Health Information Technology Advisory Committee

Interoperability Standards Priorities Task Force 2021 Virtual Meeting

Meeting Notes | May 14, 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. The ISP TF 2021 timeline was provided in the meeting presentation materials, and Arien reviewed the work that has been and will be completed by the current iteration of the TF in 2021. He also reviewed an overview of the TF's proposed recommendations. Then, Arien presented the draft ISP TF 2021 high level recommendations for TF members to review, provided background information, and invited TF members to submit comments/feedback. The co-chairs discussed the next steps necessary for preparing the TF's transmittal letter and final recommendations, 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.	Introductions
02:10 p.m.	ISP Task Force Work Schedule
02:20 p.m.	Overview
02:30 p.m.	Draft High Level Recommendations Review and Discussion
03:15 p.m.	Homework & Next Steps
03:25 p.m.	Public Comment
03:30 p.m.	Adjourn

Call to Order

Mike Berry, Acting 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
Edward Juhn, Blue Shield of California
Les Lenert, Medical University of South Carolina
Clem McDonald, National Library of Medicine

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
Jim Jirjis, HCA Healthcare
Ken Kawamoto, University of Utah Health
Victor Lee, Clinical Architecture
Ming Jack Po, Ansible Health
Raj Ratwani, MedStar Health
Andrew Truscott, Accenture

ONC STAFF

Mike Berry; Designated Federal Officer

General Themes

TOPIC: ISP TASK TF WORK SCHEDULE & OVERVIEW

The ISP TF 2021 timeline was provided in the meeting presentation materials, and Arien reviewed the work that has been and will be completed by the current iteration of the TF in 2021. He also reviewed an overview of the TF's proposed recommendations.

TOPIC: DRAFT HIGH LEVEL RECOMMENDATIONS REVIEW AND DISCUSSION

Arien presented the draft ISP TF 2021 high level recommendations for TF members to review, provided background information, and invited TF members to submit comments/feedback. The draft recommendations were included in the TF's presentation slides, and TF members discussed them.

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 presented an update on its work to the HITAC following the Public Health hearing at its May 13, 2021, meeting. The co-chairs will give a brief version of their presentation from the HITAC meeting at the current TF meeting.
- The ISP TF 2021 high-level recommendations are nearly ready, so the TF now has time to consider some more detailed/granular recommendations in time to conclude its work in June 2021.

TOPIC: ISP TF WORK SCHEDULE & OVERVIEW

Arien reviewed the timeline/schedule for the remaining work that this iteration of the ISP TF will complete in 2021. A timeline was included on slide #4 in the presentation materials, and it indicated that the ISP launched in February, presented draft recommendations to the HITAC at its May 13 meeting, and will submit final recommendations for HITAC approval at its June 9, 2021, meeting. The TF will continue to meet during its regular time period up to the June HITAC presentation and vote. David reminded TF members that their final work products will be a set of recommendations within a letter for transmittal to the National Coordinator and a slide deck for presentation to the HITAC. The co-chairs discussed the formatting and work plan for the transmittal letter and slides.

Arien stated that the ISP TF 2021 prioritized interoperability needs based on ONC priority areas and assessed the standards landscape via multiple hearings for:

- Health Equity
- Electronic Health Record (EHR) System Data Use for the "Learning Health System" based on COVD-19 experience in pragmatic trials, real world evidence, comparative effectiveness, etc. (e.g., UK RECOVERY trials).
- Burden Reduction and associated Clinical/Administrative Data and Standards Harmonization

The ISP TF 2021 also heard testimony on Public Health Situational Awareness and deferred recommendations for Public Health to the newly launched Public Health Data Systems Task Force 2021 (PHDS TF 2021).

The ISP TF 2021 determined that future work is warranted on:

- Care Plans/Chronic Dx Management
- Data Sharing Federal & Commercial Entities

TOPIC: DRAFT HIGH LEVEL RECOMMENDATIONS REVIEW AND DISCUSSION

Arien presented the draft ISP TF 2021 high level recommendations for TF members to review and provided background information. He explained that the high-level recommendations are in good shape but invited TF members to submit comments/feedback.

Following conversations at recent TF meetings, the co-chairs separated out several more general, foundational recommendations where ONC can make progress across multiple different use cases. In these recommendations, specific use case examples were pulled out and turned into more general recommendations that could be foundational across the Gravity Project's work, research needs, administrative transactions, etc., Arien discussed the reasoning behind the structure of the foundational recommendations and then he explained that additional recommendations were defined around more specific areas. The draft recommendations were included in the TF's presentation slides, and they included:

- Foundational Standards:
  - Fast Healthcare Interoperability Resources (FHIR): There are several foundational FHIR-based standards and implementation guides (IGs) that provide general support for specific usages, including the priority areas identified by the Task Force,
    - Triggers/hooks and substrate for Clinical Decision Support (CDS), incorporating questionnaires and follow-up information for public health, social determinants, prior authorization, decision support, ask at order, etc. via **FHIR CDS Hooks** or triggering offline workflows via **FHIR Subscription**
    - Standard for collecting information not routinely collected in the EHR such as additional data for clinical research and the learning health system, social determinants, public health, via **FHIR Questionnaires**
    - Framework for collecting consents, authorizations, directives, etc., for clinical research and the learning health system, social determinants, etc. via **FHIR Consent Directive**
    - **Recommendation:** ONC should invest in development, testing and production usage of these standards and related IGs for broader adoption and incorporation into certification criteria.
  - Common Data Models:

        - The USCDI forms a foundational data set for interoperability for the nation, and ONC should continue to map USCDI to HL7 FHIR and older foundational standards such as HL7 v2 and CDA
        - In order to provide a common foundation for research, social determinants/health equity, and administrative burden reduction, ONC should build a clear and rapid roadmap to expand USCDI which should incorporate research and administrative needs
        - ONC should work with industry stakeholders, and FDA, CDC, NIH and other relevant government agencies to map USCDI to broadly disseminated research data models (e.g., OMOP Common Data Model, PCORnet Common Data Model) as well as HL7 FHIR, and other concrete interoperable representations.
        - See associated specific recommendations for EHR Data Use for Research/RWE and Burden Reduction.
    - Terminology: The Interoperability Standards Advisory (ISA) and USCDI contain well founded terminology systems for interoperability. However, the lack of upstream codification and divergence between administrative and clinical terminology creates significant burden for EHR data use for real world evidence, comparative effectiveness, and other research activities and creates administrative burden by requiring dual coding.
        - ONC should use direct levers to continue to standardize terminology, while working with related agencies of HHS (primarily the Food and Drug Administration (FDA) [analyte machines] and Centers for Medicare & Medicaid Services (CMS) [CLIA]) to correctly originate codes at the source for laboratory and similar data to LOINC.
        - ONC should (directly and through coordination with CMS) harmonize procedural coding standards to open and freely available standards that are either international or clearly cross-mapped to international standards and that are optimized for clinical care, research, and administrative data use.
        - In the transition to ICD-11, ONC should work with CMS and the National Library of Medicine (NLM) to ensure SNOMED-CT and ICD-11 harmonization will allow single source use of captured clinical data for clinical care, research, and administrative workflows.
        - ONC should work with FDA and CMS to continue to harmonize NDC to RxNorm, treating RxNorm as the source terminology set, and harmonize administrative and electronic prescribing standards to use RxNorm to allow single source use of clinical data for clinical care, research and administrative workflows.
- Further Recommendations:
    - Healthy Equity:
        - The ISP TF endorses the USCDI TF recommendations that ONC should incorporate Gravity Project Standards into USCDI
        - Existing USCDI terminology for Sex, Race/Ethnicity and Address, with proposed additions for sexual identity and gender identity (SOGI) data, are sufficient to assess demographics to identify impact of social disparities
        - ONC should ensure associated interoperability standards and EHR certification requirements prioritize the capture and exchange of this data for multiple purposes.
        - ONC should continue the work to harmonize address data models and standards to provide better geolocation interoperability to allow EHR data use to correlate health outcomes with other geolocated information (pollution, food deserts, communicable disease outbreaks, etc.)
    - EHR Data Use for Research, RWE, RECOVERY-like Trials, Comparative Effectiveness:

- While the U.S. has the largest deployed base of electronic health records, the UK did the lion's share of prospective pragmatic trials for treatment for COVID-19; many US based institutions have invested in research data models and performed broad observational analyses relevant to the learning health system for COVID-19.
- The ISP Task Force found that most such systems used multiple research models, and often needed to perform lossy translation between models to accomplish research outcomes.
- The ISP Task Force found that lack of source normalization and administrative standards divergence creates burden for EHR data use for research.
- ONC should catalogue common research data models, such as OMOP, PCORI, CDISC, FDA Sentinel, etc. in the ISA and work with stakeholders to evaluate, develop and harmonize to a foundational research model mapped to the USCDI, and cross-mapped to FHIR.
- ONC should create sections in the ISA and should work with stakeholders to develop, test and promulgate standards and IGs for representation and implementation of pragmatic research studies within EHRs. Priority areas include
    - Consent (see FHIR recommendations)
    - Prospective randomization, enrollment and de-enrollment
    - Separation of research and clinical data
    - Terminology for pre-approval NDEs, biologics & devices
    - ONC should work with stakeholders to assess other EHR gaps relative to research.
- ONC should work with FDA, CDC, Federal health care providers (VA, DoD MHS, IHS) and other Federal actors to harmonize to the common research data model.
- ONC should, as noted in the foundational standards section, avoid use of proprietary standards, and use appropriate levers to source-normalize data for maximal re-use.

o Harmonization of Clinical and Administrative Data for Burden Reduction

- The ISP Task Force endorses the ICAD TF recommendations.
- ONC should add sections to the ISA to track relevant “interoperability priorities” and track items for the extant Da Vinci, FAST-FHIR, X12, NCPDP, and other related administrative standards and IGs.
- ONC should harmonize the implied administrative data model expressed in X12 and NCPDP administrative transactions to USCDI to ensure that EHR clinical data capture is maximally available to address administrative needs at low patient and clinician burden.
- See the foundational terminology standards section for recommendations on terminology for procedures and problems.

o Situational Awareness:

- The ISP TF 2021 heard from the leads on the Situational Awareness for Novel Epidemic Response (SANER) Project, which the task force found is an impressive project addressing urgent needs for the nation.
- ONC should list Situational Awareness priorities in the ISA and should list SANER as well as related standards; ONC should via work with stakeholders on pilots and early implementation, evaluate and mature towards broader adoption
- ONC should work with stakeholders at HHS to create aligned policy and funding mechanisms to harmonize adoption of a combined situational awareness standard.

Arien described the draft ISP TF 2021 transmittal letter, including the recommendations presented at the current meeting, and discussed work that needs to be completed on the letter. Arien discussed formatting concerns and asked TF members to volunteer to work on each of the sections in the letter, including

summarizing the hearings presented to the TF and drafting each of the recommendations sections. TF members may find slide decks from the expert presenters from the April 16 ISP TF 2021 meeting at https://www.healthit.gov/hitac/events/interoperability-standards-priorities-task-force-2021-4. The final recommendations will be presented at the June 9, 2021, HITAC meeting.

DISCUSSION:

- Arien explained that the comments and suggested language Ricky submitted previously on triggering offline workflows via FHIR Subscription on the FHIR Foundational Standards recommendation were received too late to be included in the presentation to the HITAC. His comments will be incorporated into the recommendations.
- Clem voiced his support for the recommendations around CDS Hooks, FHIR Subscriptions, and FHIR Questionnaire. He suggested that language should be added to indicate that the recommendations are not meant to increase burdens and disruptions to clinicians by giving them data that is not relevant. He suggested that the TF add clauses to get consent from physicians and to highlight the need for respect of a physician's time.
  - Arien responded that the preamble to the recommendation would state that CDS Hooks, FHIR Subscriptions, and FHIR Questionnaires should be configurable within EHRs to only ask for data from the clinician that the clinician and/or health systems specifically has requested. This is a workflow configuration issue, and ONC/the CDC should not try to resolve specific cases.
  - David suggested adding language to the recommendation that these items are configurable as to who they interrupt and can be routed to different people/time periods during the care encounter. Also, if they are required, they might disrupt the care encounter unless the workflow is properly configured to not do everything at the moment of care.
- David asked for TF members to share feedback given their firsthand experiences with FHIR Questionnaires. He shared his experience with the architecture of an early version that was outdated and confusing, but he added that they seem to have been widely adopted. Have they been redesigned? Are they useful and something the TF should endorse now?
  - Clem responded that it depends on implementation and the system in which they are embedded. Some FHIR Questionnaires are very long, including a Medicare Questionnaire with 700 questions. So far, there have been over 18,000 downloads of the software, so it seems that it is becoming widely adopted.
  - Sasha will look into David's questions and will share the feedback with the TF.
  - Arien reminded TF members that the high-level recommendations do not endorse specific standards IGs as they currently exist. Instead, they state that they are a priority for ONC to explore further.
  - Arien highlighted Ricky's comment in the chat to add language around FHIR Subscription, noting that it is not only relevant for offline workflows.
- Clem voiced his support of the first bullet under the Common Data Models recommendation. He commented on his recent experiences working with researchers and discussed items they have requested in data models. He explained that many projects have been undertaken to get a unified data model, though they have not been successful. He emphasized that a government push would not work and should let the players resolve issues and work on mapping. He suggested that they need funding to complete the work.
  - David responded that the TF's work will draw attention to worthy interoperability efforts for monitoring, tracking, etc.
  - Clem cautioned that some of ONC's partner organizations and agencies will have to move more slowly, and Arien stated that ONC would determine how best to work with its partners.
  - Arien summarized that the TF's recommendation is not to turn the EHR into a research instrument but to make sure that clinical documentation is maximally useful for research. The co-chairs will wordsmith the language to make sure everything is clear.

- Arien highlighted a comment Clem made previously that the FDA's analyte machines often lacked some of the contacts necessary to turn data directly into LOINC. In the past, the FDA was disconnected from the EHR community in terms of aligning standards, so the request is to line everything appropriately.
- Clem stated that Orders are more difficult to standardize than Results and highlighted issues with different/changing subsets. David suggested that the TF was focusing on Results in this recommendation. Arien discussed work that he, Clem, and the ISP did in the past on a Transmittal Letter on this topic, noted that they resolved that 95-99% harmonization was acceptable. Most clinical ordering occurs from a standardized set.
- David asked Clem to comment on the ideal state for a fully cooperative lab to code outbound results in LOINC, and Clem responded that the larger labs are close to 98%. Community labs and smaller hospital labs continue to legacy/local coding. Clem added that smaller labs have access to tables with LOINC codes and receive properly coded data from larger systems. He suggested that ONC could put an incentive in place to ensure compliance. Also, he discussed issues researchers face with mapping tables and varied LOINC codes in systems.
- David suggested that mapping codes are artifacts of systems built before the use of LOINC codes. On the in-bound side, they should work to get close to 100% LOINC codes.
- Arien noted that CLIA is regulatory that could enforce these issues, which would be helpful.

- David suggested some alternate language for the third bullet point under the Terminology Foundational Standard, which was, "…harmonized procedural coding standards to open end or freely available to U.S. clinicians."
  - Clem commented that Procedures in FHIR/US Core are defined as things that have an effect on or change to the patient. The co-chairs explained that the wording was meant to refer to billing codes that drive knowledge about what happens to a patient.
  - David, Arien, and Clem discussed whether the phrase "procedural coding standards" was confusing. They discussed which codes meet testing standards, and David explained that the TF is not weighing on which code to use for codifying a procedure.
  - Clem discussed his disagreements with the wording in the bullet, and Arien described several examples that would meet the wording criteria. They both agreed on the need for open vocabulary standards and discussed wordsmithing options. Clem highlighted international issues using several standards and suggested that the wording should be "open" or "international," not both. David responded that the standards should be mapped to international standards.
  - Sasha agreed with the bullet but submitted two questions:
    - Why is this a recommendation around procedural standards only? She stated that it really should be a recommendation about any USCDI code set, not just procedures. TF members agreed with her comment.
    - Though the recommendation is an ideal state, there are short-term consequences to removing a code set from USCDI. She cautioned the TF to be mindful of any vocabulary transitions. There could be negative impacts on current interoperability if implementers just decide to remove a code set, like the Current Procedural Terminology (CPT®) code set to bill outpatient and office procedures.
  - Arien responded that some outcomes could resolve this issue:
    - The American Medical Association (AMA) could negotiate with NLM on broad usage rights for U.S. uses for CPT and to engage with NLM to cross-map CPT with SNOMED to get a single vocabulary standard.
    - Or: there could be a transition to SNOMED as procedure coding for both administrative and clinical use, which would create a transitional period requiring a long, coordinated roll-out.

- Clem stated that physicians have memorized CPT, and other TF members agreed that changing CPT will not happen. The question is if it can be made free for all U.S. clinicians to use, which David suggested is an attainable policy.

- Clem highlighted several potential issues with the recommendations. He suggested that SNOMED is not deeply embedded in U.S. systems. Clinicians must map it.
  - Arien agreed that this is a documented problem of a typical experience in which everyone documents to the administrative standard, and then clinical uses are an afterthought. During the comment period and presentations, the research community explained this problem with coding to the TF.
  - Clem and Arien discussed whether the recommendation accidentally prejudged what the market would do following the release of ICD-11. Arien stated that it was not. They discussed the wording of the recommendation but did not change it.
  - Clem stated that it might not be possible to fully harmonize NDC and RxNorm, and the TF discussed the implications of continuing to use NDC or harmonizing to RxNorm as the single source of clinical data for research.
  - Clem suggested adding another bullet: “Encourage the use of UCUM for the analysis of numeric data.”
  - David responded researchers made this request during their presentations to the TF but suggested that the use of UCUM is already required within the standards. Clem suggested that it should be highlighted.
- Arien summarized the TF’s Health Equity recommendations and noted that the need for occupation coding was emphasized during the Public Health Hearing, which took place at the May 13 HITAC meeting. He suggested that the TF make it a future item of discussion instead of including it within the recommendations now.
  - Les agreed that the occupation coding needs more development before it is included. David raised the comment from the HITAC that it could be referred to as “usual work” and noted that the zip code where work takes place is possibly more useful.
  - Sasha suggested updating the wording so that the TF does not set an expectation that EHR certification implies anything about data capture. It would read, “EHR certification mechanisms prioritize the representation and exchange of data...”
- Arien recognized Les’ work on updating the language for the EHR Data Use for Research, etc., recommendations.
  - Clem stated that OMOP and PCORI need funding to work towards harmonization to create a single research data model. He suggested updating the language to say that the TF should recommend that ONC support continued funding so that the standards are willing to change and become more unified, thus bringing their users over.
  - TF members discussed the recommendation, noting that the issue is funding for the work OMOP/PCORI are undertaking, not their coding work.
  - David suggested using a well-mapped, upstream staging model, which was not used for these recommendations.
  - Clem stated that Medicare can do pragmatic trials and discussed the CMS process for sending data. The TF should cross-reference this work. TF members discussed other actors/organizations to add to the list of Federal actors.
  - Sasha suggested calling the EHR gaps “EHR opportunities relative to research,” and Arien voiced his agreement because EHRs were not created to serve as research instruments. David asked if those capabilities might develop and become certifiable at some point. Arien suggested that the TF should be silent on this point.

- Arien noted that funding opportunities for Situational Awareness priorities were discussed at the recent HITAC Public Health hearing.
    - In response to a question from Clem, the co-chairs clarified the meaning of SANER's name and that it is a FHIR workgroup that presented to the TF at an early meeting.

Action Items

As their homework, ISP TF 2021 members were asked to review a draft of the TF's report to the HITAC and to come to the next meeting prepared to discuss suggested changes.

The TF co-chairs are also looking for volunteers to help focus on specific areas of the report and offer thoughts/recommendations for discussion at upcoming TF meetings in the following areas:

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

Public Comment

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.

clem mcdonald: I am here-clem but missed the role call

Leslie Lenert: Hey folks here after be a few minutes late

Ricky Bloomfield: On Slide 7 I would recommend saying "or improving workflow efficiency and timeliness via FHIR Subscription" or something to that effect. It's not only relevant for offline workflows.

Ricky Bloomfield: (I was referring to this slide - looks like the slide numbers changed)

Ricky Bloomfield: Ditto - I was about to say the same thing. We just need to say it's a priority for further exploration, etc.

Sasha TerMaat: Is there a reason we're only making this recommendation on procedures? Is that the only existing example in USCDI?

Sasha TerMaat: How would EHR certification "prioritize capture" when certification is about capabilities and not usage?

John Embley: The Situational Awareness for Novel Epidemic Response (SANER) Project

Katherine Campanale 3: https://www.healthit.gov/hitac/events/interoperability-standards-priorities-task-force-2021-4

John Travis: I do have a public comment - and it aligns to a bit to the 2nd recommendation on slide 9 - ONC should segment the USCDI and not retain it as a monolith for certification

Arien Malec: @john Travis -- that comment should probably go to the USCDI task force -- our mission is to address the ISA!

John Travis: That was what I was hoping for - and will do!

Resources

ISP TF 2021 Webpage
ISP TF 2021 – May 14, 2021 Meeting Agenda
ISP TF 2021 – May 14, 2021 Meeting Slides
ISP TF 2021 – May 14, 2021 Meeting Webpage
HITAC Calendar Webpage

Adjournment

David and Arien thanked everyone for their participation and discussed the next steps toward drafting a recommendation letter. David highlighted John Travis's comment in the public chat by reading it into the record.

Mike reminded TF members that the next ISP TF 2021 meeting will be held on Thursday, May 20, 2021, from 2 p.m. to 3:30 p.m. E.T.

The meeting was adjourned at 3:25 p.m. E.T.