Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

TASK FORCE WORKING DRAFT

Interoperability Standards Priority (ISP) Task Force 2021 Report to the Health Information Technology Advisory Committee

HIGH LEVEL RECOMMENDATIONS (DRAFT)

MAY 14, 2021

Table of Contents

Background

In the 21st Century Cures Act there was a mandate for the National Coordinator to convene the HIT Advisory Committee to identify priority uses of health information technology, identify existing standards and implementation specifications that support the use and exchange of electronic health information needed to meet those identified priorities, publish a report summarizing the findings of the analysis and make appropriate recommendations.

On March 11, 2021, the ISP Task Force was restarted to carry out the charge above over the next three months, June 2021. Perhaps more is needed

ONC CHARGES TO THE ISP TASK FORCE

Overarching Charge

The ISP Task Force for 2021 is charged 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.

Detailed Charge

The Task Force's specific charges were to provide the following:

1. **(March 2021)** ISP Task Force reviews ISA and identifies opportunities to update "Interoperability Needs" within the ISA sections to address HITAC priority uses of health IT
2. **(April/May 2021)** ISP Task Force develops draft recommendations to add/modify any "Interoperability Needs" for considerations in updates to the ISA, including related standards implementation specifications. ISP Task Force considers public feedback in developing recommendations.
3. **(June 2021)** ISP Task Force submits final recommendations to the HITAC for approval. HITAC reviews, approves, and submits recommendations to the National Coordinator.

ADDITIONAL BACKGROUND INFORMATION

The ISP Task Force (TF) assembled various subject matter experts via multiple hearings and testimonies. Those topics included health equity, EHR 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 and lastly, and Public Health Situational Awareness.

Situational Awareness – April 1, 2021

"The SANER Framework," given by Keith Boone, Project Lead and Lauren Knieser, Director, Emergency Preparedness and Response, both from Audacious Inquiry

Health Equity – April 8, 2021

"Project GRAVITY," given by Robert Dieterle (Technical Director, Project Gravity)

EHR Data Use for the "learning healthcare system", comparative effectiveness, etc. – April 16, 2021

"Observational Health Data Sciences and Informatics, Interoperability, and Research," given by George Hripcsak, MD, MS, Columbia University Irving Medical Center

"PCORnet® Observations: After 13 years, has "Meaningful Use" Generated Data that is Meaningful for Research?" given by Russ Waitman, PhD, Univ Missouri School of Medicine

"The National Covid Cohort Collaborative," given by Chris Chute, MD, DrPH, Johns Hopkins School of Public Health, and Melissa Haendel, PhD, University of Colorado

Burden Reduction and associated Clinical/Administrative Data and Standards Harmonization – April 29, 2021

"ICAD Task Force Findings & Recommendations," given by Alix Goss, VP, Imprado Consulting, Member NCVHS

Note: Links to all presentation materials are available via the ISP Task Force calendar: https://www.healthit.gov/hitac-events/6871/2021

Recommendations

INTRODUCTION

The Task Force prioritized interoperability needs based on ONC priority areas and assessed the standards landscape via multiple hearings for:

- Health Equity
- EHR 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 Task Force additionally heard testimony on, and provided recommendations for:

- Public Health Situational Awareness

The Task Force deferred recommendations for Public Health to the Public Health Data Systems Task Force.

The Task Force **recommends** that a future incarnation of the ISP Task Force explores standards and implementation guidance for:

- Care Plans/Chronic Dx Management
- Data Sharing Between Federal & Commercial Entities
- Portal Data Aggregation Across Multiple Portals

HIGH LEVEL RECOMMENDATIONS

The Task Force makes high level recommendations in the following areas:

1. In order to support multiple areas that require configured extensions of EHRs we **recommend** that ONC advance standards and implementation guidance in the following foundational areas using FHIR that address multiple cross-cutting concerns:
    a. HL7 FHIR standards to address workflow hooks, including FHIR 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.

2. In order to improve interoperability and innovation, we **recommend** that ONC work with other Federal stakeholders to move the nation towards open and/or freely available terminology standards that are designed to address multiple needs (clinical care, research, administrative needs). In areas where proprietary code sets are currently required, we **recommend** that ONC work with NLM and other Federal stakeholders to either license codes nationally or transition the nation to more open terminology with national licensing.
3. 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.
4. 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.
5. 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.
6. We 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 USCDI and FHIR to the common research model as well as to the implied administrative data model.
7. In order to support use of social determinants of health to improve health, health care, and public health, we **recommend** that ONC implement the DaVinci Gravity standards.
8. 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.
9. 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 ICAD Task Force, and that ONC advance next generation administrative standards via the ISA.

LIST OF SPECIFIC RECOMMENDATIONS

1. Foundational Standards - FHIR

There are several foundational FHIR-based standards and implementation guides that provide general support for specific usages, including the priority areas identified by the Task Force, when configured to do so by clinical institutions:

- Triggers/hooks and substrate for Clinical Decision Support, 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 asynchronous 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*

Recommendations

We **recommend** that ONC ensure that these standards and implementation guides are tracked via the ISA, and invest in development, testing and production usage of these standards and related IGs for broader adoption and incorporation into certification criteria

2. Foundational Standards – Common Data Models

We found that, while the deployed EHR base in the US was used for retrospective research supporting therapies and treatment planning for Covid-19, research needs required substantial remapping and normalization of captured clinical data for research. Much of this work required potentially lossy normalization of terminology and extraction of clinical events from the often administratively driven clinical data capture. Because there are multiple research data models in place, researchers often performed sometimes lossy remapping between clinical models. The task force found that work was being performed to align on a single research model. The task force additionally found that Bulk FHIR, while potentially useful for research extracts, required remapping from the person-centered implied graphs of FHIR to the more relational-style research models.

Recommendations

We **recommend** that ONC should continue to map USCDI to HL7 FHIR and older foundational standards such as HL7 v2 and CDA, and, in order to maximize the use of captured clinical data for research, social determinants/health equity, and administrative burden reduction, we **recommend** that ONC build a clear and rapid roadmap to expand

USCDI which should incorporate research and administrative needs. (For clarity, we do **not** believe that ONC should require that EHR data capture be primarily driven by research needs; we rather believe that data captured for clinical care should be maximally useful for research).

We **recommend** that ONC should work with industry stakeholders, and FDA, CDC, CMS, 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.

For our recommendations on reducing the burden of lossy vocabulary transformations, see the next section. See also our specific recommendations for EHR Data Use for Research/RWE and Administrative Burden Reduction

3. Foundational Standards – Terminology

The task force found that the ISA and USCDI contain well founded terminology systems for interoperability. However, we found that 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. In addition, the implied mandate to use proprietary coding systems that are not freely available for implementors or are primarily designed for administrative, rather than clinical needs, inhibits maximal appropriate use of data.

Recommendations

We **recommend** that ONC work with Federal stakeholders to establish terminology policies favoring open or nationally licensed terminologies that are designed to serve multiple needs (clinical, administrative, research, public health); where there are divergences from this policy ONC, NLM and other stakeholders should either establish national licensing, or establish a roadmap to transition the nation to more open terminologies.

We **recommend** that ONC use direct levers to continue to standardize laboratory results terminology, while working with related agencies of HHS (primarily FDA [analyte machines] and CMS [CLIA]) to correctly originate codes at the source (analyte where possible, LIMS where not) for laboratory and similar data to LOINC (see, in addition, the transmittal letter of approved recommendations from the ISP Task Force's initial deliberations in 2019.

We **recommend** that ONC, 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, administrative, and public health data use. This could be done by licensing existing coding systems for national use, and cross-mapping to international standards, or could be done by building a roadmap to transition to more open coding systems.

We **recommend** that ONC, In the transition to ICD11, work with CMS and NLM to ensure that SNOMED-CT and ICD11 harmonization will allow single source use of captured clinical data for clinical care, research, and administrative workflows.

We **recommend** that ONC work with FDA and CMS to continue to harmonize NDC to RxNorm, treating RxNorm as the source terminology set, and to harmonize administrative and electronic prescribing standards to use RxNorm as the single source of clinical data for clinical care, research and administrative workflows.

4. Health Equity

The task force found that [findings on Gravity.]

The Task Force finds that USCDI terminology for Sex, Race/Ethnicity and Address, with proposed additions for gender identity and sexual preferences, are sufficient to assess demographics to identify impact of social disparities but that data does not currently flow transparently through interoperability specifications and deployed use.

Recommendations

The ISP Task Force endorses the USCDI Task Force recommendations that ONC should incorporate Gravity Project Standards into USCDI.

The Task Force recommends that ONC ensure associated interoperability standards and EHR certification requirements/deployed use of interoperability requirements prioritize the capture **and** exchange of demographic and contact data for multiple purposes, including public health.

The Task Force **recommends** that ONC continue the work to harmonize patient 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.)

5. EHR data use for research, Real World Evidence, RECOVERY-like trials, comparative effectiveness List of Specific recommendations

While the US 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.

Recommendations

In the interests of clarity, in these recommendations, we seek to reduce the effort needed to reuse clinical data for research needs. Our intent is not to prioritize research needs over clinical care as a primary task for deployed EHRs and clinical staff or suggest that research data capture should be added to the existing load of clinical and administrative data capture.

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. (For clarity, while, in the immortal words of Dr. Doug Fridsma, M.D., PhD, “in informatics, whatever you can do, I can do meta”, we are primarily calling for supporting the community in reducing duplicative deployed models rather than creating meta-models to cross map between existing models).

We **recommend** that ONC work with FDA, CDC, CMS, Federal health care providers (VA, DoD MHS, IHS), NIH/NCI, and other Federal actors to harmonize to the common research data model.

The Task Force **recommends** that ONC create sections in the ISA and works with stakeholders to develop, test and promulgate standards and IGs for representation and implementation of pragmatic research studies within EHRs. Priority areas of opportunity include

- Consent (see FHIR recommendations)
- Prospective randomization, enrollment and de-enrollment
- Separation of research and clinical data
- Terminology for pre-approval new chemical entities, biologics & devices
- ONC should work with stakeholders to assess other EHR gaps relative to research.

See also our parallel foundational recommendations for content, model and vocabulary standards.

6. Harmonization of Clinical and Administrative Data for Burden Reduction

The task force found [findings]

Recommendations

The ISA Task Force endorses the ICAD Task Force recommendations as expressed in the HITAC transmittal to the National Coordinator.

We **recommend** that ONC add sections to the ISA to track relevant "interoperability priorities" and track items being addressed by the extant Da Vinci, FAST-FHIR, X12, NCPDP as well as other HL7 FHIR Accelerator projects.

We **recommend** that ONC 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

7. Situational Awareness

The Task Force heard from the leads on the SANER project, which the task force found is an impressive project addressing urgent needs for the nation.

Recommendations

We **recommend** that ONC 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 standards towards broader adoption.

We **recommend** that ONC work with stakeholders at HHS to create aligned policy and funding mechanisms to harmonize adoption of a combined situational awareness standard

FUTURE CONSIDERATIONS

A number of additional areas of potential interoperability standards priority were identified by the Task Force members,but were unable to be fully addressed in the limited time available.

We feel that future work is warranted in the following areas:

- Care Plans/Chronic Dx Management
- Data Sharing Between Federal & Commercial Entities
- Portal Data Aggregation Across Multiple Portals
- Occupation and Location of Work

Appendix A

Task Force Roster

Name	Organization
Arien Malec (Co-Chair)	Sutter Health
David McCallie (Co-Chair)	Engaging Patient Strategy
Ricky Bloomfield	Apple
Cynthia Fisher	PatientRightsAdvocate.org
Valerie Grey	New York eHealth Collaborative
Jim Jirjis	HCA Healthcare
Edward Juhn	Blue Shield of California
Ken Kawamoto	University of Utah Health
Victor Lee	Clinical Architecture
Leslie Lenert	Medical University of South Carolina
Ming Jack Po	Ansible Health
Raj Ratwani	MedStar Health
Ram Sriram	Baptist Health
Mark Savage	National Institute of Standards and Technology
Sasha TerMaat	Epic
Andrew Truscott	Accenture