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 continue to review 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.        Opening Remarks
02:10 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, 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
Jim Jirjis, HCA Healthcare
Victor Lee, Clinical Architecture
Les Lenert, Medical University of South Carolina
Clem McDonald, National Library of Medicine
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 continue to review the Draft Recommendations Report and Draft Transmittal Letter. The TF will focus on its PowerPoint presentation to the HITAC at its next meeting.

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 has been working to 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 and review the document.

**TOPIC: DRAFT HIGH LEVEL RECOMMENDATIONS REVIEW AND DISCUSSION**
Arien explained that the co-chairs have continued to make many changes to the draft ISP TF 2021 high-level recommendations and transmittal letter for presentation to the HITAC at its June 9, 2021, meeting. TF members were sent clean and marked-up copies of the documents prior to the meeting and were asked to discuss changes. 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 high-level recommendations, were reformatted into a new executive summary, which included:
  - An introduction section
  - High-level recommendations: (Arien noted that this section might need to be updated.)
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 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 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.

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 (SDOH) 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).

Arien presented a list of specific recommendations, supported by findings, around the following foundational standards and topics. He noted that they had been lightly wordsmithed 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 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 described updates to the TF’s recommendations and noted that he had several ideas for continuing to wordsmith and update items that were not fully captured within the document.
- Clem submitted several comments and suggestions, which included:
  - Do not make licensing as prominent a suggestion under the second recommendation.
  - He commended Arien for his work on the document.
  - Change “early” to “close” in wording for recommendation three.
  - Recent feedback provided to the Public Health Data Systems Task Force (PHDS TF) related to the TF’s recommendation around maximizing use of clinical data to reduce disparities. The PHDS TF feedback identified issues with the flows of registration data, so he asked if the ISP TF has addressed this in its recommendations. Arien suggested that they have addressed this comment. Clem and Arien discussed previous work on this area, and Arien stated that they found that the information was intentionally dropped in the integration engine when sent to the lab, as the lab does not require demographic information.
  - Sasha commented that she has investigated this topic based on early concerns that demographic information has not reached public health. The impression she got was that nobody had bothered to configure the engine to transfer the information.
  - The TF makes specific recommendations around this issue later in the document.
- David commented that he submitted a series of comments around language inconsistencies on the parts of the draft document that referenced the common research model.
- Arien commented that additional work is required across the document to ensure that language is consistent between the high-level recommendations and the specific recommendations.
- David commented that the TF has used inconsistent language to refer to the idea of a common data model and asked members to discuss the exact wording.
  - Arien suggested mentioning the “no meta model” idea from later in the document. The TF is calling for a pragmatic model for research and harmonization and asked if better wording is needed or a reworking of the TF’s opinion.
  - David suggested pulling more specific language from the fifth specific recommendation, part of which stated, “The Task Force recommends that ONC support the catalogue of 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 common foundational research model mapped to the USCDI, and cross-mapped to FHIR.” Arien expanded on the reasoning and work behind this wording.
Clem commented that this language might lead toward a meta-model, and he suggested that the TF might want to recommend allowing the market and researchers to determine the best approach toward a common model. He reminded the TF that a meta-model called the Biomedical Research Integrated Domain Group (BRIDG) model already exists, but the eventual outcome was not ideal.

- Clem summarized existing work: OMOP has been adopted across several projects, PCORnet needs more funding to make changes but is not far behind in the market, HL7 and OMOP are working closely together on how FHIR data is used.
- David stated that the TF does not have the authority or the knowledge to choose a winner for the common data model, so Clem suggested removing the list or encouraging cooperation between various models.

- David stated that clarity is needed around the data included in FHIR Resources and how they are included/tied together in a relational-style model. How can this be leveraged and done appropriately?
- Arien described previous work done by ONC on regulations around mandating the use of APIs. They found that combining regulatory hammers with an allowance of time for developers/the market to figure things out has been a strategy that worked well.
- Les commented that the object-oriented part of FHIR is valuable and noted that he shared a link in the public chat to a recently published paper on the topic of mapping to PCORnet, OMOP, and FHIR subscriptions simultaneously.
- Arien discussed wordsmithing options for various specific recommendations to encapsulate the TF’s recent discussion best.

- Arien asked TF members to discuss the proposed recommendation that ONC work with Federal stakeholders to establish policy that moves terminology standards in several broad areas.
  - David confirmed that wording about national licensing would be removed, and Arien agreed. The TF should be clear that they are not prescribing the “how” part of the suggestion. Specific terminology was not listed, as it is the purview of other federal partners.
  - Clem suggested that the wording be updated to state that the federal government can support vocabulary standards, as needed, to ensure success.

- TF members revisited a previous discussion about Unified Codes for Units of Measure (UCUM), and they discussed how to mention its use. They decided to add it, along with LOINC, under one of the Terminology standards recommendations.
  - Arien suggested cross-referencing previous ISA work.

- Clem discussed adding clarity to the wording of the following Health Equity recommendation to indicate that the content and medical record of the registration data are not being sent along with the order. The wording should emphasize that the demographics that exist in the registration system need to be sent.
  -“The Task Force recommends that ONC implement policy to ensure deployment of associated interoperability standards and EHR certification requirements that prioritize the capture and exchange of demographic and contact data for multiple purposes, including public health.”

- Arien explained that there was a new section under the Harmonization of Clinical and Administrative Data for Burden Reduction, and several smaller changes were also added. He explained that existing work is being done on some of the TF’s recommendations in this section between HL7, National Council for Prescription Drug Programs (NCPDP), and X12.

- David asked TF members to check the Appendix A section of the document for errors.
  - Clem will be added back to the document.
Action Items

At their next meeting, the ISP TF will extract information from the transmittal for use in presentation slides and will review the PowerPoint.

Public Comment

Mike 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. Arien highlighted a comment that was previously submitted by the American Medical Association (AMA) for the record.

QUESTIONS AND COMMENTS RECEIVED VIA ADOBE CONNECT

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

Jim Jirjis: good afternoon

Ricky Bloomfield: I’m here.

Jim Jirjis: Is there is need for supporting national standards and availability of value sets

Arien Malec: I think we are trying to call out the open point but sustainable is an important desideratum.

Arien Malec: Clem’s angst is that if we call for NLM funding, there’s a potential budget issue there. Leslie Lenert: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7987036/

Leslie Lenert: This paper describes how you can dynamically map from FHIR to OMOP and PCORnet using subscriptions

David McCallie: @les - thank you

Leslie Lenert: +1 to support “existing work”

Jim Jirjis: A man who needs no introduction

Ricky Bloomfield: “Notorious C.M.D.” should now be included in the document.

Resources

ISP TF 2021 Webpage
ISP TF 2021 – May 27, 2021 Meeting Agenda
ISP TF 2021 – May 27, 2021 Meeting Slides
ISP TF 2021 – May 27, 2021 Draft Recommendations Report
ISP TF 2021 – May 27, 2021 Meeting Webpage
HITAC Calendar Webpage

Adjournment

David and Arien thanked everyone for their participation and discussed the next steps/continuing work on the draft transmittal letter.
Mike reminded TF members that the next ISP TF 2021 meeting will be held on Thursday, June 3, 2021, from 2 p.m. to 3:30 p.m. E.T.

The meeting was adjourned at 2:51 p.m. E.T.