



ISP Task Force 2021 Recommendations

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June 15, 2021

Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology



Task Force Recommendations and Report

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Task Force Charge

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:

- **(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
- **(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.
- **(June 2021)** ISP Task Force submits final recommendations to the HITAC for approval. HITAC reviews, approves, and submits recommendations to the National Coordinator.

Task Force Roster

Name	Organization
Arien Malec (Co-Chair)	Change Healthcare
David McCallie (Co-Chair)	Individual (retired, Cerner)
Ricky Bloomfield	Apple
Cynthia Fisher	PatientRightsAdvocate.org
Valerie Grey	New York eHealth Collaborative
Jim Jirjis	HCA Healthcare
Edward Juhn	Inland Empire Health Plan
Ken Kawamoto	University of Utah Health
Victor Lee	Clinical Architecture
Leslie Lenert	Medical University of South Carolina
Clem McDonald	National Library of Medicine
Ming Jack Po	Ansible Health
Raj Ratwani	MedStar Health
Ram Sriram	National Institute of Standards and Technology
Sasha TerMaat	Epic
Andrew Truscott	Accenture



Background on Recommendations Process

The Task Force conducted a Delphi Method process to prioritize interoperability needs based on ONC priority areas and Task Force member input.

The Task Force prioritized and assessed the standards landscape via multiple hearings for:

- Health Equity
- EHR Data Use for the “Learning Health System” based on COVID-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



Recommendations Discussion



ISP-TF-2021_Recommendation 01 - Foundational Standards - FHIR

Foundational Standards - FHIR

1a. ONC advance standards and implementation guidance in the following foundational areas using FHIR, for broader maturity, production, adoption, and eventual incorporation into certification criteria:

FHIR-based Standards

- HL7 FHIR standards to address workflow hooks, including FHIR CDS Hooks and FHIR Subscription
- HL7 FHIR standards to allow configurable flexible data collection via FHIR Questionnaire
- HL7 FHIR standards to allow collection of consents, authorizations, and directives via FHIR Consent.

******The Task Force notes that these standards are at various levels of maturity, with CDS Hooks, for at least some trigger types) being the most advanced.******

ISP-TF-2021_Recommendation 02 - Foundational Standards – Common Data Models

Foundational Standards – Common Data Model

2a-1. ONC to **map** USCDI to HL7 FHIR and older foundational standards such as **HL7 v2 and CDA**

2a-2. ONC to **build a clear and rapid roadmap to expand USCDI** which should incorporate research and administrative needs.

2b. ONC to **clarify that expanded USCDI data definitions apply to Bulk FHIR**. The Task Force believes that expanding the standardized export of codified clinical and research data via **Bulk FHIR is preferable to having researchers rely on non-standardized EHR “data dumps.”**

2c. ONC to work with industry stakeholders, and FDA, CDC, CMS, NIH and other relevant government agencies to **map USCDI to broadly disseminated research data models as well as HL7 FHIR, and other concrete interoperable representations.**



ISP-TF-2021_Recommendation 03 - Foundational Standards – Terminology

Foundational Standards – Terminology

3a. **ONC to work with Federal stakeholders to establish policy that moves 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 (though national licensing where appropriate)
- Designed to address multiple needs (e.g., clinical care, research, public health, and administrative needs).
- International or cross-mapped to international standards to allow for multi-regional pooled research

3b. **ONC to work with key Federal stakeholders (such as NLM, CMS, FDA, NIH, etc.) to transition the nation towards terminology meeting the policy through means including, but limited to, licensing, working with terminology curators to align development with the policy, or transitioning to alternate terminology standards.**

3c. **ONC to use direct levers to continue to standardize laboratory results terminology, while working with related agencies of HHS (FDA, CMS) to correctly code laboratory data to LOINC and UCUM (or other relevant terminology such as SNOMED-CT) as close to the source of the data as possible.**



ISP-TF-2021_Recommendation 03 - Foundational Standards – Terminology (continued)

Foundational Standards – Terminology

3d. ONC, directly and through coordination with CMS, **harmonize procedural coding standards to standards meeting the policy goals.**

3e. ONC, in the transition to ICD11, **work with CMS and NLM to encourage SNOMED-CT and ICD11 harmonization to allow single source use of captured clinical data for clinical care, research, and administrative workflows.**

3f. 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, replacing NDC for such purposes.**

ISP-TF-2021_Recommendation 04 – Health Equity

Health Equity

4a: ONC should **incorporate HL7 Gravity Project nomenclature and value set standards into USCDI.**

4b: ONC to ensure that the **ISA track the interoperability priorities identified by the Gravity Project**, including the **capture of SDOH inside regular clinical workflows** via standards such as FHIR Questionnaires, and the **capture of individual consent** (potentially using FHIR Consent) to authorize such sharing.

4c: ONC should **implement a 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.**

4d: ONC continues 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.)



ISP-TF-2021_Recommendation 05 – EHR data use for research, Real World Evidence, RECOVERY-like trials, comparative effectiveness

EHR data use for research, Real World Evidence, RECOVERY-like trials comparative effectiveness

5a. **ONC support the *catalogue* of common research data models in the ISA and support existing work by stakeholders** to evaluate, develop and harmonize to a single 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 achieving a common deployed model rather than creating meta-models to cross map between existing models).

5b. **ONC to work with FDA, CDC, CMS, Federal health care providers (VA, DoD MHS, IHS), NIH/NCI, and other Federal users of research models to harmonize to the common research data model.**

5c. **ONC create sections in the ISA and work 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 to document not yet approved drugs, biologics & devices given (likely blinded) during a clinical trial
- ONC should work with stakeholders to assess other EHR opportunities relative to research



ISP-TF-2021_Recommendation 06 – Harmonization of Clinical and Administrative Data for Burden Reduction

Harmonization of Clinical and Administrative Data for Burden Reduction

6a. ONC should **add sections to the ISA to track relevant “interoperability priorities”** related to the **harmonization of clinical and administrative data**, and **track items** being addressed by the **extant Da Vinci, FAST-FHIR, X12, NCPDP** as well as **other HL7 FHIR Accelerator projects**.

6b. ONC to **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.



ISP-TF-2021_Recommendation 07 – Situational Awareness

Situational Awareness

7a: **ONC to list Situational Awareness interoperability priorities in the ISA and should catalog SANER as well as related standards and IGs; ONC should work with stakeholders on pilots and early implementation, evaluate and mature standards towards broader adoption.**

7b: **ONC to work with stakeholders at HHS to create aligned policy and funding mechanisms to harmonize adoption of a combined situational awareness standard that maximizes readiness and minimizes state-by-state divergence**

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
- Data Exchange Formats for Price Transparency



Questions?