Health Information Technology Advisory Committee

Interoperability Standards Priorities Task Force 2021 Virtual Meeting

Meeting Notes | April 16, 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. Presenters from OHDSI, PCORNET, and N3C presented on their recent work and topics centered around real-world evidence, comparative effectiveness, and leveraging data in electronic health record systems. A list of additional potential experts and presenters who may offer input at future meetings 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
02:05 p.m.	Introductions
02:10 p.m.	Improving the Use of EHR Data and Staging Questions
02:15 p.m.	Presentation on OHDSI and OMOP/FHIR
02:30 p.m.	Presentation on PCORNET
02:45 p.m.	Presentation on N3C
03:00 p.m.	Discussion
03:20 p.m.	Obtaining Additional Expert Input
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 2:01 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
Edward Juhn, Blue Shield of California
Victor Lee, Clinical Architecture
Ming Jack Po, Ansible Health

Ram Sriram, National Institute of Standards and Technology
Sasha TerMaat, Epic

MEMBERS NOT IN ATTENDANCE

Valerie Grey, New York eHealth Collaborative
Jim Jirjis, HCA Healthcare
Ken Kawamoto, University of Utah Health
Les Lenert, Medical University of South Carolina
Clem McDonald, National Library of Medicine
Raj Ratwani, MedStar Health
Andrew Truscott, Accenture

ONC STAFF

Michael Berry, Branch Chief, Policy Coordination, Office of Policy (ONC); Designated Federal Officer

General Themes

TOPIC: EXPERT INPUT PRESENTATIONS

The ISP TF 2021 continued to receive expert input via presentations by OHDSI, PCORNET, and N3C. TF members discussed each presentation and submitted feedback during a general discussion session following the completion of all presentations.

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. They welcomed the presenters, noting that each would be allotted 15 minutes, and explained that a general discussion session would be held following the completion of all three presentations.

David highlighted the following items:

- Results of ISP TF 2021 Priority Voting process: the Health Equity Standards topic was determined to be the TF's top priority using the voting and scoring process, while the Real World Evidence (RWE)/Comparative Effectiveness/RECOVERY Electronic Health Record (EHR) System data use topic was the second highest rated priority area.
- A set of staging questions was distributed to TF members via email before the meeting to guide discussion feedback and questions. It was included on slide #6 in the TF's presentation slide deck.

TOPIC: OHDSI AND OMOP/FHIR PRESENTATION

George Hripcsak, MD, MS, Chair and Vivian Beaumont Allen Professor of Biomedical Informatics, Columbia University and New York-Presbyterian Hospital, thanked the ISP TF 2021 for the opportunity to present, introduced himself, and highlighted the mission of Observational Health Data Sciences and Informatics (OHDSI – pronounced "Odyssey"), which was included in the presentation slides along with a graphic depiction of the OHDSI network. He presented on OHDSI's recent work on informatics, interoperability, and research, especially in relation to its common data model and Fast Healthcare Interoperability Resources (FHIR).

George explained that OHDSI seeks to generate observational data and is an Open Science effort. OHDSI's data model for querying, interpretation, and publishing was depicted in the presentation slides. George stated that OHDSI's common data model was formerly called the Observational Medical Outcomes Partnership (OMOP) and is managed by a schema, standardized vocabularies (153 across 41 domains, coming from disparate sources), and conventions. An open committee structure is used to govern it. George briefly

referred to additional background information on each, which was included in the presentation slides.

George stated that OHDSI maps the world's data to a core set using RxNorm (and RxNorm extensions for non-United States data), LOINC, and SNOMED CT (ICD-10 is converted to SNOMED). He briefly discussed their standardized conventions, the tools and process OHDSI uses for preparing data, their data quality dashboard, and the ATLAS unified web interface for their tools. ATLAS includes ontology support, cohort building, visualization, and observational analysis components. He gave an overview of some examples of their recent work, which included the OHDSI "LEGEND" Hypertension Study (including the resulting knowledge base and academic/medical publications) and COVID-19 research (patient record aggregation and 41 related studies that were generated). More information on the studies, including links to medical/academic papers and OHDSI's partnerships were expanded upon in the presentation slides. As of March 1, 2021, OHDSI and HL7 announced that they will align their standards to capture data in a clearly defined way into a single common data model. This will allow clinicians, as well as researchers, to pull data from multiple sources and compile it in the same structure, without degradation of the information. He discussed this new partnership and related projects.

George emphasized that research is not an afterthought or a "secondary use," as it drives healthcare and can save millions of lives. He suggested that, after patient care, research should become paramount, and the billing process should adjust. He stated that either data can be stored or evidence can be generated and emphasized that a tightly coupled enterprise of evidence generation and standards development is needed. He explained that someone has to pay the price for data quality, and the generator should perform as much data quality assessment as possible instead of a FHIR dump of all data to a distance-central warehouse.

George emphasized that a continued focus on U.S.-specific standards hurts the population in the long run and stated that more data is needed, as research cannot be done on just the U.S. population. He thanked the TF and provided contact information in the presentation slides.

DISCUSSION:

- David thanked George for the presentation and asked where OHDSI's data mapping occurs.
    - George responded that the data mapping is performed as close as possible to the data generator. Academic medical centers do their own mapping, and commercial data aggregators are often used in other cases. He stated that the conversion to the OMOP model is easier than the data quality work, which is more difficult and takes more time.

TOPIC: PCORNET PRESENTATION

Russ Waitman, PhD, Professor and Vice Chair, Professor and Associate Dean for Informatics, University of Missouri, and Professor and Director of Health Insights, University of Missouri-Kansas City, thanked the ISP TF 2021 for the opportunity to present, introduced himself, and gave a brief overview of his background. Russ stated that his presentation would cover 13 years of observations, PCORnet® observations, and some information from his time at the Kansas Central Clinical and Translational Science Awards (CTSA) Program. He directed ISP TF 2021 members to his presentation deck for additional information, noting that he would not cover everything in the slide deck in his presentation.

Russ described CTSA's informatics work around creating the HERON data platform and the aim of the platform. He discussed the results of HERON over the years and described how the data querying process was refined over time while referencing illustrative slides in his presentation. He explained that about 60% of requests were for identified (versus deidentified) data, which reinforced George's point that mapping close to the data generator is more useful for those who are querying their local data; this also aids in the discovery of data problems. He added that some data that clinicians query to support their work is not always codified to national standards (SNOMED, LOINC, etc.). He highlighted challenges related to reproducing the data initiatives, matching data nationally, and the pre-coordination of data.

Russ stated that PCORnet (the National Patient-Centered Clinical Research Network) was envisioned in 2013 as a response to previously encountered challenges, and it is now a vibrant network of networks with access to secure, curated data from millions of patients across the largest health systems in the U.S. It is partnered with patients and offers access to EHR data, exceptional research teams, expertise in integrating research with clinical care, and streamlined administrative processes. It can connect with patients and clinicians for observational studies and clinical trials.

Russ described some examples of how PCORnet can be used in site selection and cohort identification, descriptive analytics, data characterization and quality assessments, and exposure and outcome assessments. He described how PCORnet has partnered with clinical research networks (CRNs) and health plan research networks (HPRNs) to help users access real-world data from medical encounters from over 66 million people across the U.S. He described how PCORnet does foundational data curation, in which a baseline level of data quality is established, in a continuous –not static—learning cycle. Russ directed TF members to the presentation slides that illustrative the workflow process of taking data from the EHR, billing, and ancillary clinical system(s) and loading it into the common data model (CDM).

Russ discussed some of the highlights of the PCORnet Phase 3 renewal for 2022-2024, which was due on April 6, 2021. These included:

- A renewed call for supporting federal agencies and their research portfolios (including working with the Centers for Disease Control and Prevention (CDC) on their COVID-19 relief efforts)
- Diverse populations with complete clinical data, claims but not explicit funding of health plans
- Efficient patient engagement/recruitment
- A renewed call for Natural Language Processing (NLP) which needs text notes as substrate
- Embed Research in clinical and patient workflows: (e.g. REDCap and FHIR, https://www.hl7.org/fhir/)
- Data Security, Privacy and Trust Building
- Continued focus on data quality; go back to source to investigate quality issues
- Ability to Link Data Assets with Datavant

Russ provided an overview of feedback on PCORnet's recent work and highlighted challenges described in quotes from various stakeholders in the presentation slides. He presented his observations on the context and data, which were included on slide #19 in the presentation. He stated that they are behind schedule, given the amount of money invested since 2008. Some of his own feedback and recommendations were included on slide #20. He emphasized that current pre-coordinated standardization needs to be complemented with late binding approaches and analyses and an environment that incentivizes data flow. He stated that blocking is seen as a vendor problem when it is often a system bias.

TOPIC: N3C PRESENTATION

Chris Chute, MD, DrPH, Bloomberg Distinguished Professor, Johns Hopkins School of Public Health, and Melissa Haendel, PhD, Chief Research Informatics Officer, University of Colorado, thanked the ISP TF 2021 for the opportunity to present on behalf of the National Covid Cohort Collaborative (N3C) and gave a brief overview N3C's timeline, which began in April 2020, and a dashboard, which included information on the increasing number of data transfer agreements (DTAs), data use agreements (DUAs), analytic approaches, and participants.

Chris explained that N3C has 29 domain teams that contribute analysis and stated that their goal is not to create a data repository but rather, it is to identify the evidence. He described the N3C data ingestion and harmonization pipeline, which spans the manual curation of mapping resources to industrial scale production transformation. He stated that while many clinical data research networks are federated, N3C is centralized. Centralized datasets have some advantages where data quality (DQ) assessment is concerned. He highlighted a presentation slide that depicted the transformations in normalization pipelines that are managed in their platform and explained how automated data health checks are used when the CDM mapping pipeline

is deployed for each new site. He described how unit harmonization has been used to increase usable data in cases when the unit of measure was missing and was able to be inferred through N3C's processes.

Melissa discussed lessons learned from the creation of N3C and explained how N3C's work could be leveraged at the individual site and aggregate levels. She stated that N3C is a unique resource because it has aggregated and harmonized data from many sites that has already been standardized according to common data models. She discussed mapping, which comes from source terminologies, "mappers" (groups like OHDSI, UMLS, and NIH's National Cancer Institute), coded data and uncoded/locally coded data, and code sets to unify data. She stated that mapping can be problematic for computational use and is lossy, and this needs to be addressed. There is not enough information around curation rules or the provenance of data. She highlighted potentially problematic areas along the N3C pipeline of evidence generation. She emphasized the importance of local codeset mapping and helping sites with tools to support mapping their local codes to CDM terminology. Other challenges included field/value set mappings to OMOP, terminology mappings to OMOP concepts, and codeset creation across institutions. They have been working with OHDSI on some of these efforts.

Melissa discussed N3C's main takeaways, in terms of needs, which included:

- Syntactic (FHIR to OMOP) and semantic (common vocabulary/codeset mapping provenance and management) are needed to advance interoperability
- Approach data harmonization from an end-to-end data life cycle perspective
- Leverage the USCDI, but also build for interoperable semantic modeling and extensions – balance is needed

The co-chairs thanked all of the presenters and opened up the meeting for a general discussion section. TF members were encouraged to share feedback on any/all of the three presentations.

DISCUSSION:

- David stated that there appear to be several starting common data models (OMOP, PCORnet's model, etc.) and asked if an effort should be made to get to one staging model/area. Is diversity a strength for the system?
    - Chris discussed the plurality of common data models and issues/loss points/extra costs that occur during the "transform" part of the pipeline. He stated that maintaining multiple common data models is inefficient for the research community, and there would be a benefit to picking a single analytic research data model that is well-support and well-adopted.
    - Russ discussed how OHDSI/OMOP's model is geared toward pharma, while PCORnet was built in connection to the FDA (as they had a Coordinating Center Grant from the FDA). While OMOP and PCORnet have been leveraged together, he suggested that they could have been aligned more closely during 2013 or 2014. This is a small problem relative to other issues faced by the U.S.
    - George agreed with Russ that OMOP and PCORnet are related like cousins; they differ on the data schema, which can be translated. I2B2 differs, but it had a different purpose. Variety is due to different purposes, thought getting to fewer models could be a goal.
    - Arien reiterated the point that the vocabularies, terminology, and data representation are the hardest parts, not the actual data models. Then, he asked George to comment on the usefulness of the OMOP model for observational and prospective research (enrolling patients, fully randomized and controlled trials, etc.)
        - George stated that OMOP users use it for these purposes, but PCORnet has focused more on this area. OHDSI/OMOP has focused on observational (retrospective and/or prospective) studies, not reaching out to the patient, which PCORnet has done. This is not a modeling issue but an organizational orientation issue.
        - Melissa stated that there are large gaps in the context of the modeling and the terminological content and ways in which data are collected/studied. Good coverage does not exist in CDMs for observational data, so the community should think about how to make

everything fit together more gracefully. Just putting everything into FHIR will not solve the problem if the models and terminologies are not there, too.
        - Arien and Melissa discussed examples of specialized models that collect data that are unlikely to be representable in the CDM. Changes in this space should include extending the CDM, adding terminologies, and ensuring updates are extended systematically and not as one-off updates.
        - Russ stated discussed how PCORnet has approached getting clinical researchers to use data standards and data models instead of the process they previously used. He discussed areas across the broader data ecosystem that are not standardized but that are popular and being leveraged now.
        - Arien asked about areas in which there are U.S.-only standards that differ from the rest of the world.
        - George stated that these include the standards for diagnosis/conditions and procedures and the use of ICD-10-CM. The gap for addressing RxNorm is a different and easier issue.
- Jack asked the presenters to provide feedback on or suggestions for ways in which ONC could accelerate or impact (through mandates) the efforts of OMOP, PCORnet, and N3C.
    - Russ asked ONC to continue their work and suggested working toward the standardization of data instead of waiting for harmonization on the precoordinated outbound FHIR interface. He suggested focusing on getting health IT in community hospitals, medical centers in underserved/rural communities, and smaller family practice clinics to turn on a FHIR interface, which could be complemented by federal processes to incentivize the flow of data. Also, he suggested that they might have underrepresented nonbillable providers, and an emphasis should be added on how the full care team (beyond the main provider) impacts a patient's care.
    - George suggested focusing on getting unified, rational procedural vocabulary standards.
- David asked how the processes described by the presenters could be scaled up to engage more sites and how it could be scaled out to involve smaller sites (ambulatory, LTPAC, etc.).
    - Chris responded that a previous committee compromised by suggesting that standardization occurs as data goes out, not where it is generated or is stored in the EHR. Interoperability is now baked in at the API level, which has created the mapping problems Melissa discussed. ONC should discuss this question again (Where does standardization occur?) and determine if a new policy (national or international) should be put together.
    - Arien summarized Chris's points:
        - Standard data should be collected at the source.
        - Analyze machines emitting LOINC codes.
        - Clinical laboratory information systems should normalize LOINC instead of using their own proprietary terminology.
        - Do not intentionally adopt a different set of procedural codes (in the U.S.) than the rest of the world.
        - The more work done to capture source information cleanly and clearly, that is normalized, the less work there will be downstream in renormalizing it for analytic purposes.
    - Russ stated that the problem is getting the data out. If ONC wants to focus on scalability, there should be incentive programs for big hospitals to share information. Billing processes should be made to align with clinical processes. For example, lab results would be passed with a claim.
- David asked if a template could be created for a broad, top-down implementation guide for aggregating evidence generating data. He suggested it could be useful in the event of another pandemic.
    - George stated that the standards community responded quite quickly and efficiently to the COVID-19 pandemic. Databases were created, and data was directed there quickly. Lessons learned would be applied to a future situation. A whitepaper could be created to discuss these experiences.
    - Russ stated that the data needed for COVID-19 relief efforts were available and helpful, but more work could be done on getting codes out and codifying data that was not coded in the beginning

(e.g., for lab tests). He discussed the work that needs to be done on representing transitions between ventilation and intensive care.
    - Melissa explained that a paper is being written about this topic now and stated that the work that has been done has advanced the overall quality of data for everyone. Measuring the change in this quality would be useful. She stated that tools that use codes/codesets to make the process go faster are important.
    - David noted that he would like to get more information about the tools Melissa mentioned later.
- Arien asked about the presenters' perspectives on representational issues between the FDA, OMOP, and PCORnet and how the work of sponsored/formally investigational clinical trials comes together with the observational/RWE perspective. Could better mapping be done?
    - Russ explained that it depends on the sponsor of the trial and how data collection is done.
    - George suggested that it is a compliance issue with the FDA, not applicability of use issue.
    - Chris discussed active work that is being done to map Clinical Data Interchange Standards Consortium (CDISC) projects and structures in OMOP and highlighted some questions the project has raised. CDISC predates all common data models and FHIR, so they should explore its future.

TOPIC: ADDITIONAL EXPERT INPUT

The ISP TF 2021 will continue to gather input on its recommendations from a variety of experts and a list of scheduled and potential experts/affiliated groups which could present to the TF, including:

- CDC Modernization: Paula Braun from the CDC will present at the TF's April 29 meeting
- Clinical and Administrative data and standards prioritization: Intersection of Clinical and Administrative Data Task Force (ICAD TF) might present at the April 29 meeting (TBA)
- Data sharing across federal and non-federal boundaries: someone from CommonWell, DirectTrust, and/or eHealthExchange?

Action Items

None

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

Jack Po: this hold music is intense

Wanda Govan-Jenkins: LOL @the music is intense...

Jack Po: also, can we as a tech advisory group suggest that a priority is to stop using adobe connect =P

Wanda Govan-Jenkins: My daughter just ask "Mommy what are you listening to"...lol

Jack Po: loo

Jack Po: loo

Jack Po: ;)

Victor Lee: Meeting conflict, apologies for joining late

Jack Po: thanks!!

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

Resources

ISP TF 2021 Webpage
ISP TF 2021 – April 16, 2021 Meeting Agenda
ISP TF 2021 – April 16, 2021 Meeting Slides
ISP TF 2021 – April 16, 2021 Meeting Webpage
HITAC Calendar Webpage

Adjournment

David and Arien thanked everyone for their participation.

The next ISP TF 2021 meeting will be held on Thursday, April 29, 2021, from 2 p.m. to 3:30 p.m. E.T.

The meeting was adjourned at 3:29 p.m. E.T.