Health Information Technology Advisory Committee

Interoperability Standards Priorities Task Force 2021 Virtual Meeting

Meeting Notes | May 20, 2021, 2:00 p.m. – 3:30 p.m. ET

Executive Summary

The focus of the Interoperability Standards Priorities Task Force 2021 (ISP TF 2021) meeting was to 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. Arien presented the draft ISP TF 2021 transmittal letter, which included high-level and more detailed recommendations for review, provided background information, and invited TF members to submit comments/feedback. The draft transmittal was shared with TF members, and a discussion took place. The co-chairs asked TF members to review the Draft Recommendations Report and Draft Transmittal Letter. The co-chairs explained that they are looking for volunteers to help focus on specific areas of the transmittal, which will be presented to the HITAC at its June 9, 2021, meeting.

There were no public comments submitted by phone, but there were several comments submitted via the chat feature in Adobe Connect.

Agenda

02:00 p.m.	Call to Order/Roll Call
02:05 p.m.	Opening Remarks
02:10 p.m.	Draft High-Level Recommendations Review
03:15 p.m.	Homework & Next Steps
03:25 p.m.	Public Comment
03:30 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 2:02 p.m. and welcomed members to the meeting of the ISP TF 2021.

Roll Call

MEMBERS IN ATTENDANCE

Arien Malec, Change Healthcare, Co-Chair
David McCallie, Individual, Co-Chair
Ricky Bloomfield, Apple
Jim Jirjis, HCA Healthcare
Ken Kawamoto, University of Utah Health
Clem McDonald, National Library of Medicine
Ming Jack Po, Ansible Health
Ram Sriram, National Institute of Standards and Technology

Sasha TerMaat, Epic

MEMBERS NOT IN ATTENDANCE

Cynthia Fisher, PatientRIghtsAdvocate.org
Valerie Grey, New York eHealth Collaborative
Edward Juhn, Blue Shield of California
Victor Lee, Clinical Architecture
Les Lenert, Medical University of South Carolina
Raj Ratwani, MedStar Health
Andrew Truscott, Accenture

ONC STAFF

Mike Berry; Designated Federal Officer (ONC)

General Themes

TOPIC: DRAFT HIGH-LEVEL RECOMMENDATIONS REVIEW AND DISCUSSION

Arien presented the draft ISP TF 2021 transmittal letter, which included high-level and more detailed recommendations for review, provided background information, and invited TF members to submit comments/feedback. The draft transmittal was shared with TF members, and a discussion took place.

TOPIC: ISP TASK TF HOMEWORK & NEXT STEPS

The co-chairs asked TF members to review the Draft Recommendations Report and Draft Transmittal Letter. The co-chairs are also looking for volunteers to help focus on specific areas of the transmittal.

Key Specific Points of Discussion

TOPIC: WELCOME AND ISP TF 2021 OVERVIEW

David and Arien welcomed ISP TF 2021 members, briefly reviewed the agenda, and summarized the following points:

- The ISP TF 2021 will refine its draft recommendations and transmittal letter for presentation to the HITAC at its June meeting.
- The co-chairs added edits and comments received from TF members but encouraged members to continue to submit feedback.

TOPIC: DRAFT HIGH-LEVEL RECOMMENDATIONS REVIEW AND DISCUSSION

David explained that the co-chairs worked in between meetings to mirror the information within the ISP TF 2021 high-level recommendations and PowerPoints and create a draft transmittal letter for presentation to the HITAC at its June 9, 2021 meeting. Arien presented a walk-through of the working draft of the transmittal letter and explained that the co-chairs followed a set format for the letter, which the HITAC will be asked to endorse. Then, the HITAC will transmit it to Micky Tripathi, the National Coordinator for Health IT.

Arien presented an overview of the draft transmittal letter, which included the following sections, and asked for feedback from TF members:

- Background information, including ONC's charges to the ISP TF 2021
- Summaries of the hearings the ISP TF conducted, including expert presentations received and web links to materials
- A set of nine (9) high-level recommendations, which included:

- In order to support multiple areas that require configured extensions of electronic health record systems (EHRs), we recommend that ONC advance standards and implementation guidance in the following foundational areas using Fast Healthcare Interoperability Resources (FHIR) that address multiple cross-cutting concerns:
  - a. HL7 FHIR standards to address workflow hooks, including FHIR Clinical Decision Support (CDS) Hooks and FHIR Subscriptions
  - b. HL7 FHIR standards to allow configurable flexible data collection via FHIR Questionnaires
  - c. HL7 FHIR standards to allow collections of consents, authorizations, and directives via FHIR Consents.
- In order to improve interoperability and innovation, we recommend that ONC work with other Federal stakeholders to move the nation towards open and/or freely available terminology standards that are designed to address multiple needs (clinical care, research, administrative needs). In areas where proprietary code sets are currently required, we recommend that ONC work with National Library of Medicine (NLM) and other Federal stakeholders to either license codes nationally or transition the nation to more open terminology with national licensing.
- In order to reduce the expense of downstream normalization and maximize appropriate data use, we recommend that ONC, in conjunction with other Federal stakeholders, promulgate policy to ensure that data are captured in a normalized way as early to source as possible, and that Federal stakeholders converge on common terminology standards where there is current divergence.
- In order to reduce the expense associated with pragmatic research we recommend that ONC, in conjunction with other Federal stakeholders, supports the current work to align towards a common research model.
- In order to maximize the use of the deployed EHR base to research and the learning health system, we recommend that ONC work with stakeholders to develop key standards and implementation guidance to enable clinical research using EHRs.
- We in order to reduce the expense of research and administrative processes by enabling maximal appropriate reuse of data captured for clinical care, we recommend that ONC map the U.S. Core Data for Interoperability (USCDI) and FHIR to the common research model as well as to the implied administrative data model.
- In order to support use of social determinants of health to improve health, healthcare, and public health, we recommend that ONC implement the DaVinci Gravity standards.
- In order to maximize use of clinical data to reduce disparities, increase health equity, and support public health we recommend that ONC ensure that deployment of published standards and implementation guidance prioritize the interoperability of key demographic and social determinant data.
- In order to reduce clinical burden and improve the experience of individuals in the health care system, we recommend that ONC advance the recommendations of the Intersection of Clinical and Administrative Data Task Force (ICAD TF), and that ONC advance next generation administrative standards via the Interoperability Standards Advisory (ISA).

- A list of specific recommendations, supported by findings, around the following foundational standards and topics (the TF has separated its findings from its recommendations):
  - Foundational Standards - FHIR
    - FHIR CDS Hooks or triggering offline workflows via FHIR Subscription
    - FHIR Questionnaires
    - FHIR Consent Directive
  - Foundational Standards – Common Data Models
  - Foundational Standards – Terminology

- Healthy Equity
- EHR Data Use for Research, Real World Evidence (RWE), RECOVERY-like Trials, Comparative Effectiveness
- Harmonization of Clinical and Administrative Data for Burden Reduction
- Situational Awareness

DISCUSSION:

- Arien submitted several comments and suggestions, which included:
  - He explained that he took part in another task force of the HITAC, the ICAD TF, and he found their transmittal letter's executive summary section to be helpful. He suggested that the ISP TF 2021 include a similar section in its transmittal letter with its high-level recommendations.
  - The TF should describe the Delphi scoring and prioritization process that it used to determine the priority/ordering of its topics.
- Clem asked to change the phrase "freely available and/or" to simply "open" in the second recommendation and suggested that the ISP TF not specifically call out NLM in its recommendation.
  - Arien summarized Clem's comments that the TF should observe that the NLM has historically done the nation a service by adopting open standards for terminology and by building national licensing/payment/funding of those standards as a way of addressing the standard vocabulary maintenance sustainability issue. That has been a good working model.
  - David suggested that the vocabularies should have a rigorous control apparatus to control the creation of new codes. He asked if the wording "open" could also refer to this controlled process. He added that SNOMED is well-managed but also highly controlled nomenclature. However, its production is expensive, and that it is not free/open.
  - Clem responded that there is a group that has asked for "open vocabulary," but they have written their documentation yet, so "open" means that people can submit to it freely. He will try to get a copy of the group's document for the TF.
  - Arien suggested that the TF use text from the executive order around standards organizations, and he asked the ONC team to help find it. The two elements the TF will address are the level of open standards, which involves the process by which the terminology is maintained, and the national licensure that makes the use of terminology freely available to everyone in the U.S.
  - David suggested that the TF's executive summary in the transmittal has high-level information, and the detailed recommendations that follow will have more information about how to solve the issues. He suggested that the TF discussed the detailed recommendations later.
  - Clem complimented the overall structure of the draft transmittal and the quality and clarity of the writing. He asked if the Gravity Standards are Da Vinci, and David responded that they were incubated through Da Vinci. The text will be updated to reflect that HL7 is now involved.
- The co-chairs will wordsmith recommendation #6 to clarify it in response to an inquiry submitted in the chat.
- Arien explained that Sasha provided feedback on the recommendations around CDS Hooks in the foundational standards section. She noted that CDS Hooks is the most mature of the four FHIR-based standards and IGs mentioned in the recommendations and that the other three require more support for development, testing, production, and use for broader adoption. The four standards are foundational to getting national adoption and would help solve a wide range of downstream problems. She stated that there is ambiguity around the FHIR consent work mentioned in the recommendation and asked for clarification on whether there is a specific IG.

- Arien stated that he looked at the FHIR Consent Resource, which is called "Consent," when he drafted the recommendation. He will update the text to refer to it.
- David stated that this topic surfaced during the TF's conversations around supporting health equity through capturing permission to share SDOH. Arien added that it is also useful for pragmatic research and capturing consent while performing prospective research of randomization.
- Clem asked about where CDS Hooks is located in the FHIR hierarchy, and David stated that it is an IG that has been balloted through HL7. Ken shared the IG that operates over multiple HL7 resources, and it is located at https://cds-hooks.hl7.org/ The actual HL7 CDS Hooks provides hook maturity at various levels. In response to an inquiry from Clem, Arien stated that consent is in HL7 at a Level Two maturity.
- Sasha suggested adding footnotes throughout the document to refer to specific standards.
- David asked Arien to review the wording of the TF's recommendations to ensure that particular standards are identified in response to ISA's interoperability priorities.

- Arien displayed the TF's more detailed findings and recommendations sections and discussed updates that have been made to the text since it was shared at the previous TF meeting.
  - Clarifications were added to several sections based on previous feedback from Clem and Les, especially around the need for funding and aligning resources and not calling out OMOP, specifically.
  - David asked if there was any further discussion about the broader EHR export capabilities that go beyond bulk FHIR and if there is a need to mention the possibilities of working toward making that standard spaced. Is this out of scope?
  - Arien responded that bulk FHIR already has a track toward certification and requirement, so the TF does not need to comment.
  - Clem responded that the current specification could be more standardized, and David responded that the hope was that bulk FHIR would accomplish this goal. In the meantime, raw data dumps are happening, though they were not intended to address research needs. Perhaps the TF could address the topic by stating that bulk FHIR should be made sufficient to address the research community's needs.
  - Sasha explained that the Electronic Health Record Association (EHRA) has talked about the vision that the expansion of the USCDI would cover an increasing amount of electronic health information (EHI). She asked David to clarify how standardized bulk EHI exports would work, and he responded that the expansion of USCDI and expansion of bulk FHIR would address the needs of the research community. Then, there would be no need to rely on unstandardized bulk data dumps. Sasha agreed that the needs of the research community should be considered.
  - Arien noted that the TF's recommendations would note the assumption that the expansion of the USCD (to include more data classes/elements) will be accompanied by a corresponding expansion of FHIR export capabilities, which will enable broad support of those export capabilities for research purposes.
  - Clem stated that specifications for the structure are needed, and USCDI will not cover everything. Arien explained that the differences between USCDI, which described data classes and elements, and HL7.
  - David suggested raising this question with the USCDI TF.
- Sasha noted that she retracted a comment she made earlier regarding the use of LOINC under the Terminology foundational standards findings and recommendations.
  - Arien asked the TF to examine the other recommendations under the Terminology foundational standards topic and provide feedback on wordsmithing.
  - David asked to add "broad" before "licensing" in the third recommendation in this section.
  - Arien suggested that these bullets would refer to the TF's policy statement, which would be written very clearly. The statement was meant to be positive, not negative.

  - Clem suggested adding mentions of the Unified Code for Units of Measure (UCUM) and SNOMED in the source coding, and Arien responded that UCUM is already included in LOINC. It is already included under USCDI and HL7, but it will be clearer in the recommendations.
  - Clem also suggested mentioning ICD-11 (and its implications for research) and the HL7 standard that specifies the mappings for instrument codes (where new COVID-19 codes were added). Arien responded that they could add this to the recommendations around source coding.
  - Clem asked about international standards called out under the TF's recommendation around harmonization and suggested that the TF call out the need for the FDA to use RxNorm. Arien described how the WHO would be impacted by the TF's recommendations and confirmed that the FDA already works to determine that generic names are done in accordance with international standards. This naming process will be used to align with and map over to RxNorm.
- Arien explained that he missed the Gravity Project's presentation to the TF and called for assistance in completing the findings part of this section.
  - Arien explained that he tried to capture a statement from a member of the Public Health Data Systems Task Force (PHDS TF) that the CDC's terminology is appropriate for capturing race and ethnicity and sexual orientation and gender identity (SOGI) data. He will correspond with that member to get their statement in writing. The ISP TF has stated that this code set is adequate but that the data does not flow appropriately downstream to be monitored for disparities.
  - Clem suggested adding links to web URLs when the document mentions outside information and suggested that the full CDC terminology set is adequate.
  - Sasha asked if the SOGI standards would be included in the TF's recommendations around the standardization and the flow of demographic data. Arien stated that when SOGI standards are adopted by USCDI, they will be included in IGs for interoperability and will be able to flow. David asked about privacy concerns related to the flowing of these data. Arien suggested looking at Minimum Necessary as the controlling language and suggested adding "where appropriate." TF members discussed whether it should be assumed that this data should flow and that it depends on what the patient wants. Clem agreed that this is a sensitive issue and stated that, like the race/ethnicity information, people who are collecting and offering this information might not want to collect/share it.
- Arien stated that the wording for the findings and recommendations around the EHR data use topic would be wordsmithed to emphasize the need for source code normalization.
  - Clem asked for clarification around source data, and Arien explained situations in which this occurs. The language will be updated for clarity, and Arien suggested referencing the previous iteration of the ISP TF's report for this section (especially for LOINC).
- In response to Arien's description of the recommendation to adopt the recommendations of the ICAD TF, Clem commented that X12 has been fairly cooperative with HL7 over the years, though some of their work has not been included in CMS. Arien provided some background on the ICAD TF's findings.

Action Items

As their homework, ISP TF 2021 members were asked to review the agenda for the next meeting, as well as the TF's Draft Recommendations Report (redline), Draft Recommendations Report (clean), and Draft Transmittal Letter, which the TF will review at the May 27, 2021, meeting. TF members were asked to come prepared with suggested changes.

The co-chairs are also looking for volunteers to help focus on specific areas of the transmittal:

- Executive summary, testimony, and high-level recommendations
- Foundational (FHIR, Models, Vocabulary)
- Social Determinants of Health (SDOH)
- Research
- Administrative Burden Reduction
- Situational Awareness

The TF will extract information from the transmittal for use in presentation slides.

Public Comment

QUESTIONS AND COMMENTS RECEIVED VIA PHONE

There were no public comments received via phone.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

The following comment was received via email:

Nancy Spector, AMA: I want to support the comments made by Dr. Wah to HITAC during its meeting last week about the AMA's work with the CPT code set.

The AMA would greatly appreciate having the opportunity to present to this task force on the work we are doing with SNOMED, our work internationally, and our work to support innovation in interoperability and data liquidity. In addition, we can provide an overview of the open CPT code request process and rigorous maintenance process by the CPT Editorial Panel.

Arien made a comment during the HITAC meeting that the task force has heard from the AMA. I want to clarify that the AMA's only presentation was to the ICAD Task Force last year and it was specific to our work on prior authorization and not on coding for procedures. We believe, as members from the HITAC do, that the ISP Task Force would greatly benefit hearing from CPT and other terminology experts prior to finalizing its report.

The AMA has a vested interest in reducing administrative burden on physicians and other clinicians. The CPT code set is tightly integrated in many clinical environments across the US and around the world. Without a full examination of the terminology space, the ISP Task Force's report may be incomplete or inaccurate – resulting in recommendations that could disrupt health care and health information technology. We also must ensure current administrative workflows are not broken, which would only add to the burden on clinical staff, as well as payers, health plans, clearinghouses, revenue cycle vendors, and other industry stakeholders.

The AMA stands ready to support the task force's charge to meet all health care stakeholders' needs and we look forward to presenting to this group. Thank you.

QUESTIONS AND COMMENTS RECEIVED VIA ADOBE CONNECT

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

Norman Stone: Item 6 -- Check wording. Little awkward.

Norman Stone: Perhaps keep the "In order to. . ." paradigm

Norman Stone: Yes

Sasha TerMaat: https://www.hl7.org/fhir/consent.html

Norman Stone: "Consent"

Norman Stone: PACIO group is working on Advance Directives, but not at a product -- perhaps too nascient *[sic]*

Norman Stone: https://confluence.hl7.org/download/attachments/91997445/Overview%20of%20ADI%20FHIR%20IG%20Proposal%20for%20HL7%20WGs_20201007.pdf?version=1&modificationDate=1602109665038&api=v2

Ken Kawamoto: In HL7: https://cds-hooks.hl7.org/

Arien Malec: https://cds-hooks.org/

Sasha TerMaat: https://cds-hooks.hl7.org/

Arien Malec: thanks Ken.

Ken Kawamoto: Hook maturities are i nthe *[sic]* Hooks tab

Ken Kawamoto: e.g., patient-view is maturity 4. The rest are maturity 1

Sasha TerMaat: Are the recommendations intended to be about sex, race, ethnicity, and address, or those 4 plus gender identty *[sic]* and sexual preference?

Sasha TerMaat: I'm not sure how to interpret the top paragraph in relation to the recommendations.

Clement McDonald: I think most of it reads pretty well. Do you really need heavy volunteer work?

Clement McDonald: PS my phone ran out of batter. its slow to load up on electrons

Resources

ISP TF 2021 Webpage
ISP TF 2021 – May 20, 2021 Meeting Agenda
ISP TF 2021 – May 20, 2021 Recommendations Report
ISP TF 2021 – May 20, 2021 Meeting Webpage
HITAC Calendar Webpage

Adjournment

David and Arien thanked everyone for their participation and discussed the next steps toward drafting the transmittal letter.

Mike reminded TF members that the next ISP TF 2021 meeting will be held on Thursday, May 27, 2021, from 2 p.m. to 3:30 p.m. E.T.

The meeting was adjourned at 3:17 p.m. E.T.