# Health Information Technology Advisory Committee Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | May 24, 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

11:55 a.m. Public Comment

12:00 p.m. Adjourn

#### Call to Order

Michael 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 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)

Jim Jirjis, HCA Healthcare

John Kilbourne, Department of Veterans Health Affairs

Hung S. Luu, Children's Health David McCallie, Individual

Mark Savage, Savage & Savage LLC

Abby Sears, OCHIN

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 Rajesh Godavarthi, MCG Health, part of the Hearst Health network Kensaku (Ken) Kawamoto, University of Utah Health Leslie (Les) Lenert, Medical University of South Carolina Clem McDonald, National Library of Medicine

#### **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 reviewed the WG's plan of work, the agenda for the meeting, and the HITAC Priority Uses of Health IT. He reminded WG members that the draft recommendations should be finalized prior to the WG's presentation to the HITAC at its June 16 meeting. Finally, he welcomed members of the public and invited them to submit commentary during the public comment period.

#### **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:
  - 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**

The co-chairs displayed 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:

- HIPAA Right to Request Corrections, Presenter: Grace Cordovano, Item #12
- ISA Optimization, Presenter: Christina Caraballo, Item #18
- Care Plans/Chronic Disease Management, Presenter: Mark Savage, Item #1
- HL7 Fast Healthcare Interoperability Resources (FHIR) Accelerators Supporting Clinical Translational Research Implementation Guides (IGs), Presenters: Hans Buitendijk and David McCallie, Item #13

- Topic: Lab Orders/Results: SHIELD/LIVD (Model), Presenter: Hung Luu, Topic #31
- Topic: Lab Orders/Results: SHIELD/LIVD (Results), Presenter: Hung Luu, Topic: #32a

#### DISCUSSION:

- Grace discussed the recommendations she submitted around the HIPAA Right to Request Corrections. She explained that she originally submitted recommendations related to the structure and content (global and granular) of the ISA, but most of the structural recommendations were moved to a different set of recommendations.
  - Grace confirmed that one of her structural recommendations was already included under a different recommendation, so it was removed.
  - O Michelle asked if the recommendation that patients should be able to make corrections through an API be changed to "patients are able to request corrections." Grace responded that the intent was for patients to be able to request corrections, not make them. The recommendation text was updated.
  - O Hans suggested adding "and therefore" between "designated record set" and "all EHI" in the first recommendation, and lke agreed, noting that that public health data is all a subset of the designated record set. He stated that patient corrections are constrained to the HIPAA-covered record set. Arien suggested giving ONC greater flexibility to work with federal stakeholders and other partners. He offered to work on this language.
  - Arien and Grace discussed how to edit the recommendations to promote broader education regarding and promotion of the HIPAA Right to Request Corrections and updated the text of the recommendation.
  - O John asked for clarification around what happens to the patient requests for corrections after they are submitted and if/how they should be reviewed. Steven responded that the WG does not need to submit a recommendation because HIPAA already gives guidance on how this works. Grace agreed, noting that the recommendation is around how to use technology to digitize and make these requests.
  - O lke suggested combining several recommendations, and Arien made edits to the text. Grace commented that one of the recommendations was related to certification criteria to enable requests, while the other was related to establishing a floor. WG members discussed the wording, and Arien explained that he considered past feedback from ONC that the WG should not be too prescriptive with a recommendation when he added his updates to the text. Mark suggested that the WG track previous work and recommendations made around certification criteria. Arien briefly described those comments.
  - O Steven commented that the WG would review all recommendations later to determine which were specific to the ISA and which were directed more at ONC.
  - Arien reviewed updates he made to the text in the shared working document, and WG members agreed to move forward with the recommendations.
- Christina reviewed the recommendations she submitted around optimizing the structure of the ISA and described how she reformatted her recommendations to include items from the previous IS WG Draft Recommendation #20. She noted that she worked with Mark and Grace on these items and described how their recommendations call for an expansion of the use cases in the ISA and to create a place for people to contribute to high-priority interoperability needs. She invited WG members to share questions and comments.
  - O Hans described related recommendations he drafted, which were edited and incorporated by Christina, and Arien asked for greater clarification on the recommendation that "Accelerator" be added to the Standards Process Maturity classification. Hans explained that including standards in the work of an accelerator brings awareness but that it does not mean that these standards are more/less mature. Arien asked the WG to comment on whether the recommendation should be removed or rewritten, and David responded that the fact that a use case is included in an accelerator is a substantial flag of interest, which should be tracked somewhere, and it is not a definition of a standard's maturity. Arien

- suggested a new recommendation that ONC add an indication if a use case is being addressed through an accelerator, and David agreed, noting that accelerators reflect broad coalitions of entities doing real-world work.
- O Ike commented that issues that touch on public health and that crosscut with the USCDI in the recommendations should be denoted in some way. Steven commented that ONC has already identified priority target areas, including public health, so the IS WG should add those to this list or remove the ones that have already been acknowledged. David asked for clarification on how use cases are included in the ISA, and Steven explained that the WG should identify that a use case is a priority, as well as choose some use cases that will have a place in the ISA. The WG discussed if and how to denote when priority use cases were submitted. Arien suggested that the WG indicate the high-level use cases that are crosscutting to the rows in the ISA and that they recommend that there be a place where all content of the ISA is viewable, crosscut by the use case. He explained that this is the reason why the WG removed the word "priority" during a previous discussion. David noted that different administrations will have different prioritizations of use cases and suggested that there should be a way to track priorities as they shift. ONC will determine prioritization.
- O Al Taylor asked the WG to clarify what is being asked of ONC in the recommendations as far as who will be responsible for researching, prioritizing, and advocating for the use cases. Arien responded that the WG is recommending creating views across the ISA for each of the topic areas. Al explained how pages in the ISA would need to be manually edited/tagged to achieve the goal Arien described, and Arien agreed that if a person at ONC is tasked with maintaining the tagging of use cases, it could add a burden. Christina asked if there is a better, less burdensome way for ONC to bundle use cases across the ISA to increase navigability. She asked the WG to consider ONC's availability to build this over the next year and how the WG might reprioritize the use cases, keeping in mind the increased burden. Arien suggested a recommendation that recommends that ONC review the human factors associated with the ISA search function and consider technology and usability changes to make the ISA more useful for users.
- O The WG reviewed whether Hans' recommendations in #20 were fully added to #18, and Hans asked that #20 be left as is.
- The WG decided to merge sub-recommendations I and J under #20.
- O Steven and Christina updated the draft recommendations in the WG's shared working document following members' discussion.
- Mark discussed the updates he made to the recommendations he submitted around care plans and chronic disease management. He updated these recommendations following a previous discussion to reflect comments made on care coordination and the importance of including a specification about dynamic longitudinal care plans.
  - O Steven called for WG member feedback, and David voiced his support for the updates. David asked Mark to comment on the ground floor of care plan management and asked if "coordination" includes basic communication. The use of "plan" in the language sounds official like something written. Mark stated that the word "dynamic" refers to the idea that the document may be updated regularly and is not static. More explanation was included in a series of included links.
  - o Hans suggested several wordsmithing updates to the text.
- Hans and David discussed the recommendations they submitted around the various HL7 FHIR Accelerators (Vulcan, Helios, CodeX, CARIN, etc.) that support Clinical Translational Research IGs. Hans commented that they created these recommendations prior to the recent WG discussions, in which the WG decided to incorporate the same concepts under different ISA topics.
  - WG members agreed to strike through recommendations #13 through #16, as they were already included in other areas.

- Steven described how several WG members edited the recommendations around Lab Orders/Results and the SHIELD/LIVD model and results, which were originally submitted by Hung.
  - o Hung explained that, in recommendation #31, he worked to harmonize the ISA and the USCDI so that they are realigned to reflect each other more cohesively. WG members reviewed the recommendations and explanatory text. David asked if the recommendation adequately addressed the notion of comparability for lab tests, and Hung responded that this concept was included in recommendation #32a. WG members discussed how to add the "why" to the recommendation the WG is making, and Arien suggested including it in a preamble within the official transmittal. He suggested adding the following "why" text: "There is decent adoption of electronic resulting. However, there is lower adoption of interoperable electronic ordering, but the lack of standardization in practice creates an administrative workload on all the actors associated with the supply chain, and it limits the comparability and broad use of lab data to improve patient health and improve care, facilitate public health, and broaden research. David commented that the "why" should include the example that clinicians cannot tell if the test answers the question because they do not understand the test kit. The WG discussed how the recommendation was connected to their previous recommendations made during their work on the USCDI and how to update the text for clarity.
  - O Hung described recommendation #32a and explained that it lays out the central strategy of SHIELD, in which the digital standard print of that test is represented with a series of codes across the healthcare ecosystem. The intent is to thoroughly describe each test. Arien described how he separated a larger recommendation (#32) to focus on establishing a policy framework for all the actors in the supply chain. Recommendations #32b through #32h include the details associated with each of the pieces required.
  - O Hung described #32b and #32c, and Arien suggested adding text noting that the process should start with the IVD. Hans commented that the recommendation should address this topic from both angles, and Arien offered to update the text.
  - O Hung described the intent behind recommendation #32d, noting that it came from learnings related to the COVID-19 pandemic regarding how quickly organizations moved to develop new codes. David asked if there is data in SHIELD spreadsheets that is not included elsewhere, and Hung stated that this recommendation is separate. David's concerns are addressed in later recommendations.
  - O Hung described #32e, #32f, #32g, and #32h. Arien and Hans summarized the key concepts from the recommendations and how the capabilities of the ISA would connect with SHIELD. Arien and Hans proposed changing the wording in #32b to "AOE answer." WG members accepted all recommendations under #32.

# **Action Items and Next Steps**

Homework for the May 31, 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.

Please note, the following WG members will present next week:

- Topic: Lab Orders/Results: SHIELD/LIVD (Orders), Presenter: Hung Lu, Topic #33
- Topic: Lab Orders/Results: SHIELD/LIVD (Patient), Presenter: Hung Lu, Topic #34
- Topic: Lab Orders/Results: SHIELD/LIVD, Presenter: Hans Buitendijk, Topic #35
- Topic: SDOH Standards: CDC Race/Ethnicity Vocabulary Subsets, Presenter: Mark Savage, Topic #7
- Topic: Communications and Referrals Between Providers and Community, Presenter: Steven Lane, Topic # 21
- Topic: Use-cases for Consumer Downloads, Presenter: David McCallie, Topic #s 22 and 23
- Topic: FHIR Endpoint Standards, Presenter: David McCallie, Topic #24
- Topic: Increasing the Usage and the Accuracy of Standard Codes in Lab Test Messages, Presenter: Clem McDonald, Topic # 25

## **Public Comment**

# **QUESTIONS AND COMMENTS RECEIVED VERBALLY**

There were no public comments received verbally.

#### QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mark Savage: Mark Savage here. Had to move the car for street sweepers.

Arien Malec: Oakland street sweeper panic is real

Jim Jirjis: Jim Jirjis here

Mark Savage: But if the question is, "public health" as an overall use case to collect these specific topics, that may be a needed addition.

Steven Lane: Note that the ISA already has direction from HITAC to focus on the priorities: (1) Use of Technologies that Support Public Health, (2) Interoperability, (3) Privacy and Security, (4) Patient Access.

Steven (Ike) Eichner: Public health needs to be listed as a priority. While some services for PH may be addressed through FHIR, not all functions will necessarily use FHIR.

Steven (Ike) Eichner: In re-examining the bullet list, many of the listed items intersect or are subsets of public health (or PH-maintained data sets drive the activity).

Steven (Ike) Eichner: "Research" needs additional definition- clinical trial research? population health research? There is a high cross-over with registries.

Mark Savage: Agree--accelerator a relevant factor to be tracked. Does not mean "maturity".

Grace Cordovano: Also agree

Abby Sears: also agree

Steven (Ike) Eichner: The list either needs to be in a priority order or an alphabetical order, specifying that the list ISN'T in a particular priority order.

Hans Buitendijk: Perhaps need to drop "high-priority" in the fourth >,

Ann Phillips: from someone who uses the ISA PLEASE!!!!

Ann Phillips: it could be much more useful and accessible with a redesign

Hans Buitendijk: Suggest to adjust "and all EHI" in 1) to "and therefore all EHI".

David McCallie: @Michelle +1

Mark Savage: Make-->request

Arien Malec: my edits are done.

David McCallie: Could you include language like "...such as certification or condition of participation..."

Steven Lane: Members of the public: Please raise your hand early if you are interested in providing oral public

comment.

Steven (Ike) Eichner: 32b minor correction: Should probably be "responses" rather than "answers."

Steven (Ike) Eichner: In 32b, is "encourages" the correct word?

Hans Buitendijk: @Steve: Would "result values" work?

Arien Malec: @Ike: Question -> Answer I think is the right pairing.

Arien Malec: This is AOE question & encoding of AOE answers.

Grace Cordovano: Thank you to Steven & Arien for navigating this beautifully.

Grace Cordovano: Arien

Mark Savage: What a village!

# **QUESTIONS AND COMMENTS RECEIVED VIA EMAIL**

There were no public comments received via email.

#### Resources

IS WG Webpage

IS WG - May 24, 2022 Meeting Webpage

IS WG - May 24, 2022 Meeting Agenda

IS WG - May 24, 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 31, 2022. The meeting was adjourned at 12:00 p.m. E.T.