charges To the Interoperability Standards Work Group, Overarching Charge, Specific Charges, and Additional Background Information), an executive summary, ISA recommendations (ISA Structure and Process, ISA Content, Expanding ISA Standards Adoption for Lab Orders, and Results), and an appendix. He discussed how the WG chose to divide its ISA-related recommendations into three sections, which make up the bulk of the report.

Steven thanked IS WG members for their many editorial comments on the document and explained that most

of the comments were accepted during the review and editing process and did not warrant discussion by the overall WG. He invited WG members to review and come to a consensus regarding the remaining comments on the document, which included:

- Grace submitted a comment on IS-WG-2022-Phase 2_Recommendation 09 regarding the HIPAA Right to Request Corrections to One's Medical Records.
- Ike submitted a comment on Recommendation 16a under the IS-WG-2022-Phase 2_Recommendation 16 – Lab Orders/Results: SHIELD/LIVD (Information Model).
- Ike submitted a comment on IS-WG-2022-Phase 2_Recommendation 18 – Lab Orders/Results: SHIELD/LIVD (Results).
- Ike submitted two comments on IS-WG-2022-Phase 2_Recommendation 21 – Lab Orders/Results: SHIELD/LIVD (ELR and eCR alignment).

Steven invited Ram to present a new recommendation related to use cases (e.g., artificial intelligence and the use of decision-making algorithms) in the future of EHR.

DISCUSSION:
- Grace discussed the comment she submitted on Recommendation 09, noting that the policy levers that were specified previously in the WG spreadsheet are missing from this section.
  - o Steven responded that policies ONC could lever were captured in workbook item #12, including the HIPAA privacy rule, as well as Certification Criteria. Arien added that the items Grace shared seemed more like policy background information and suggested adding it to the report document as a preamble.
  - o Grace explained that sharing this information emphasizes that, even though a workgroup discussed the topic over a decade ago and policies have been put in place, the HIPAA Right to Request Corrections to One's Medical Records is not currently working effectively for patients in the real-world. Arien offered to capture this information in preamble text during offline work. Steven explained that he moved some of this information to the Supporting Recommendations section in the text below the ISA Recommendations and invited Grace to review it.
  - o Mark suggested adding a reminder that the 2011 recommendations from the ONC Policy Committee included a certification recommendation that a correction must be passed on to anyone who received information.
  - o Grace shared reference links and suggestions in the public chat via Zoom, and Steven considered how to best include this background information, noting that it might be too much detail for the WG's presentation to the HITAC. Grace emphasized the need to include this additional information because it is often glossed over from the perspective of the patient and care partner. She offered to put the references in chronological order with the dates clearly referenced. Steven discussed how the presentation slides could portray this recommendation to the HITAC. WG members agreed to the updates.
- Ike submitted a comment on Recommendation 16a that electronic laboratory reporting (ELR) requirements are still included in the Meaningful Use Promoting Interoperability (PI) measures.
  - o WG members confirmed that Ike's comment was correct and discussed how to update the text of the recommendation to reflect this. Ike shared suggested updates to the language.
  - o Arien explained that no recommendations were made that were specific to the Centers for Medicare and Medicaid Services (CMS), though they were included in the phrasing that ONC works with other Federal partners." He described how changes to policies and new measures created a situation where there are no certification requirements for Results. Also, there are no interoperability requirements for the programmatics, so there is little incentive for labs or electronic health record systems (EHRs) to use the Laboratory Order Interface (LOI) or Laboratory Results Interface (LRI) implementation guides (IGs). He

described current gaps/points of friction in the system and explained how the recommendation would ask ONC to address general policy frameworks. He suggested adding the following language: "Note that ELR is still included as a public health reporting measure in PI."

- Ike submitted a comment on Recommendation 18b that explained that he added text to the recommendation to support the use of standard codes throughout to avoid multiple re-coding/mapping/translation issues.
  - o Hans agreed with the intent but shared wordsmithing suggestions. Steven updated the text to read: "Recommend that ONC, coordinating with other Federal partners, and with SDOs and industry stakeholders, enable standards, implementation guidance and policy that encourages LOINC and SNOMED encoding as early in the process as possible and maintenance of that coded data throughout the process." Ike agreed with the suggestion.
- Ike submitted two comments on IS-WG-2022-Phase 2_Recommendation 21 – Lab Orders/Results: SHIELD/LIVD (ELR and eCR alignment) that added the following phrases: "unless that data is collected directly by the laboratory" and "Information necessary for accurately matching submissions must be included in all relevant messaging."
  - o Steven asked Ike to explain his reasoning, noting that the wording changes could make the WG's recommendation too restrictive.
  - o Ike explained his concerns around situations in which the patient interacted directly with the lab or submitted a sample, but the relevant information necessary for matching submissions was not collected at the point the sample was taken.
  - o Hans summarized concerns around who can/should be/is required to pass the data and, instead, asked the WG to explore other pathways (other than lab reporting) for allowing information to flow to public health.
  - o Steven stated that Ike's second wording suggestion seemed to go beyond Hans' original recommendations to draw a more distinct line between ELR and electronic case reporting (eCR). Ike responded that the challenge is that public health is interested in both the lab and case reports; if data gets separated, there should be an easier way to link that data again. Hans agreed that there should be a way to ensure that records can be linked.
  - o WG members discussed wordsmithing options and agreed on the following updates crafted by Arien:
    - "Where eCR is adopted, laboratories should not be encumbered with the collection, storage, and transmission of data not relevant to the processing of test orders, conducting tests, and reporting of the laboratory test orders/results. Such data should be sent by the ordering provider using eCR methodologies combined with any other data that is relevant to PH that the performing Lab would not have or need. Information necessary for accurately matching submissions must be included in all relevant messaging."
    - "These recommendations would not apply when eCR is not available (and the result is the only reasonable source of data for public health) or when the laboratory itself is the source of contextual information (e.g., direct to consumer tests or information collected at the specimen collection itself)."
- Ram presented a new recommendation that ONC, in conjunction with appropriate stakeholders, develop and track use cases to address encoding and communicating decision rationale. Once this is done, then an appropriate representation scheme can be developed. He shared background information and explained how artificial intelligence (AI) and its decision-making algorithms will play an increasingly important role in future healthcare systems and decision making. He stated that this is a recommendation for the future and not something that is immediately necessary.
  - o WG members discussed the recommendation to track this use case in the ISA.
  - o Arien agreed with the sentiment behind the suggestion but noted that it was not apparent how it could be added to the WG's recommendation. He asked if there are standards that

should be named in the ISA, noting that related ethical use standards and guidelines are missing from the ISA. However, he commented that it is not clear if this recommendation is focused on ISA standards or policies.

o Grace disagreed that this was a completely new recommendation and explained that the current WG and previous iterations of the United States Core Data for Interoperability USCDI Task Force (USCDI TF) touched on the topic in past discussions. She shared a link to a related recommendation in the ONC New Data and Class (ONDEC) Submission System, noting that it is currently at the Comment Level. She commented that if this information is being used to guide patient care it should be part of the designated record set (DRS) and available for exchange. Arien voiced his agreement but stated that it should be a policy recommendation and is not relevant to the current charge to focus on the ISA. If the WG wants to include this recommendation, they should determine how it relates to the ISA.

o Hans agreed that this recommendation is useful but stated that more discussion is needed around use cases and the scope for this recommendation. The WG discussed how to frame the recommendation in the context of the ISA, and members posted several related comments in the public chat in Zoom.

o Arien asked Ram if there is a need to ensure an output (using clinical decision support (CDS) hooks or other mechanisms) for incorporating decisions into the EHR. Then, there would be a corresponding mechanism to be able to tell what part of CDS may already be included . Also, he asked Ram if there is a need for a clear standards mechanism by which the output of an algorithm, including the tailoring of the output to the patient, can be incorporated back into the EHR. Arien stated that there is an existing standard in the ISA that refers to CDS Hooks, so this could be a natural extension to the preexisting CDS content structure recommendations in the ISA. He explained how the output of a CDS process includes a set of cards that can and should be incorporated into the EHR.

o Ram commented that this would be future work and that the WG should prepare ONC for the process and not tell them how to approach it. David discussed how the AI community uses the term "explainability" of AI-recommended decisions and recommendations and suggested that the ISA should track this as a use case.

o Grace commented that the information that does exist is not patient or individual facing; rather, it is all internal information that is available mainly to physicians at the point of care.

o Following a discussion around its rationale and wordsmithing options, the WG reviewed the following potential Phase 2 recommendation:
  • Recommendation: EHR Clinical Decision Support Rationale:
  • Recommend that ONC include and track in the ISA the use case of documenting, encoding, and communicating the decision rationale utilized in generating decision support alerts/recommendations.
    • This should include the ability to standardize, document, and display the rationale/explanation behind recommendations generated by predictive analytics, machine learning, and artificial/augmented intelligence (AI) tools.
  • Background
    • There are some existing standards in the ISA related to CDS Hooks and other clinical decision support standards. Current standards do not address the desirability of making this information available to individuals.

o ONC did not express any concerns, so the WG agreed to accept the recommendation. David suggested that it is a placeholder for emerging/future work.

Action Items and Next Steps
Homework for the June 14, 2022, IS WG Meeting:

- Review and provide final feedback on the draft recommendations report by Thursday, June 9th 9:00 a.m. ET.
- Workgroup members are welcome to join the June 16, 2022, HITAC meeting and listen to the presentation. Register at https://www.healthit.gov/hitac/events/health-it-advisory-committee-46

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): Good morning, and thank you for joining the Interoperability Standards Workgroup. We will be starting soon.

Jim Jirjis: Jim Jirjis Just joined late. Sorry I had a conflict *[sic]*

Steven Lane: > Recommend that ONC, in conjunction with appropriate stakeholders, develop use cases to address encoding and communicating decision rationale. Once this is done then an appropriate representation scheme can be developed.

Steven Lane: Background: AI and its decision making algorithms will play a very important role in future healthcare systems.

David McCallie: there is a lot of research underway on "explainable AI", so this makes sense as a tracked item for the future

Grace Cordovano: I have also submitted clinical decision support outputs to ONDEC and it was accepted at comment level: https://www.healthit.gov/isa/taxonomy/term/4431/comment

David McCallie: The use-case could be the ability to standardize and present the rationale for AI generated recommendations

Grace Cordovano: From the patient and carepartner perspective, the OUTPUTS of the AI/ML/NLP powered predictive analytics that are leveraged to guide clinical decision support at point of care, if used to make decisions about an individual, are theoretically part of the designated record set and will also technically fall under the definition of all EHI come 10/6/22. Here's my publication in J of AHIMA https://journal.ahima.org/page/ai-ml-and-nlp-snub-patients-right-of-access

David McCallie: The distinction is not the output, but the rationale used to generate the output.

Arien Malec: The standard is relative to the incorporation of the output, which should include the raationale… *[sic]*

Grace Cordovano: David, the outputs will likely be a lower hanging fruit as the outputs will consist of structured data classes and elements that we already have being exchanged. Agree that overall decision making rationale should be documented and exchanged.

Andrew Hayden: CDS in ISA is here: https://www.healthit.gov/isa/section/clinical-decision-support

Hans Buitendijk: The output, e.g., creation of orders, plans, diagnoses, etc., are mostly there, but the reason why they were create is not necessarily there (although in FHIR resources some of them have that available, while there is further work in flight in CDS space on "evidence" used).

Grace Cordovano: Hans, re: "The output, e.g., creation of orders, plans, diagnoses, etc., are mostly there," the info may be "there" but the info (outputs) are NOT accessible or available to patients.

Andrew Hayden: CDS in ISA is also here: https://www.healthit.gov/isa/section/clinical-decision-support-services

Hans Buitendijk: In FHIR the Evidence, EvidenceReport and EvidenceVariable may be applicable to reference.

David McCallie: @John - yes

Hans Buitendijk: I need to jump, but support the recommendations. Thank you!

Christina Caraballo: Super excited about these recs! Big thanks to our chairs and ONC! High five team!

Mark Savage: woohoooo!

Mark Savage: Appreciations to all!!

Hung S. Luu: Thank you to the co-chairs!

Rajesh Godavarthi: Well done!

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

Resources
IS WG Webpage
IS WG – June 7, 2022 Meeting Webpage
IS WG – June 7, 2022 Meeting Agenda
IS WG – June 7, 2022 Meeting Slides
HITAC Calendar Webpage

Meeting Schedule and Adjournment
Steven and Arien thanked everyone for their participation over the course of the IS WG 2022, summarized key achievements, and explained that if the next/final meeting of the WG were to be canceled, it would be announced on Monday, June 13. WG members thanked the co-chairs for their leadership.

If the June 14, 2022, IS WG meeting is held, it will focus on the presentation slides that accompany the transmittal.

The meeting was adjourned at 11:07 a.m. E.T.