

Health Information Technology Advisory Committee Adopted Standards Task Force 2022 Virtual Meeting

Meeting Notes | August 9, 2022, 10:30 a.m. - 12:00 p.m. ET

Executive Summary

The focus of the Adopted Standards Task Force 2022 (AS TF) meeting was to review draft recommendations for ASTM E2147-18, CDC Race and Ethnicity Code Set Difference Between v1.0 and v1.2, Syndromic Surveillance, USCDI, Review Draft Dispositions, and Group 6 standards. There were no public comments submitted verbally, but there was a discussion held via the chat feature in Zoom Webinar.

Agenda

10:30 a.m.	Call to Order/Roll Call
10:35 a.m.	Update on Draft Recommendations
10:45 a.m.	ONC Standards Review – ASTM E2147-18, CDC Race and Ethnicity Code Set Difference
	Between v1.0 and v1.2, Syndromic Surveillance, USCDI, Review Draft Dispositions, Group 6
11:50 a.m.	Public Comment
11:55 a.m.	Next Steps
12:00 p.m.	Adjourn
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Call to Order

Mike Berry, Director, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:31 a.m. and welcomed members and the public to the meeting of the AS TF 2022.

Roll Call

MEMBERS IN ATTENDANCE Steve (Ike) Eichner, Texas Department of State Health Services, Co-Chair Hans Buitendijk, Oracle Cerner, Co-Chair Jeff Danford, Altera Digital Health Jim Jirjis, HCA Healthcare John Kilbourne, Department of Veterans Health Affairs (VA) Hung S. Luu, Children's Health Deven McGraw, Invitae Eliel Oliveira, Dell Medical School, University of Texas at Austin Vassil Peytchev, Epic Samantha Pitts, Johns Hopkins University School of Medicine Alexis Snyder, Individual Fillipe Southerland, Yardi Systems, Inc. Raymonde Uy, National Association of Community Health Centers (NACHC) Debi Willis, PatientLink Enterprises, Inc.

MEMBERS NOT IN ATTENDANCE

Rajesh Godavarthi, MCG Health, part of the Hearst Health network Clem McDonald, National Library of Medicine Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Mike Berry, Designated Federal Officer Liz Turi, Task Force Co-Lead Scott Bohon, Task Force Co-Lead

Key Specific Points of Discussion

TOPIC: CALL TO ORDER AND CO-CHAIR REMARKS

Steve Eichner and Hans Buitendijk, AS TF 2022 co-chairs, welcomed everyone. Hans discussed the standards the TF was scheduled to review and the timeline for the TF's upcoming work. Steve explained that the TF has started to shift its work from the spreadsheet-based worksheet documents to a Google document as the TF's draft recommendations to the HITAC are developed. TF members were encouraged to use red-line text when editing the working document. The TF aims to complete its work by the end of August 2022, after which it will submit a report to the HITAC for its consideration and transmittal to the Office of the National Coordinator for Health IT.

TOPIC: ONC STANDARDS REVIEW

Steve briefly shared the AS TF 2022 charge and related 21st Century Cures Act (the Cures Act) Requirement that the charge fulfills. These included:

- Beginning 5 years after the date of enactment [December 13, 2016] of the 21st Century Cures Act and every 3 years thereafter, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to
 - o (A) maintain the use of such standards and implementation specifications; or
 - o (B) phase out such standards and implementation specifications.

Reference: 42 U.S. Code § 300jj-13 - Setting priorities for standards adoption

- Charge: Review the existing set of ONC adopted standards and implementation specifications and make recommendations to maintain or phase out such standards and implementation specifications, as required by 42 U.S. Code § 300jj–13 (Setting Priorities for Standards Adoption). The current set of ONC adopted standards and implementation specifications are maintained on the <u>ONC Standards Hub</u>.
- This charge does not seek recommendations for new standards and implementation specifications for ONC to adopt through rulemaking.

The AS TF reviewed the following standards, and subject matter experts shared information:

- ASTM E2147-18 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems
- Centers for Disease Control and Prevention (CDC) Race and Ethnicity Code Set Difference Between v1.0 and v1.2
 - o Presentation by Carmela Couderc, ONC
- PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Care, Inpatient, and Ambulatory Care, and Inpatient Settings, Release 2.0, April 21, 2015
 - o Presentation by Caleb Wiedeman, TN Department of Health
- United States Core Data for Interoperability (USCDI)



- o Presentation by Carmela Couderc, ONC
- Review Draft Depositions
- Group 6 Standards

DISCUSSION:

- TF members discussed the ASTM E2147-18 Standard and whether an update that was made in 2019 had enough changes to be materially significant.
 - Liz Turi commented that, upon further review, the ASTM E2147-18 is the same as the 2019 version posted on the ASTM website.
 - Hans noted that there are no other alternative standards for the TF to consider, and TF members agreed with the recommendation to maintain the standard.
- Hans invited Carmela Couderc, ONC, to discuss the CDC Race and Ethnicity Code Set Version 1.0 (March 2000). Steve noted that the TF previously attempted to review the difference between version 1.0 (v1.0) and v1.2
 - Carmela described how she researched changes between the versions of the standard, noting that she could not find changes between v1.0 and v1.1. However, there was one change between v1.1. and v1.2: a change to fix a typo in the Ethnicity code for Israeli. In response to a question from Hans, Carmela stated that the old or new versions can be used.
 - Alexis provided an overview of a previous conversation held by the TF in which members emphasized that version 1.0 of the standard is outdated (from March 2000) and should be replaced in the future with something (to be determined) that includes content that better aligns with what is referenced in Version 3 of the USCDI (USCDI v3). TF members confirmed that the USCDI references v1.2 of the CDC standard.
 - TF members agreed to recommend that the most current version of the CDC standard should be used and that it should be aligned with the most current version of the USCDI.
- Steve and Hans reviewed TF member comments on the PHIN Messaging Guide for Syndromic Surveillance and asked TF members to consider whether the HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm 2019-07-26 could be recommended as a replacement for the previous standard. The co-chairs stated that, before making a recommendation, the TF will investigate the future of syndromic surveillance and assess related needs/gaps that need to be accommodated.
 - O Caleb Wiedeman, Tennessee Department of Health, explained that the newer standard included corrections to errors and updates to areas of the previous standard that were deemed confusing. The newer standard also gives vendors greater clarity on the expectations of public health and provides updates to legacy information. Rosa commented that many of the updates codify interpretations that are already in place regarding how data for syndromic surveillance are requested. The new version adds clarity and does not change any interpretations. The presenters commented that the public health community would support the adoption of the newer standard and added that they have not heard about another, even newer version being developed by HL7.
 - TF members agreed to draft a recommendation to replace the syndromic surveillance standard with the newer version.
- Carmela gave a brief presentation on the USCDI before the TF discussed it as a standard under review. She described why the USCDI matters, discussed its core principles, provided an overview of additional data classes and data elements (added since USCDI v1 and v2), and listed key examples of changes to existing data classes and elements. She elaborated on these topics in the <u>USCDI v3 presentation slides</u>, which were created by AI Taylor, ONC. She shared answers to specific questions posed by the AS TF within the slides and her presentation and invited TF members to share feedback and/or questions.
 - o In response to Lisa Anderson's question from the public chat in Zoom, Carmela explained



that mentions of specific value sets and referenced code sets; they use the implementation guides (IGs) from HL7 to reference specific value sets. Additionally, in the Interoperability Standards Advisory (ISA), ONC provides a compendium (of value sets or code systems), and the code sets can be used to define each of these elements.

- Steve asked Carmela to explain how ONC ensures alignment between what is promoted via the Standards Version Advancement Process (SVAP) and the USCDI (in case of a conflict). Carmela stated that the data elements within the USCDI may reference a code system, but code system version are referenced within and do not move throughout the SVAP. Standards that ONC regulates, not code system versions, move through the SVAP. If a standard within the USCDI references a version of a code set that has also been referenced within something in the SVAP but the code set versions are not aligned, Carmela explained that updates to terminology can move forward at a different pace than the IGs, and Hans agreed that the terminology can point to a value set either tightly or a little more loosely as exemplars. He explained that updates to code systems do not go through SVAP. Carmela and Hans clarified that SVAP participation is voluntary.
- o Raymonde asked for clarification on where to find comprehensive references to specific IGs on the web version of the USCDI, and Carmela explained that USCDI will not declare specific IGs. However, as a compendium of standards, the ISA will show what standards are available to be used and includes an evaluation as to whether certain items are required to be used. Hans explained that the USCDI includes certification guides that detail which IGs are required for developers (in full or in part, depending on the certification criteria). He discussed the different uses of the ISA and the USCDI.
- o Hans explained that the current standard referenced is USCDI v1 but noted that USCDI v2 is referenced in SVAP. He asked if the TF would like to assume that the SVAP will pick up USCDI v3 and asked whether the TF should recommend that the newest version of the USCDI should be the listed standard, including the referenced IGs. Vassil discussed considerations that must be made for certification regarding the versions of the USCDI, US Core, and CDA IGs; there are timing concerns between when something is released, and when it can be required for certification, so the TF should use specific language in its recommendation. Deven noted that the updates to the USCDI are being released quickly and raised concerns around which version(s) should be required for certification. Steve added that standards in regulation have gone through the notice of the public rulemaking process.
- O TF members agreed that there is a general desire to eventually use newer versions of the USCDI, though there are complexities around mandating the use of updated versions, and they reviewed a variety of options for a recommendation to the HITAC (drafted in the TF's working spreadsheet document). The TF discussed different definitions of "sufficient maturity" for a standard. Vassil suggested that the TF could add a recommendation that the version must have at least two years of availability in the SVAP, and Hung commented that the process should reside with ONC, not HL7. Hans described examples of maturity, including widely deployed and operational.
- The TF agreed to recommend the use of a newer version of the USCDI and for ONC to address dependencies between the USCDI, C-CDA, and FHIR US Core to ensure mature and interoperable support of the adopted USCDI version.
- The TF reviewed the draft depositions that were created following the previous meeting and provided comments.
 - The TF recommended that the Secure Hash Standard, 180-4 (August 2015), is outdated. NIST is holding a public comment period to update the specification. The TF recommends that the updated edition following the comment period is referenced. If the updated edition is not available at the time when the regulation is published, then the reference to the August 2015 edition should continue to include a note that SHA-1 is disallowed (what the updated edition will accomplish).
 - o The TF reviewed its previously discussions around the CDC Race and Ethnicity Code Set

Version 1.0 (March 2000) and recommended that ONC retires reference of the version referenced in the 21st Century Cures Act Federal Rule r(the Cures Act) and uses the then most current version of the code set in the next regulatory update to the Cures Act. At the same time, the TF supports the current process to enable health IT to be certified to a more current version of the code set as they become available while also recognizing the need to recognize the use of code systems and values in historical documentation, i.e., not requiring conversion to more current code systems of historical data.

- o The TF reviewed the HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor. Vassil commented that the current work of the Gender Harmony Project concludes that there is a legal sex, sex assigned at birth, and gender identity. Vassil explained that AdministrativeGender allows different states to map data at the lowest common denominator. Following a discussion, the TF created a draft recommendation that the value set represents current approaches for describing legal sex and, therefore, it should be maintained minimally for administrative purposes. If there are changes to legal sex descriptors, the standard will need to change. However, it should reference the work of the Gender Harmony Project for a more comprehensive view and be consistent with other discussions on sex and gender identity related attributes. Gender Harmony does not include a definition of legal sex. Vassil suggested that this is a useful value set that should be maintained as changes to legal sex descriptors evolve.
- o The TF reviewed the Office of Management and Budget (OMB) Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997, and recommended that ONC retire references to the version referenced in the Cures Act and uses the then most current version of the code set in the next regulatory update to the Cures Act. At the same time, support the current process to enable health IT to be certified to a more current version of the code set as they become available while also recognizing the need to recognize the use of code systems and values in historical documentation (i.e., not requiring conversion to more current code systems of historical data). Carmela commented that this standard is different because it does not define a code system. TF agreed to review the recommendation to clarify the language so that it contains the proper references to the code set/value set.
- The TF reviewed members' comments on the FHIR® US Core Implementation Guide STU V3.1.1 standard, and Hans explained that newer versions have been released.
 - Hans suggested that the TF consider the then most current published version. However, depending on the USCDI version, there may be a need to maintain an earlier version unless there is a better way to support sub-sets of USCDI.
 - The TF drafted a recommendation that a newer version of US Core should be used and for ONC to address dependencies between the USCDI, C-CDA, and FHIR US Core to ensure mature and interoperable support of the adopted version.
- The TF reviewed comments on the HL7® FHIR® Bulk Data Access (Flat FHIR®) (V1.0.0:STU 1) standard.
 - Hans noted that a more current version was published in November 2021 and will become available on August 29, 2022.
 - o The TF agreed to recommend that the most current version should be considered.
- The TF reviewed the HL7® Version 4.0.1 FHIR® Release 4, October 30, 2019 standard, and Hans noted that there is work underway on Version 5, which will not have normative differences (expected in the first half of 2023). IGs will need to be updated, as well as other activities.
 - Jeff commented that shifting this standard would require updates to many other pieces but noted that it is important to move ahead past Release 4 (R4). Vassil agreed but added that the new subscription framework in FHIR is in R4B and R5. ONC should consider adding one of these versions to promote the new framework. Hans discussed the IGs that would need to be updated to support this shift.
 - o The TF agreed to draft a recommendation that a newer version (e.g., R4B or R5 for new



capabilities such as subscription) that would be valuable while recognizing that any IGs referenced are based on FHIR R4, thus requiring work. Depending on timing, this may be a challenge with the next version to align fully. Consider that any uptake would require a lot of signaling and runways to give everybody opportunity to advance.

Action Items and Next Steps

Homework for the August 16, 2022, AS TF 2022 Meeting – due by Monday, August 15:

- Review the standards listed in Group 6 (see "Review Cycle Grouping" in Column E) on the disposition tracking spreadsheet on Google Sheets.
 - Click on the link to the standard (Column B) and begin to get familiar with the standard. We will discuss each standard during our next task force meeting.
 - Please note that the spreadsheet is now locked, so you are not required to add your comments on dispositioning for these standards, but please come prepared to discuss.
- We will continue to refine our draft final dispositions in the Google Document.
 - Please review and provide comments or suggestions on the current wording in the Google Document. For version control, you will not be able to edit the document but can add your comments with your name.
- If anyone has questions, please reach out to the co-chairs or the ONC program team by email.

Public Comment

QUESTIONS AND COMMENTS RECEIVED VERBALLY

Mike Berry opened the meeting for public comments. There were no public comments received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Welcome to the Adopted Standards Task Force. Please remember to change your chat to "Everyone" so that everyone can see your chat. Thanks!

Raymonde Uy: Thanks Carmela. Anything between 1.0 and 1.1?

Raymonde Uy: Thanks so much Carmela! :)

Jim Jirjis: Jim Jirjis Had to join I ate

Lisa Anderson: In the USCDIv3 publication, it seems to note the data element and the code system or standard to use in some cases, but how do implementers know the actual codes to use for exchange https://www.healthit.gov/isa/sites/isa/files/2022-07/USCDI-Version-3-July-2022-Final.pdf

Lisa Anderson: for example, SDOH data elements

Raymonde Uy: ISA: https://www.healthit.gov/isa/isa-document-table-contents

Hans Buitendijk: Note that there are concerns with considering USCDI as a block as not all HIT that wishes to be certified would need to support all data. Perhapsh *[sic]* EHRs more than other HIT, but certification is not limited to HIT. This is however a separate debate in progress as USCDI grows, outside of this task force's charter.

Raymonde Uy: @Lisa, great point that the value set OIDs, IGs and codes are not comprehensively populated on each data class/element on the USCDI document published/referenced on the site. I usually rely on the IGs and specs on the main page: https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v3



Raymonde Uy: For SDoH in your example, Gravity is referenced for all data elements, and they publish it on VSAC.

Carmela Couderc: Check out the Standards Bulletin that explains the changes from v2 to v3. <u>https://www.healthit.gov/sites/default/files/page/2022-07/Standards_Bulletin_2022-2.pdf</u> ISA is referenced there.

Lisa Anderson: It would be good to have the specific code/code systems/etc. spelled out in a human readable document in order to re-use the data elements for other use cases, like quality reporting

Carmela Couderc: There is a PDF version of ISA that might help. https://www.healthit.gov/isa/isa-publications

Carmela Couderc: Draft v4 in January 2023

Raymonde Uy: Thanks @Carmela! This is very helpful. I should have explored the ISA publication tab more.

Carmela Couderc: As an example, USCDI v1 in the Cures Update at 4/5/2021 but not required for exchange by certified health IT until 12/31/2022.

Carmela Couderc: From the current Gender Harmony IG: Of particular note in HL7 models is the use of "Administrative Gender/Sex" as a core data element for sex or gender exchange. Given the lack of clarity and consistency in the use of this "administrative" element, and the lack of a well established clinical value of use for all populations, there has been inconsistency in understanding and significant concern [sic] regard proper patient care. This guide exists to improve upon that.

Carmela Couderc: The passport example falls into the Gender Harmony notion of Recorded Sex or Gender.

Samantha Pitts: I agree with that more general statement

Jim Jirjis: agree

Patrice Kuppe: FYI - Newest version of SCRIPT Standard is V2022071. But recommend to stay on 2017071 which is under Rule

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources

AS TF Webpage AS TF – August 9, 2022 Meeting Webpage AS TF – August 9, 2022 Meeting Agenda AS TF – August 9, 2022 Meeting Slides HITAC Calendar Webpage

Meeting Schedule and Adjournment

Steve thanked everyone for their participation and support. He requested that AS TF members continue to share feedback in the working Google spreadsheet document and briefly reviewed the Group 6 standards that the TF will focus on at upcoming meetings. The co-chairs summarized key achievements from the current



meeting, shared a list of upcoming AS TF meetings, and described how the TF will begin to craft its recommendations report to the HITAC. The TF will present an update to the HITAC at its August 17, 2022, meeting and a final presentation and vote will occur at the September 14, 2022, HITAC meeting.

The next meeting of the AS TF will be held on August 16, 2022. The meeting was adjourned at 11:28 a.m. E.T.