ISP Task Force Update to HITAC

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Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Task Force Roster

Name	Organization
Arien Malec (Co-Chair)	**Change Healthcare**
David McCallie (Co-Chair)	**Individual**
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

Name	Organization
Victor Lee	Clinical Architecture
Leslie Lenert	Medical University of South Carolina
Ming Jack Po	Ansible Health
Raj Ratwani	MedStar Health
Ram Sriram	National Institute of Standards and Technology
Sasha TerMaat	Epic
Andrew Truscott	Accenture

HITAC ISP Task Force Timeline 2021

	February	March	April	May	June
HITAC	ONC charges HITAC to convene ISP Task Force	HITAC reviews ISP Task Force progress		HITAC reviews and approves recommendations	
ISP Task Force	ISP Task Force launches and begins meetings	ISP Task Force reviews ISA and identifies opportunities to update the ISA "Interoperability Needs" within the ISA sections to address HITAC priority uses of health IT	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.		ISP Task Force submits final recommendations to the HITAC for approval

Task Force Work Timeline

- Today: Present Draft High Level Recommendations for HITAC Input
- May 14th, 20th, 27th, June 3rd : Prepare, Discuss & Finalize Detailed Recommendations
- June 9th: Present Final Recommendations to HITAC; HITAC Vote

Overview

- 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
- We also heard testimony on Public Health Situational Awareness
- We deferred recommendations for Public Health to the Public Health Data Systems Task Force
- Future work is warranted on
  - Care Plans/Chronic Dx Management
  - Data Sharing Federal & Commercial Entities

Draft High Level Recommendations

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
  - 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 offline workflows via ***FHIR Subscription***
  - Standard for collecting information not routinely collected in the EHR such as additional data for 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***

- **ONC should** invest in development, testing and production usage of these standards and related IGs for broader adoption and incorporation into certification criteria

Foundational Standards – Common Data Models

- The USCDI forms a foundational data set for interoperability for the nation, and **ONC should** continue to map USCDI to HL7 FHIR and older foundational standards such as HL7 v2 and CDA

- In order to provide a common foundation for research, social determinants/health equity, and administrative burden reduction, **ONC should** build a clear and rapid roadmap to expand USCDI which **should** incorporate research and administrative needs

- **ONC should** work with industry stakeholders, and FDA, CDC, 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.

- See associated specific recommendations for EHR Data Use for Research/RWE and Administrative Burden Reduction

Foundational Standards – Terminology (1)

- The ISA and USCDI contain well founded terminology systems for interoperability. However, 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.

- **ONC should** use direct levers to continue to standardize terminology, while working with related agencies of HHS (primarily FDA [analyte machines] and CMS [CLIA]) to correctly originate codes at the source for laboratory and similar data to LOINC.

- **ONC should** (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 AND administrative data use.

Foundational Standards – Terminology (2)

- In the transition to ICD11, **ONC should** 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.

- **ONC should** 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.

Health Equity

- The ISP Task Force endorses the USCDI Task Force recommendations that **ONC should** incorporate Gravity Project Standards into USCDI.
- Existing 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.
- **ONC should** ensure associated interoperability standards and EHR certification requirements prioritize the capture and exchange of this data for multiple purposes.
- **ONC should** 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.)

EHR data use for research, Real World Evidence, RECOVERY-like trials, comparative effectiveness (1)

- 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.

- **ONC should** *catalogue* 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 foundational research model mapped to the USCDI, and cross-mapped to FHIR.

EHR data use for research, Real World Evidence, RECOVERY-like trials, comparative effectiveness (2)

- **ONC should** *create sections in the ISA and should work with stakeholders to develop, test and promulgate standards and IGs for representation and implementation of pragmatic research studies within EHRs. Priority areas include*
  - *Consent (see FHIR recommendations)*
  - *Prospective randomization, enrollment and de-enrollment*
  - *Separation of research and clinical data*
  - *Terminology for pre-approval NDEs, biologics & devices*
  - *ONC should work with stakeholders to assess other EHR gaps relative to research.*

- **ONC should** work with FDA, CDC, Federal health care providers (VA, DoD MHS, IHS) and other Federal actors to harmonize to the common research data model.

- **ONC should**, as noted in the foundational standards section, avoid use of proprietary standards, and use appropriate levers to source-normalize data for maximal re-use.

Harmonization of Clinical and Administrative Data for Burden Reduction

- The ISP Task Force endorses the ICAD Task Force recommendations.
- **ONC should** add sections to the ISA to track relevant “interoperability priorities” and track items for the extant Da Vinci, FAST-FHIR, X12, NCPDP and other administrative standards and IGs.
- **ONC should** 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.

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.

- **ONC should** 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.

- **ONC should** work with stakeholders at HHS to create aligned policy and funding mechanisms to harmonize adoption of a combined situational awareness standard.

Discussion/Questions