Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

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

JULY 14, 2021

Table of Contents

Background

In the 21st Century Cures Act there is a mandate for the National Coordinator to convene the Health Information Technology Advisory Committee (HITAC) 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, delivering portions of the final report to the HITAC on June 9, 2021.

At the HITAC's request the ISP Task Force performed an additional listening session on vocabulary standards and revised recommendations related to vocabulary standards. This report serves as addendum to the previously accepted recommendations.

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.

External testimony included the following presentations:

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, Former member of NCVHS

Vocabulary Standards – June 17, 2021

"AMA Presentation on International Standards & CPT," given by Peter Hollmann, MD, Chief Medical Officer at Brown Medicine

"NCVHS Recommendations Presentation," given by Rich Landen, MPH, MBA, NCVHS

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

Executive Summary

INTRODUCTION

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 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 standards and implementation guidance to the Public Health Data Systems Task Force.

On request by the HITAC, the Task Force heard additional testimony on vocabulary standards and provides these revised recommendations for Recommendation 03.

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

- 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

HIGH LEVEL RECOMMENDATIONS

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

~~1.~~ **Recommendation 03** - In order to improve interoperability and innovation as well as maximize the deployed EHR base for pragmatic research, we **recommend** that ONC work with other Federal stakeholders to move the nation towards terminology standards that are developed in accordance with OMB Circular A-119[1] (on Voluntary Consensus Standards) ~~[add footnote]~~ and with the 2019 NCVHS Vocabulary Recommendations~~2019 recommendations by NCVHS~~ [2]~~[add footnote]~~, have licenses that allow for ~~open~~ free or low cost use by providers, researchers, developers, patients and other stakeholders ~~(through national licensing where appropriate)~~, and ~~and~~ are designed to address multiple needs (clinical care, research, public health, administrative needs~~) and otherwise meet the 2019 recommendation by NCVHS~~.) In areas where code sets that do not conform to this policy are currently required by Federal actors, we **recommend** that ONC work with key Federal stakeholders ~~(such as NLM, CMS, FDA, NIH, etc.)~~ and terminology curators to ~~transition the nation towards terminology meeting the policy through means including, but not limited to, licensing, working with terminology curators to align development with the policy, or transitioning terminology standards~~align national terminology with this policy.

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[1] https://www.whitehouse.gov/wp-content/uploads/2020/07/revised_circular_a-119_as_of_1_22.pdf
[2] https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Criteria-and-Guidelines-for-Health-T-V-Standards.pdf

Recommendations

LIST OF SPECIFIC RECOMMENDATIONS

ISP-TF-2021_Recommendation 03 - 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 (normalizing data as close to source creation as possible) 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 coding systems that were not designed by voluntary consensus standards processes, are not open or broadly licensed to be freely available for all stakeholders or are primarily designed for administrative, rather than clinical needs, inhibits maximal appropriate use of data. The Task Force recognizes that professional maintenance of vocabulary standards requires work that needs to be funded; in parallel with the recommendations of NCVHS we note that broader interoperability calls an approach to sustainability for terminology curation while alsowhile also maximizesmaximizing the interoperability, patient engagement, and innovation that depends on barrier-free access to the nation's health data.

We reference in our recommendations the 2019 NCVHS Vocabulary Recommendations to the Secretary of Health and Human Services[3].

Recommendations

a. We **recommend** that ONC work with Federal stakeholders and terminology curators to establish policy that moves the nation towards terminology standards that are:
    i. Developed in accordance with OMB Circular A-119 (on Voluntary Consensus Standards) and the 2019 NCVHS Vocabulary Recommendations.

[3] https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Criteria-and-Guidelines-for-Health-T-V-Standards.pdf

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ii. Have licenses that allow for free or low cost ~~open free or low cost~~ use (using the language of the 2019 NCVHS Vocabulary Recommendations) by providers, researchers, developers, patients and other stakeholders. ~~(though national licensing or funding where appropriate)~~
iii. Are designed to address multiple needs (e.g., clinical care, research, public health, and administrative needs).
iv. Are international or cross-mapped to international standards (where available) to allow for multi-regional pooled research.

b. In areas where code sets that do not conform to this policy are currently required by Federal actors, we **recommend** that ONC work with key Federal stakeholders (such as NLM, CMS, FDA, NIH, etc.) and terminology ~~stakeholders~~ curators to transition the nation towards terminology meeting the policy through means including, but not limited to, licensing terminologies, funding terminology curators, working with terminology curators to align development with the policy, or managing the transition~~ing~~ to alternate terminology standards, taking reasonable efforts to minimize workflow disruption during ~~the~~any transition.~~.~~

c. 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]) and terminology curators to correctly code as close to source (e.g., analyte machine or LIMS) as possible the identity of laboratory tests/measures (the "question"), to LOINC; for tests whose value (the "answer"), is a quantity, code their units of measure (e.g. mg/dL) to UCUM; and for tests whose value, (the "answer"), is reported as a named code (e.g. "not detected"), code the value to SNOMED-CT; see, in addition, the transmittal letter of approved recommendations from the ISP Task Force's initial deliberations in 2019[4]~~:~~ ~~https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf)~~.

[4] https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf

d. We **recommend** that ONC, directly and through coordination with CMS and terminology curators, harmonize procedural coding standards to standards meeting the policy goals listed above.

e. We **recommend** that ONC, In the transition to ICD11, work with CMS and NLM to encourage ~~SNOMED-CT and ICD11~~ harmonization to allow a single ~~source use~~nomenclature ~~of captured~~for capture and encoding ~~clinical data~~problems and diagnoses for clinical care, research, and administrative workflows ~~using singular problem list terminology~~.

f. 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, replacing NDC for such purposes.

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Appendix A

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