Health Information Technology Advisory Committee

Interoperability Standards Priorities Task Force 2021 Virtual Meeting

Meeting Notes | June 3, 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 finalize its work on identifying 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 final 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 submit final feedback on the Draft Recommendations Report and Draft Transmittal Letter, 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.	Report Overview
02:10 p.m.	Draft Recommendations Review and Discussion
03:20 p.m.	Public Comment
03:25 p.m.	Final Remarks
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. He thanked everyone for their work on preparations for the TF's presentation to the HITAC on June 9, 2021.

Roll Call

MEMBERS IN ATTENDANCE

Arien Malec, Change Healthcare, Co-Chair
David McCallie, Individual, Co-Chair
Ricky Bloomfield, Apple
Cynthia Fisher, PatientRIghtsAdvocate.org
Victor Lee, Clinical Architecture
Les Lenert, Medical University of South Carolina
Clem McDonald, National Library of Medicine
Ming Jack Po, Ansible Health

Ram Sriram, National Institute of Standards and Technology

MEMBERS NOT IN ATTENDANCE

Valerie Grey, New York eHealth Collaborative
Jim Jirjis, HCA Healthcare
Edward Juhn, Blue Shield of California
Ken Kawamoto, University of Utah Health
Raj Ratwani, MedStar Health
Sasha TerMaat, Epic
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: FINAL REMARKS

The co-chairs will present the Draft Recommendations Report and Draft Transmittal Letter to the HITAC at its next meeting, which is scheduled for June 9, 2021.

Key Specific Points of Discussion

TOPIC: WELCOME AND ISP TF 2021 REPORT OVERVIEW

David and Arien welcomed ISP TF 2021 members, briefly reviewed the agenda, provided a summary of all of the work the TF has completed leading up to the creation of its current Transmittal Letter and Recommendations to the HITAC, and summarized the following points:

- The ISP TF 2021 has been working to refine its draft recommendations and transmittal letter for presentation to the HITAC at its June 9, 2021, meeting.
- The co-chairs have continued to work on the document and plan to forward it to the ONC team by Friday, June 4 (ideally). HITAC members will have time to review the ISP TF 2021 materials prior to voting on them at the meeting.

TOPIC: DRAFT RECOMMENDATIONS REVIEW AND DISCUSSION

Arien explained that the co-chairs have continued to make many changes to the draft ISP TF 2021 recommendations and transmittal letter for presentation to the HITAC at its June 9, 2021, meeting. TF members have had opportunities to review copies of the documents prior to the current meeting. Arien presented an overview of recent edits to the draft transmittal letter, which included the following sections, and asked for final feedback from TF members:

- Background information, including ONC's charges to the ISP TF 2021 and membership roster
- Summaries of the hearings the ISP TF conducted, including expert presentations received and web links to materials
- High-level recommendations, which were reformatted into a new executive summary in the transmittal letter, included an introduction section and the following high-level recommendations:
    - 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 Questionnaire
    - c. HL7 FHIR standards to allow collections of consents, authorizations, and directives via FHIR Consent.
  - In order to reduce the expense of research and administrative processes by enabling appropriate reuse of data captured for clinical care, we recommend that ONC support the mapping 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 improve interoperability and innovation, we recommend that ONC work with other Federal stakeholders to move the nation towards terminology standards that are developed in accordance with OMB Circular A-119 (on Voluntary Consensus Standards), have licenses that allow open use by providers, researchers, developers, patients and other stakeholders (through national licensing where appropriate), and are designed to address multiple needs (clinical care, research, administrative needs). In areas where code sets that do not conform to this policy are currently required by Federal actors, we recommend that ONC work with key Federal stakeholders (such as the National Library of Medicine [NLM], the Centers for Medicare & Medicaid Services [CMS], the Food and Drug Administration [FDA], National Institutes of Health [NIH], etc.) to either license codes nationally or transition the nation to more open terminology.
  - In order to support use of social determinants of health (SDOH) to improve health, healthcare, and public health, we recommend that ONC implement the HL7 Gravity Project 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 key existing interoperability flows are updated to use 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).
  - In order to reduce the expense and delays 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 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 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.

- Arien presented a list of specific recommendations, supported by findings, around the following foundational standards and topics. He noted that they had been reorganized and formatted for clarity with small updates based on past TF feedback, and they included recommendations in the following areas:
  - Foundational Standards - FHIR
    - FHIR CDS Hooks or triggering offline workflows via FHIR Subscription

        - FHIR Questionnaires
        - FHIR Consent Directive
    - Foundational Standards – Common Data Model
    - 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 and David described the updates made to the text and formatting of the documents and asked TF members to share any final feedback.
- Cynthia Fisher discussed recent work on another task force that worked with tech innovators to create mobile apps that provide pricing information/shopping to patients. She also discussed work on correcting data from tech parsers (who parse price information for hospitals) and efforts to promote a standard for price transparency that is machine-readable and can be implemented by January 1, 2022. She discussed a study of how hospitals provide pricing information, noting that very few were very transparent, and many were obfuscating. They have decided to promote CSV as a format. She asked if the TF has addressed this topic and urged them to include recommendations around easily implementable standards. She asked why this topic was not investigated or discussed by this TF or others at HHS, and she discussed related issues and strategies to promote greater price transparency, including posting prices (in CSV). She stated that the TF could implement this suggestion quickly, and it is in line with the recent insurance compliance.
    - Arien suggested that the TF's terminology recommendations will help promote greater price/consumer transparency, but he suggested that the TF can include this item on a list of future. He stated that the TF went through a prioritization process, but unfortunately, this topic was not mentioned as a suggestion and was not included in the prioritization process. Arien and David suggested that because the TF needs time to review this suggestion and the recommendation document is due to ONC very soon, Cynthia was asked to put together a written recommendation to ONC for the implementation of full price transparency. He voiced his support for the recommendation and stated that it could be circulated to TF members for an email vote. Therefore, her recommendation could possibly be included in the TF's recommendations if it can be completed in time.
    - Clem noted that the CSV format might cause issues.
- Clem raised concerns around the Terminology Foundational Standards recommendations and asked how CMS and NLM will work together to ensure that SNOMED-CT and ICD-11 harmonization will allow single source use of captured clinical data. He stated that wording could be softened in case the organizations will not work together effectively and briefly mentioned several barriers between the organizations.
    - Arien stated that the TF should call for what they want going forward, and should be bold in its recommendations. TF members discussed wording choices and will continue the discussion offline.
    - David stated that "ensure" captures the strength of the TF's intentions but emphasized that the TF's recommendations are not binding.
- Cynthia asked where a standard for allowing patients to opt-in/out of having data shared for research was included in the EHR data recommendation. Does this include clinical data?
    - Arien stated that this is information is included in the first bullet of the recommendation and later in bullets.
    - Cynthia discussed problems around signing consent forms through vendor systems (Epic).

Patients might be denied care if they refuse to consent to their information being shared because the consent form is connected to the payment screen. Patients who have refused to sign have not received care. She urged the TF to consider this issue.

- Arien explained that previous policy committee work has called for intentional language around Meaningful Choice frameworks, which would include the topic Cynthia raised. It is possible that the National Coordinator has already called for changes. He stated that the current TF's role is to ensure that there are places where consent and authorization can be captured in a meaningful and structured way. He suggested that they could ask ONC for an update on related policy work.
- David agreed with everyone that this issue is important but noted that it is a policy issue, not a legal issue. Issues with vendor platforms cannot be fixed with standards compliance work.
- Arien encouraged Cynthia to share her concerns with Micky Tripathi and offered to share a link to the Privacy and Security tiger team.
- Clem stated that the 5b recommendation was confusing, and Arien responded that it is a continuation of the 5a recommendation. He also stated that items listed under the 5c recommendation were confusing and needed clarification around terminology. He was concerned that more information is needed around how much or little work has been done on each of the items listed. Where are they lacking?
- Arien stated that the intent of the 5c recommendations focused on pragmatic clinical trials, which primarily conducted using data captured in EHRs. Arien stated that there is no place in the chart to capture terminology as described in the recommendation, and the recommendation is that ONC create sections in the ISA to address gaps. The TF is trying to keep recommendations at a higher level and to call out items while directing the reader to the ISA for additional references. He encouraged Clem to share additional wording suggestions around the challenges the TF has highlighted in its recommendations, and they discussed several potential examples.

- Clem asked for clarification around how voluntary consensus standards are defined in the transmittal letter, noting that there might be issues in the other document. He explained that policies and procedures that are relevant to terminology must be considered.
  - David and Arien reviewed both documents to ensure matching language around the TF's recommendations and discussed the topic.
- David and Arien will review all documents a final time to ensure that the ordering of the recommendations corresponds accordingly across all items and is clear.
- Clem discussed issues identifying approved drug codes in major drug vocabulary systems.
- Clem asked the co-chairs to ensure that the TF's work aligns with the National Committee on Vital and Health Statistics (NCVHS) goals and recent work. Arien responded that the ICAD TF's membership included many members from NCVHS, so their opinions should be represented in the ICAD TF recommendations, which the ISP TF has endorsed. Further efforts to link the work of the HITAC and the NCVHS will be endorsed and might be underway now.
- Arien summarized all outstanding work to be completed, including items discussed and requesting by Cynthia and Clem.

Action Items

This is anticipated to be the final meeting of this iteration of the ISP TF 2021. Any feedback TF members would like to share must be submitted as soon as possible, so the TF can submit all documentation to ONC by the close of business on Friday, June 4, 2021.

Public Comment

Cassandra Hadley invited members of the public to comment and reminded everyone that comments may also be submitted by email following TF meetings.

QUESTIONS AND COMMENTS RECEIVED VIA PHONE

There were no public comments received via phone.

QUESTIONS AND COMMENTS RECEIVED VIA ADOBE CONNECT

Mike Berry (ONC): Welcome back to the Interoperability Standards Priorities Task Force! We will be getting started soon.

Ram D. Sriram: Ram Sriram Present

Leslie Lenert Md: Hey folks, sorry to be a bit late but I am here

Leslie Lenert Md: This issue of lack of standards for pricing data is really a problem

Leslie Lenert Md: PDFs and wide variation prevent folks from actually shopping everywhere

David McCallie: https://www.healthcareitnews.com/news/tiger-team-calls-providing-patients-meaningful-choice-consent-decisions

David McCallie: https://www.healthit.gov/sites/default/files/hitpc_transmittal_p_s_tt_9_1_10.pdf

David McCallie: https://obamawhitehouse.archives.gov/omb/circulars_a119_a119fr

David McCallie: https://www.nist.gov/system/files/revised_circular_a-119_as_of_01-22-2016.pdf

Arien Malec: https://obamawhitehouse.archives.gov/omb/fedreg_a119rev/

Arien Malec: (See i & j)

Resources

ISP TF 2021 Webpage
ISP TF 2021 – June 3, 2021 Meeting Agenda
ISP TF 2021 – June 3, 2021 Meeting Slides
ISP TF 2021 – June 3, 2021 Draft Recommendations Report
ISP TF 2021 – June 3, 2021 Meeting Webpage
HITAC Calendar Webpage

Adjournment

David and Arien thanked everyone for their participation in the ISP TF 2021's work over the past few months and discussed the final work that will occur on the draft transmittal letter.

The meeting was adjourned at 2:58 p.m. E.T.