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 co-chairs reviewed the proposed frameworks for prioritization of the TF’s areas of focus and recommendations. TF members discussed the recommendations and issued initial rankings. The TF briefly discussed obtaining expert input at future meetings, and a list of potential presenters was shared.

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
02:15 p.m. Introductions
02:25 p.m. Review of Ideas from March 11 Meeting
02:45 p.m. Framework and Prioritization Discussion
03:05 p.m. Obtaining Expert Input
03:15 p.m. Homework
03:25 p.m. Public Comment
03:30 p.m. Adjourn

Call to Order
Michael Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 2:00 p.m. and welcomed all members.

Members in Attendance
Arien Malec, Change Healthcare, Co-Chair
David McCallie, Individual, Co-Chair
Ricky Bloomfield, Apple
Valerie Grey, New York eHealth Collaborative
Jim Jirjis, HCA Healthcare
Edward Juhn, Blue Shield of California
Victor Lee, Clinical Architecture
Les Lenert, Medical University of South Carolina
Clem McDonald, National Library of Medicine
General Themes

TOPIC: REVIEW OF IDEAS FROM MARCH 11 MEETING
The co-chairs reviewed the ideas for topics/areas of focus submitted at the March 11 meeting of the ISP TF 2021.

TOPIC: FRAMEWORK AND PRIORITIZATION
Arien and David described the proposed framework for prioritizing the ISP TF 2021’s areas of focus and work. TF members submitted feedback and will complete ranking using Delphi scoring during online work.

Key Specific Points of Discussion

TOPIC: WELCOME AND ISP TF 2021 OVERVIEW
- The co-chairs, David and Arien, welcomed ISP TF 2021 members to the third meeting of the reconvened TF, and David reviewed the following items:
  - Arien thanked David for taking the lead on offline work for the TF over the past week.
  - New participants were welcomed to the virtual meeting and were encouraged to request clarification on terms or other concepts, as necessary.
  - The ISP TF 2021 mandate was included in the presentation materials on slide #4.

TOPIC: REVIEW OF PREVIOUSLY SUBMITTED IDEAS
David explained that both broad and specific recommendations have been submitted by ISP TF 2021 members. David provided a brief overview of the list of topics submitted during previous ISP TF 2021 meetings, which were in no particular order in terms of importance, and included:
- Clinical/Administrative data & standards harmonization/burden reduction
- Data sharing between federal & commercial health care entities (mismatch between security policies)
- Vaccine/Immunization registry reporting (data flows around maintenance and access to registries)
- Health Equity Standards (including social determinants of health (SDOH) data standards)
- Real-world evidence (RWE)/comparative effectiveness/RECOVERY-type data use – from electronic health record (EHR) systems
- Public health (PH) situational awareness (including required reporting by state/local PH to national level)
- Syndromic surveillance (detecting the emergence of a PH issue or emergency)
- Care plans and chronic disease burden management
- Adverse event (AE) reporting (including, but not limited to, adverse drug event reporting)
- Patient to device (mobile, medical device) linking
• Contact tracing and exposure notification (use of standard around these practices)
• Vaccine credentials (aka Vaccine Passport) – the ISP TF 2021 will defer to ONC, because they already have active work underway

**TOPIC: PROPOSED FRAMEWORKS FOR PRIORITIZATION**
Arien provided an overview of the ISP TF 2021’s proposed framework for prioritization. The proposed framework included:

- Assume the ISP TF 2021 has more areas that require the focus of the TF, ONC, and the industry than all stakeholders have time, energy, and focus to address.
- When prioritizing, the TF should prefer:
  - Areas that align with ONC’s declared priority areas:
    - COVID-19
    - Health equity
    - 21 Century CURES Act enablement
    - Unmet needs on the existing ONC Roadmap
  - Avoid areas already being covered through existing ONC initiatives
  - Foundational and/or leveraged areas (solutions that unlock other areas) over general areas, over specific solutions
  - Existence of well-defined policy levers, over novel policy levers required
  - Areas with where jobs are already being done inefficiently, over areas the TF wants the health system to focus on
- Consider timeframe of recommendations
  - Near term (months) – work can be done immediately
  - Medium term (6 months – 2 years) – work requires planning and coordination
  - Long term (2 – 5 years) – work requires standards development, piloting, legislative action, etc.
- Consider type of action required
  - ONC/industry alignment and voluntary action around existing standards
  - ONC/industry/SDO alignment and standards development
  - Incentive alignment
    - ONC and other HHS rulemaking (and other non-HHS actors)
    - Congressional action/appropriation
    - Multistate action

**TOPIC: PRIORITY SCORING AREAS & DISCUSSION**
The co-chairs stated that the framework and prioritizations assigned by the ISP TF 2021 will be fluid, and all TF members were encouraged to give feedback. Arien explained the proposed priority scoring, in which high equals 9 points, medium equals 3 points, and low equals 1 point. Overall scores will be calculated and adjusted during the TF’s offline work period. The scoring system included:

- Is this a Priority Area for ONC (High / Medium / Low)
  - COVID-19
  - Health Equity
  - 21st Century Cures Act Enablement
  - ONC Roadmap
- Potential Impact
Foundational (H): the topic will unlock a large number of possible uses that are currently being done as one-off capabilities due to the lack of this capability

General purpose (M): the topic can be deployed for a large number of Americans or within a large number of uses (even if it is not foundational for those uses)

Specific (L): the topic solves a particular problem

Applicable Policy Levers

Well-defined (H): successful rollout needs only well-defined policy levers that are in the control of ONC - or - requires only moderate coordination with other federal partners and are in line with that partner’s mission

Maybe / unclear (M): successful rollout requires significant coordination between ONC and other federal partners, requiring addition or alteration of perceived mission

New policies or regulations needed (L): successful rollout requires multiple policy levers and coordination between multiple actors to succeed (e.g., ONC, federal partners, state/local actors)

Current Burden

High: this area currently causes significant burden or administrative cost, and/or addressing this area by itself would solve substantial cost reduction for the U.S. Health Care System.

Medium: this area currently causes moderate burden, or could be a part of a solution to drive cost reduction for the U.S. Healthcare System.

Low: this job is already getting done, but could be done with more efficiency with additional standards coordination/development

DISCUSSION:

Jack suggested that it would be useful to do a survey of what is available, from a standards and an existing API perspective, to see how the ecosystem needs are currently being met. Then, a website would be maintained to share this information.

Arien explained that ONC maintains a list of standards on the ISA website at https://www.healthit.gov/isa/

ONC or the ISP TF 2021 will do a survey and will update all information. APIs and alternatives beyond standards are not included in the ISA website. These could be captured in a survey.

David stated that the current process allows all TF members to state their opinions on each recommendation. Usually, an online voting process would not allow for the capture of TF member opinions on why topics were weighted as high/medium/low.

TF members discussed scoring for each of the recommended topics for TF focus and added their general scores to a spreadsheet.

Clinical/Administrative Data & Standards Harmonization/Burden Reduction

TF members rated this recommendation as a high priority under the 21st Century Cures Act area and a medium priority under the ONC Roadmap area.

TF members rated the impact of this topic as general purpose/medium.

There are federal policy levers, though many may not be widely used.

Current burden is high.

- Arien summarized the work of the HITAC’s Intersection of Clinical and Administrative Data Task Force (ICAD TF), which focused on electronic prior authorization (ePA), claims attachments, the requirement for clinical data to be used when adjudicating administrative transactions, etc.

Data sharing between federal & commercial health care entities

TF members rated this recommendation as a high priority under the 21st Century Cures Act area and a medium priority under the ONC Roadmap area.
In response to Clem’s request for clarification, Arien discussed conflicts in standards for data sharing between federal and non-federal/commercial actors and described several ways standards may/may not work together. Generally, federal standards are tougher and more limiting.

- TF members rated the impact of this topic as specific/lower to general purpose/medium, as it affects a broad, yet specific, group.
- Applicable policy levers are at the federal level.
- Current burden is medium.

**Vaccine/Immunization Registry Reporting (data flows in all directions but excluding drug selection tracking)**

- TF members rated this recommendation as a high priority under the COVID-19 category, a medium priority under the Health Equity area, and low in the ONC Roadmap and 21st Century Cures Act priority areas.
- TF members rated the impact of this topic as specific/low.
- The policy levers are held between the CDC, state/local public health, and ONC.
- Current burden is high.

**Health Equity Standards (including social determinants of health (SDOH) data standards)**

- TF members rated this recommendation as a high priority under the COVID-19 area, a high priority under the Health Equity area, and low priority in the ONC Roadmap and 21st Century Cures Act areas.
- TF members rated the impact of this topic as general purpose/medium to higher.
  - Valerie suggested that, because this topic affects many people, it should be ranked higher on the spectrum of general/medium.
- ONC holds all/most applicable policy levers.
- Current burden is high.

**Electronic health record (EHR) system data uses (including Real-world Evidence (RWE)/Comparative Effectiveness/UK RECOVERY-type data use)**

- TF members rated this recommendation as a medium/high priority under the COVID-19 area, a medium priority under the Health Equity area, and medium in the ONC Roadmap and 21st Century Cures Act areas.
  - In response to an inquiry from Ed, Arien discussed the breadth of items covered by the Health Equity priority area/rating column, including SDOH data flows and related analytics.
- TF members rated the impact of this topic as foundational/high.
- ONC holds all/most applicable policy levers, and ONC already has a policy framework.
- Current burden is medium.
  - TF members discussed if this area would be resolved with the use of FHIR (Fast Healthcare Interoperability Resources) Bulk Data Access/Flat FHIR. They decided that it was a complex area, and the ISP TF 2021 would ask for outside/public testimony.

**Public Health (PH) Situational Awareness (including the work of the Situational Awareness for Novel Epidemic Response (SANER) Project)**

- TF members rated this recommendation as a high priority under the COVID-19 area, a low priority under the Health Equity area, and low/not applicable priority in the ONC Roadmap and 21st Century Cures Act areas.
- TF members rated the impact of this topic as specific/low.
- ONC, CDC, and states/localities hold data levers (low)
- Current burden is medium (has been changing over time).
• Syndromic Surveillance (including the existing items that have standards certification requirements and items that do not have standards certification but have been promoted by the Centers for Disease Control and Prevention (CDC) like the use of electronic case reporting (eCR)
  o TF members rated this recommendation as a high priority under the COVID-19 area, a low priority under the Health Equity area, and not applicable in the ONC Roadmap and 21st Century Cures Act areas.
  o TF members rated the impact of this topic as specific/low.
  o ONC, CDC, and states/localities hold data levers (low)
  o Current burden is low.
• Care plans and chronic disease burden management (the ability to share, prioritize, and engage with a plan of care; was the fourth priority for the previous version of the ISP TF)
  o TF members rated this recommendation as not applicable under the COVID-19 area, a medium priority under the Health Equity area, and low on the ONC Roadmap and 21st Century Cures Act areas.
    * TF members discussed whether a burden reduction case could be made for this topic, noting that it would be difficult to do.
  o TF members rated the impact of this topic as specific/low.
  o ONC holds the majority of policy levers (medium).
  o Current burden is medium/mixed.
    * David stated that care coordination is still a large burden for patients, and hospitals/providers just do not do this work (low burden for them).
    * Jack summarized feedback from the chat and noted that aligning standards would be important now that many entities are using more virtual care. Ricky agreed that improving and standardizing virtual communication between patients and providers would have a big impact right now.
• Adverse Event (AE) Reporting (includes the ability to use clinical terminology, as opposed to Food and Drug Administration (FDA) clinical trials terminology to capture and report adverse events into FDA-managed surveillance systems)
  o TF members rated this recommendation as a high priority under the COVID-19 area, not applicable under the Health Equity and 21st Century Cures Act areas, and low in the ONC Roadmap area.
    * Clem highlighted the burden this topic could pose for physicians. Arien agreed and discussed how online forms are/could be used. He added that this could fall under the real-world evidence category. TF members discussed how signal detection could be used in adverse event reporting and how causality is established.
  o TF members rated the impact of this topic as specific/low.
  o ONC and the FDA hold the majority of policy levers (medium) in a split.
    * TF members discussed asking ONC to issue a recommendation to the FDA to change its policy levers.
    * Clem suggested using RWE/lab data to support the recommendation to the FDA.
  o Current burden is low (not being done broadly at this time).
• Patient to device linking (including mobile and medical devices)
  o TF members rated this recommendation as a high priority under the COVID-19 area, not applicable under the Health Equity and 21st Century Cures Act areas, and low/medium in the ONC Roadmap area.
    * David asked ONC staff to follow up on whether there was a device and implant real-world evidence tracking requirement in the 21st Century Cures Act.
  o TF members rated the impact of this topic as specific/low.
  o ONC holds the majority of policy levers (medium).
  o Current burden is low (not being done broadly).
Contact Tracing and Digital Exposure Notifications (including contact tracing/tracking APIs embedded in smartphone operating systems by vendors)
  - TF members rated this recommendation as a high priority under the COVID-19 area, not applicable under the Health Equity, 21st Century Cures Act areas, and in the ONC Roadmap areas.
    - TF members discussed differences in the two efforts listed. The title of this topic might be updated.
    - Arien stated that this might overlap with health equity and data sharing topic areas regarding work on data flows.
  - TF members rated the impact of this topic as specific/low.
  - ONC, CDC, and states/localities hold data levers (low)
  - Current burden is high (traditional contact tracing is high/expensive, key sharing of a positive test is a high burden, lots of manual activity)
    - TF members discussed nuances of how contact tracing is being done at this time, getting information to devices, and related burdens/challenges.
    - Ricky suggested dividing this topic into traditional contact tracing and exposure notification as separate topics due to the differences in burdens. The current burden for exposure notification is low.
    - Clem discussed issues related to social distancing/space recommendations.

TOPIC: POTENTIAL EXPERT INPUT
The ISP TF 2021 will get input on its recommendations from various experts, and a list of potential/suggested experts and affiliated groups was included on slide #12 in the TF meeting slide deck. Presentations that will be given at future TF meetings will be announced.

Action Items
ISP TF 2021 members will review the proposed ISP TF 2021 frameworks for prioritization and recommendations and will use Delphi scoring to rate the topic areas by the prioritization attributes. The final composite scores will be calculated to rank the recommendations.

TF members will volunteer suggestions for additional expert presenters to the co-chairs via email.

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: Welcome to the Interoperability Standards Priorities task force. We will be getting started soon.

Leslie Lenert: Les Lenert is present

JackPo: jack is here too

Jim Jirjis: Jim Jirjis just joined

Arien Malec: thanks Jack & Jim!

Andy Truscott: I have a potential addition. Want to noodle on it more first.
Clem McDonald: i am on Clem

David McCallie: https://www.healthit.gov/isa/

JackPo: this is great, will look through and send come ts [sic]

JackPo: comment's

Andy Truscott: We will raise our hands!

Andy Truscott: (Violently)

Andy Truscott: Is this focused upon IIS->State/CDC or Provider->IIS as well?

David McCallie: andy - both?

Andy Truscott: i got kicked out the call

Andy Truscott: on adobe

Andy Truscott: need mic privs.

Andy Truscott: David: I hope both - but Arien clearly called out the former not the later

Andy Truscott: still not back in

Andy Truscott: :

Ann Phillips: 21st century cures on careplan?

JackPo: I think high for COVID 19 makes sense, the other ratings also make sense

JackPo: I wonder about the general field that's now coming around "Return to Work"

JackPo: there's a lot of companies there, and no standards

Andy Truscott: Is RTW as as field dependent upon many of what's being prioritized? e.g. Vaccination Data Flows would include Vaccination Status Query/Response.

JackPo: yea, it's somewhat of a mix around demographics, PH, soem device linking, and different defintiion of exposure tracing

JackPo: but nothing living in the EHR

JackPo: interestingly even in hospitals

Valerie Grey: health equity affects many and is also an important group

JackPo: +1

JackPo: yes, definitely

JackPo: Yes, let's call it medium. I Wouldn't say we know how to do it. But the feds and hospitals have met in the middle
JackPo: of like do spreadsheets and fax if you have to

JackPo: Care plans I would say high. Especially since industry is entering heavily into care coordination, and CMS is now heavily pushing chronic care mgmt.

JackPo: and hospital at home

JackPo: Pt + systems now coordinating

Mike Berry: We will be taking public comments soon. To make a comment please call: 1-877-407-7192 (once connected, press "*1" to speak).

Victor Lee: I have CommonWell connections and could probably get someone to join a future ISPTF meeting if desired

David McCallie: Thanks Victor. Both Arien and I have deep CW ties as well

**Resources**

ISP TF 2021 Webpage
ISP TF 2021 – March 25, 2021 Meeting Agenda
ISP TF 2021 – March 25, 2021 Meeting Slides
ISP TF 2021 – March 25, 2021 Meeting Webpage
HITAC Calendar Webpage

**Adjournment**

The co-chairs of the ISP TF 2021 thanked everyone for their work at the current meeting.

The next TF meeting will be held on Thursday, April 1, 2021 from 2 p.m. to 3:30 p.m. E.T. The 2021 ONC Annual Meeting will be held on March 29 and 30, and Michael directed participants to the online registration link located on the 2021 Annual Meeting webpage at [https://www.healthit.gov/news/events/2021-onc-annual-meeting](https://www.healthit.gov/news/events/2021-onc-annual-meeting).

The meeting was adjourned at 3:27 p.m. E.T.