Health Information Technology Advisory Committee

Interoperability Standards Priorities Task Force 2021 Virtual Meeting

Meeting Notes | May 6, 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. These will be presented to the HITAC at its May 13, 2021 meeting. The draft recommendations were included in the TF's presentation slides, and TF members discussed them. The co-chairs discussed the next steps necessary for preparing the TF's 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 Timeline 2021 & Proposal
02:20 p.m.	ISP Task Force Work Timeline
02:30 p.m.	Draft High Level Recommendations Review and Discussion
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
Cynthia Fisher, PatientRIghtsAdvocate.org
Jim Jirjis, HCA Healthcare

Edward Juhn, Blue Shield of California
Ken Kawamoto, University of Utah Health
Victor Lee, Clinical Architecture
Les Lenert, Medical University of South Carolina

MEMBERS NOT IN ATTENDANCE

Valerie Grey, New York eHealth Collaborative
Ming Jack Po, Ansible Health
Raj Ratwani, MedStar Health
Ram Sriram, National Institute of Standards and Technology
Sasha TerMaat, Epic
Andrew Truscott, Accenture

ONC STAFF

Mike Berry; Designated Federal Officer

General Themes

TOPIC: ISP TASK FORCE TIMELINE 2021 & PROPOSAL

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 and briefly reviewed the agenda. Arien stated that the TF is set to conclude its work in June 2021.

TOPIC: ISP TF TIMELINE FOR 2021 & PROPOSAL

Arien reviewed the timeline for ISP TF work that has been and will be completed in 2021. The ISP launched in February, will present 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 timeline was included on slide #4 of the TF presentation deck.

Arien reviewed the TF's proposal to make recommendations on:

- Health Equity Standards
- Real-World Evidence (RWE)/Comparative Effectiveness/RECOVERY-type Electronic Health Record (EHR) data use
- Clinical/Administrative Data & Standards Harmonization and Burden Reduction

The TF will consider recommendations on:

- Public Health Situational Awareness
- Care Plans/Chronic Disease Management (pending expert presentations or TF deliberation)
- Data Sharing Federal & Commercial Entities (have experts, but there are timing issues)

The TF will defer public health recommendations to the newly launched Public Health Data Systems Task Force 2021 (PHDS TF 2021).

Arien reviewed the updated ISP TF 2021 work timeline, which was included on slide #6 in the presentation. TF members were encouraged to participate in offline work before the May 13, 2021 HITAC meeting.

TOPIC: DRAFT HIGH LEVEL RECOMMENDATIONS REVIEW AND DISCUSSION

David emphasized that the ISP TF 2021's work at the current meeting would focus on high level recommendations, as there will be more time to flesh out the recommendations in the future.

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 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,
    - FHIR Clinical Decision Support (CDS) Hooks
    - FHIR Questionnaires
    - FHIR Consent Directive
    - Recommendation: ONC should invest in testing and development activities to track these standards and related IGs for broader maturity and incorporate into certification criteria.
  - Common Data Models:
    - Recommendation: The United States Core Data for Interoperability (USCDI) forms a foundational data set for interoperability for the nation, and ONC should continue mapping of the USCDI to HL7 FHIR and older foundational standards, such as USCDI Version 2 (USCDI v2) and CDA.
    - Recommendation" In order to provide a common foundation for research, social determinants of health (SDOH)/health equity, and administrative burden reduction, ONC should build a clear and rapid roadmap to expand USCDI which should incorporate research and administrative needs.
    - Recommendation: ONC should identify common staging data models and should map USCDI to those staging data models (e.g., OMOP) as well as HL7 FHIR, other concrete interoperable representations.
    - See associated specific recommendations for EHR Data Use for Research/RWE and Administrative 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.
    - Recommendation: 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.

        - Recommendation: 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.
        - Recommendation: 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 to allow single source use of captured clinical data for clinical care, research, and administrative workflows.
        - Recommendation: 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:
        - Recommendation: The ISP TF endorses the USCDI TF recommendations that ONC should incorporate Gravity Project Standards into USCDI
        - Recommendation: 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
        - Recommendation: ONC should ensure associated interoperability standards and EHR certification requirements prioritize the capture and exchange of this data for multiple purposes.
        - Recommendation: 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:
        - The ISP Task Force found that the OMOP data model was the preferred data model for research and was heavily and impressively used for emergent research during the pandemic. PCORI, however, selected the FDA Sentinel model to harmonize with Federal actors, leading to data providers cross mapping to OMOP as the foundational standard.
        - The ISP Task Force found that lack of source normalization and administrative standards divergence creates burden for EHR data use for research
        - Recommendation: ONC should list OMOP in the ISA and work with stakeholders to mature OMOP, harmonize to the USCDI, and cross-map to FHIR.
        - Recommendation: ONC should create sections in the ISA to address standards and IG needs for randomization in the EHR (e.g., through FHIR CDS Hooks or other mechanisms)
        - Recommendation: ONC should work with FDA, Federal health care providers (VA, DoD MHS, IHS), and other Federal actors to harmonize to the common research data model
        - Recommendation: 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.
    - Harmonization of Clinical and Administrative Data for Burden Reduction
        - The ISP Task Force endorses the ICAD TF recommendations
        - Recommendation: ONC should add sections (“interoperability priorities”) to the ISA to track administrative standards and create items for relevant Da Vinci, FAST-FHIR, x12, NCPDP and other related administrative standards and IGs.

        - Recommendation: 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.
    - 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.
        - Recommendation: ONC should list SANER in the ISA and work, via pilots and early implementation, to evaluate and mature towards broader adoption
        - Recommendation: ONC should work with stakeholders at HHS to create aligned policy and funding mechanisms to harmonize adoption of a combined situational awareness standard.

Arien explained that these were the highest level recommendations that were submitted to the ISP TC/co-chairs, and other, more granular/detailed recommendations are being prepared. They will be presented later, following HITAC feedback on the high-level recommendations. He asked for feedback from TF members on whether the correct topics and recommendations were identified, and David responded that there were two topics that were not addressed: "Data sharing across federal and non-federal boundaries" and "Care plans and chronic disease burden management." Arien responded that the TF did not have enough time/bandwidth to fully explore these topics, nor did they receive enough testimony/expert input on them. These will be passed forward to the next iteration of the TF.

DISCUSSION:

- Ricky commented that FHIR Subscription (helps with a reduction in polling) could be added to the list of standards/IGs in the FHIR recommendation. Work is underway on an IG and at Argonaut, but there is a question of whether it is mature enough right now to be added.
    - Arien responded that it could be added to the list at a lower level of maturity.
    - David suggested that an alternate way to express the list could be as interoperability priorities with the applicable standards listed underneath.
    - Les commented that the last sentence in the FHIR recommendation could be more forceful, as some of these suggestions are more mature than items being pushed by other task forces (like the USCDI). It could include language about testing toward production and corporation certification criteria. He suggested adding Advanced Directives as a use case area under Consent Directive.
    - Ed suggested adding "advancing and adoption" to the last sentence and agreed that it could be strengthened.
    - Les suggested adding "decision support" as a use case under CDS Hooks, and Arien agreed that it should be the primary use case. He discussed his thought process about the "Hooks" area and why he added CDS.
- Arien commented that the language in the Common Data Models set of recommendations needs additional wordsmithing and invited TF members to submit feedback.
    - Les asked if Arien if he meant "OMOP" or "OMOP/OHDSI" and suggested calling it a "longitudinal data analysis model" instead of a "staging data model" (both in the third recommendation).
    - David responded that he borrowed "staging data model from the N3C presentation given by Chris Chute at the April 16 ISP TF meeting. His intent was to get the data into the Common Data model as step one before it is processed/optimized in the second data model. The Common Data model does not have to be the core, just a step in the process.

  - Arien suggested “high priority data models,” and Les suggested “research data models.” Arien reminded TF members that the specific data models would be described in the research section of the recommendations. This section should be more general to cover organizations from dealing with multiple mappings because they are dealing with different representations of the same data and not to suggest one model over another.
- Arien discussed the use of RxNorm and suggested that the following should be added as a recommendation under the Terminology foundational standard: “ONC should work with FDA and CMS to continue to harmonize National Drug Code (NDC) to RxNorm, treating RxNorm as the source terminology set, and harmonize administrative and electronic prescribing standards to use RxNorm.” He will add additional language as a bullet and will work on the wording.
  - Victor asked about the reference to “harmonizing procedural coding standards” in the second recommendation is related to Current Procedural Terminology (CPT) and voiced his agreement with Arien’s comments on RxNorm.
  - Arien responded that CPT is the non-open/not freely available code that is only used in the U.S., so that was one of the code sets referenced in the comment.
  - Arien and Victor discussed wording suggestions for the potential recommendation about continuing harmonization/mapping efforts between NDC and RxNorm. They stated that the logical, procedural terminology for administrative use is ICD-10/ICD-11, with SNOMED as the logical choice for clinical terminology. Arien stated that these recommendations would be supported by the information presented by experts and the ICAD TF.
  - David reminded TF members that the high-level recommendations will be expanded to be granular in future versions.
- Arien explained the work complete behind the Health Equity recommendations and asked TF members to comment.
  - David stated that, following the Gravity Project’s presentation to the TF, he saw three levels of work that would correspond to ONC’s staging efforts, and they included:
    - Level one: the expansion of the nomenclature to capture SDOH data,
    - Level two: the design and promulgation of specific FHIR Questionnaires to capture the expended vocabularies in a workflow,
    - Level three: (furthest out) an API exchange would be possible between systems to share SDOH/related data in an unattended fashion.
  - Arien offered to update the wording in the recommendations/on the slide.
- Arien noted that he would update the references to OMOP in the EHR data use for research, etc., recommendations, which were incorrectly written as “OMAP.”
  - Les suggested that instead of suggesting OMOP, specifically, the recommendation should say “the preferred data model.” It is too politically difficult to suggest a specific model. He discussed the challenges of choosing OMOP as the specific model.
  - Arien suggested that there should be a preferred model of some sort to avoid mapping data multiple times (which leads to excess work and lossy conversions). However, he recognized the political implications of choosing one model over another but suggested that Federal actors have an interest in a single, aligned research data model. He discussed feedback from the expert presenters.
  - Les suggested the following wording: “work to conduct comparative analyses of existing models with the view of converging on a single model.” An analysis of analytics of the PCORnet and OMOP has not been done. He stated that he would have suggested mapping to FHIR as the representation language, and Arien responded that FHIR would be the representational model for the detailed underlying model. Les and the co-chair will work on the final language in advance of the HITAC presentation.
  - David responded that presenters to the TF stated that they put their data into FHIR first before entering data into other models. FHIR could be part of the staging pipeline.

  - David asked Les to comment further on a suggestion he submitted (that was not included) around enhancing the ability of EHRs to perform randomized trials, like randomized drug dosage or drug choice. Is this related to the U.K. RECOVERY trials? Was this comment properly recognized in the recommendations?
  - Les responded that, for EHR vendors (like Epic, Cerner, etc.), clinical packages have certain functions and exist outside the scope of meaningful use speculations. There a not standards for how trials are represented in electronic records, nor are there standards for experimental medicines/placebo-controlled drugs as part of studies; these must be invented whenever they are deployed inside of the EHR. The lack of clinical trial functionality in the EHR slows things down.
  - David agreed that this topic should be called out more specifically.
  - Arien discussed the missing feature, which is the ability to randomize, and discussed the need to support clinical trials across EHRs. Arien, Les, and David discussed the differences between the abilities of the U.K. and the U.S. to do randomization at a nationwide level. They also discussed the need for recognizing a “pragmatic trial” or an “adaptable trial” and across EHRs, in addition to characterizing comparative effectiveness research. This point will be better supported in the recommendations following wordsmithing work by the co-chairs. They acknowledged that it would push existing boundaries.
- Arien summarized the Harmonization of Clinical and Administrative Data for Burden Reduction recommendations and called for TF member comments.
  - David explained that he added the first recommendation as a way to ensure that the broader context of the specific acronyms used by various groups to refer to standards/IGs is captured in the ISA. These solutions should be matched against problems they are trying to solve, so the problem would come first, with choices of solutions nested underneath.
  - They discussed where some of the standards would be placed and acknowledged Alix Goss’ comments and suggestions in the public chat.
- Arien stated that the Public Health Data Systems Task Force will also be working on Situational Awareness (SA) recommendations, but the ISP TF 2021 made several recommendations based on the SANER presentation to the TF. His biggest takeaways from that presentation were that the issues were not with a lack of standards but rather were due to the ecosystem and a lack of stakeholder alignment, funding mechanisms, and policy harmonization.
  - David commented that this work could be broken down into stages, starting with clarifying the underlying FHIR Resources.
  - Les, David, and Arien discussed challenges related to implementing the API, and Les discussed his background work on SA and what simple items can be captured within the EHR.

Action Items

As their homework, ISP TF 2021 members were asked to review slides the ISP TF 2021 has proposed to present to the HITAC at its Thursday, May 13, 2021 meeting. The co-chairs integrated the comments from the TF’s review and discussion. TF members were asked to review and submit any suggested changes directly to the co-chairs by Monday, May 11.

Les was invited to take a close look at the "EHR data use" slides to make sure the TF was not "waving too many red flags.”

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): Thanks for joining the Interoperability Standards Priorities task force. We will be starting soon.

Jim Jirjis: Jim Jirjis Joined

Ricky Bloomfield: I just joined.

Mike Berry (ONC): Thanks Jim and Ricky.

Victor Lee: I just joined as well

Cynthia: Cynthia Fisher logged in and attending

Cynthia: In and out as having wifi problems

Mike Berry (ONC): Welcome Victor & Cynthia. glad you can join

Adele Stewart: Hi - first time here, so not sure what the comment protocol is, but woould *[sic]* it be appropriate to recommend standardized capture of information that originates with the patient as part of the health equity conversation? E.g. terminology associated with patient reported outcomes measures as part of patient-centered care? That may be too granular.

Leslie A Lenert: Robert Califf was the FDA Commissioner that I was thinking of as a major advocate for pragmatic trials

Alix Goss (imprado): Suggest use of HL7 when referencing Da Vinci or Gravity or CARIN - as HL7's Accelerators - using the HL7 FHIR standard. Further, the X in X12 is capitalized.

Alix Goss (imprado): :)

Ricky Bloomfield: Sorry, I have to jump off!

Alix Goss (imprado): Quite likely!

Leslie A Lenert: sure...glad to help and anything to keep this from being sent back

Arien Malec: thanks!

Resources

ISP TF 2021 Webpage
ISP TF 2021 – May 6, 2021 Meeting Agenda
ISP TF 2021 – May 6, 2021 Meeting Slides
ISP TF 2021 – May 6, 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 Adele Stewart's comment in the public chat by reading it into the record, but the TF did not discuss the comment at the meeting.

Mike reminded TF members that the next ISP TF 2021 meeting will be held on Friday, May 14, 2021, from 2 p.m. to 3:30 p.m. E.T.

The meeting was adjourned at 3:15 p.m. E.T.