## **Meeting Notes**

# HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)

June 16, 2022, 10:00 a.m. - 12:00 p.m. ET

**VIRTUAL** 



#### **EXECUTIVE SUMMARY**

**Micky Tripathi**, the National Coordinator for Health IT, welcomed everyone to the June 16, 2022, virtual meeting of the HITAC and provided an overview of ONC's recent program updates. The co-chairs of the HITAC, **Denise Webb** and **Aaron Miri**, welcomed members, reviewed the meeting agenda, and presented the minutes from the May 18, 2022, HITAC meeting, which were approved by voice vote. **Seth Pazinski** reviewed the Adopted Standards. On behalf of the Interoperability Standards Workgroup (IS WG), **Steven Lane** and **Arien Malec** presented the IS WG's recommendations on ONC's 2022 Interoperability Standards Advisory (ISA). HITAC members submitted comments and questions on the presentation and held a voice vote to accept the IS WG Recommendations Report. One public comment was submitted by phone during the meeting. There was a robust discussion in the public meeting chat via Zoom.

#### **AGENDA**

10:00 a.m. Call to Order/Roll Call 10:05 a.m. Welcome Remarks

10:15 a.m. Opening Remarks, Review of Agenda, and Approval of May 18, 2022

**Meeting Minutes** 

10:20 a.m. Adopted Standards Review

10:35 a.m. Interoperability Standards Workgroup Recommendations on ONC's 2022

Interoperability Standards Advisory - HITAC Vote

11:45 a.m. Public Comment

12:00 p.m. Final Remarks and Adjourn

#### CALL TO ORDER/ ROLL CALL

**Mike Berry,** Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the June 16, 2022, meeting to order at 10:02 a.m.

#### **ROLL CALL**

Aaron Miri, Baptist Health, Co-Chair Denise Webb, Individual, Co-Chair

Medell Briggs-Malonson, UCLA Health

Hans Buitendijk, Oracle Cerner

Steven (Ike) Eichner, Texas Department of State Health Services

Cynthia A. Fisher, PatientRightsAdvocate.org

Lisa Frey, St. Elizabeth Healthcare

Rajesh Godavarthi, MCG Health, part of the Hearst Health network

Valerie Grev. State University of New York

Steven Hester, Norton Healthcare

Jim Jirjis, HCA Healthcare

John Kansky, Indiana Health Information Exchange

Kensaku Kawamoto, University of Utah Health

Steven Lane, Sutter Health

Hung S. Luu, Children's Health

Arien Malec, Change Healthcare

Clem McDonald, National Library of Medicine

Aaron Neinstein, UCSF Health

Eliel Oliveira, Dell Medical School, University of Texas at Austin

Brett Oliver, Baptist Health

Abby Sears, OCHIN

Alexis Snyder, Individual

Fillipe Southerland, Yardi Systems, Inc.

Sheryl Turney, Anthem, Inc.

#### HITAC MEMBERS NOT IN ATTENDANCE

Leslie Lenert, Medical University of South Carolina James Pantelas, Individual Raj Ratwani, MedStar Health

#### **FEDERAL REPRESENTATIVES**

Thomas Cantilina, Military Health System, Department of Defense (DoD) (Absent)
Sanjeev Tandon, Centers for Disease Control and Prevention (CDC) (Standing in for Adi V. Gundlapalli)
Ram lyer, Food and Drug Administration (FDA) (Absent)
Meredith Josephs, Federal Electronic Health Record Modernization (FEHRM) Office
Elaine Hunolt, Department of Veterans Affairs (Standing in for Jonathan Nebeker)
Michelle Schreiber, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology

#### **ONC STAFF**

Micky Tripathi, National Coordinator for Health Information Technology Elise Sweeney Anthony, Executive Director, Office of Policy Avinash Shanbhag, Executive Director, Office of Technology Seth Pazinski, Director, Strategic Planning and Coordination Division Mike Berry, Designated Federal Officer

#### WELCOME REMARKS

**Micky Tripathi**, the National Coordinator for Health IT, welcomed everyone and provided an overview of ONC's recent program updates, including:

- He thanked everyone for joining the latest Social Determinants of Health (SDOH)
   Information Exchange Learning Forum webinar on June 14, 2022. ONC was pleased
   with its federal partners' engagement with this high priority area. He invited listeners to
   register for the next webinar, which is scheduled for July 19, 2022. More information is
   available at <a href="https://www.healthit.gov/news/events/oncs-social-determinants-health-information-exchange-learning-forum">https://www.healthit.gov/news/events/oncs-social-determinants-health-information-exchange-learning-forum</a>.
- He thanked the co-chairs and members of the Interoperability Standards Workgroup (IS WG) for their dedication and explained that the co-chairs would present the IS WG's Charge 2 recommendations 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. At the HITAC's April meeting, the IS WG co-chairs presented their recommendations on Version 3 of the draft United States Core Data for Interoperability (USCDI v3). He discussed the importance of working to improve the USCDI and the ISA and to move them forward for all stakeholders.
- ONC is launching the HITAC Adopted Standards Task Force 2022 to review and make recommendations on the existing set of ONC-adopted <u>standards</u> and implementation specifications.
- The ONC Buzz Blog has published several articles recently, including:
  - 13 Areas to Improve Electronic Prior Authorization (ePA) (Alex Baker and Michael Wittie | May 31, 2022)
  - Information Blocking and the President's Fiscal Year 2023 (FY23) Budget for ONC (Steven Posnack | May 24, 2022)



- The GAO is now accepting nominations for HITAC appointments. From these
  nominations, GAO expects to appoint at least four new HITAC members, focusing
  especially on patients or consumers, health care providers, ancillary health care
  workers, and individuals with technical expertise on health care quality, system
  functions, privacy, security, and the electronic exchange and use of health information.
  Members serve 3-year terms beginning January 1, 2023, with the terms subject to
  renewal.
  - Interested nominees should submit letters of nomination and resumes to HITCommittee@gao.gov no later than July 22, 2022.
  - Refer to the Federal Register announcement for more information.
- The next HITAC meeting will be held on August 17, 2022. The July HITAC meeting will be canceled. Micky thanked all HITAC members for their dedication and participation at HITAC and sub-committee meetings.

## OPENING REMARKS, REVIEW OF AGENDA, AND APPROVAL OF MAY 18, 2022, MEETING MINUTES

**Aaron Miri** and **Denise Webb**, HITAC co-chairs, welcomed all members and presenters. **Aaron** thanked **Micky** and the team from ONC for the excellent blog posts and for being accessible to help all stakeholders in the healthcare community. **Denise** said she was glad to hear that the proposed new authority for ONC to be able to issue binding advisory opinions for the information blocking regulations was included in the FY23 budget. She explained that, as a GAO appointee, her term on the HITAC would be completed at the end of 2022 and, therefore, would not be able to finish her full term as co-chair. **Aaron** thanked her for her contributions, and **Denise** added that she would relish her final months as co-chair of the HITAC.

**Denise** reviewed the agenda for the meeting and invited members to examine the minutes from the May 18, 2022, meeting of the HITAC. She called for a motion to approve the minutes. The motion was made by **Aaron Miri** and was seconded by **Hans Buitendijk**.

The HITAC approved the May 18, 2022, meeting minutes by voice vote. No members opposed or abstained.

#### ADOPTED STANDARDS REVIEW

**Seth Pazinski**, Director, Strategic Planning & Coordination Division, ONC, presented a review of the ONC Adopted Standards and announced the kick-off of a new task force of the HITAC, the Adopted Standards Task Force 2022 (AS TF 2022). He explained that this HITAC Task Force fulfills a requirement of the 21<sup>st</sup> Century Cures Act requirement:

- "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-
  - (A) maintain the use of such standards and implementation specifications; or
  - (B) phase out such standards and implementation specifications."

He stated that the Overarching Charge of the task force is to:

- 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 is maintained on the ONC Standards Hub.
- This charge does not seek recommendations for new standards and implementation specifications for ONC to adopt through rulemaking.

**Seth** explained that members of the AS TF 2022 will include both current HITAC members and industry experts and AS TF meetings will be open to the public. He shared a roster of members and a timeline of meetings, which were included in the <u>Adopted Standards Review presentation slides</u>. Any other HITAC member who would like to be added to the TF should contact **Mike Berry**, the Designated Federal Officer, by email. The final report and recommendations from the AS TF 2022 will be presented to the HITAC at its September 14, 2022, meeting. The TF's recommendations are expected to inform ONC's future work. This new process will ensure a transparent and repeatable approach for reviewing adopted standards and implementation specifications that support the advancement of interoperable electronic health information. He stated that ONC encourages all interested stakeholders to follow TF meetings and that stakeholders may also provide written or verbal comments during TF meetings.

#### **Discussion:**

- Steven Lane expressed his excitement about everyone who signed up as a member
  of the TF and thanked Hans Buitendijk and Steven Eichner for their contributions to
  previous task forces, adding that they will be well informed to lead the new task force.
- Aaron Miri thanked everyone for volunteering to serve on the TF and asked if there is a mechanism in place for industry groups to weigh in on the proposed standards or to share feedback on others that the TF should address.
  - Seth encouraged anyone who is interested in sharing feedback to do it through the verbal public comment period during each meeting or by writing, either in the public chat feature in Zoom or by email. Information about the cadence and focus of TF meetings will be shared by the cochairs following the kick-off meeting on June 28.

# INTEROPERABILITY STANDARDS WORKGROUP RECOMMENDATIONS ON ONC'S 2022 INTEROPERABILITY STANDARDS ADVISORY – HITAC VOTE

**Steven Lane** and **Arien Malec**, co-chairs of the Interoperability Standards Workgroup (IS WG), presented the WG's recommendations on their Phase 2 work. The IS WG was chartered to replace the work of the prior United States Core Data for Interoperability Task Force 2021 (USCDI TF 2021) and the Interoperability Standards Priorities Task Force 2021 (ISP TF 2021). **Steven** presented an overview of the IS WG's membership, background, charges, methods/phased work approach, meeting schedule, and deliverable due dates, all of which were <u>detailed in the IS WG presentation slides</u>. He thanked the WG's members for their engagement and contributions.

### The charges included:

- Overarching charge: Review and provide recommendations on the Draft USCDI Version 3 and other interoperability standards
- Specific charges:
  - Due to the HITAC by April 13, 2022:



- Evaluate Draft USCDI v3 and provide HITAC with recommendations for:
  - 1a New data classes and elements from Draft USCDI v3
  - 1b Level 2 data classes and elements not included in Draft USCDI v3
- Due June 16, 2022:
  - 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.

**Steven** described the areas of focus for this iteration of the WG and HITAC priority uses of health IT: the use of technologies that support public health, privacy and security, interoperability, and patient access. Then, he shared a list of high priority topics on which ONC requested WG recommendations. These included:

- Lab Orders and Results
- Social Determinants of Health (SDOH) Standards
- Patient Access/Portals related standards (including patient corrections)
- Electronic Case Reporting (eCR)
- Proposed Interoperability Standards Advisory (ISA) system enhancements

**Steven** provided an overview of ISA and its role in the health IT ecosystem, including what it is, how it is used, the ongoing update process, its high-level structure, and ISA content, additional ISA resources, key challenges, and a sample ISA need. All of this information, including additional resources, is <u>detailed in the IS WG presentation slides</u>. He added that it is available at <u>www.healthit.gov/ISA</u>.

**Arien** described the method and approach the IS WG took to create and provide its recommendations to the HITAC, noting that they broadly covered three areas. These included:

- Process and structure of the ISA:
  - Ability of stakeholders to discover current standards available/necessary for use cases
  - Coordination and alignment with the USCDI
  - Alignment with federal programs
  - Ties to standards development organizations (SDOs) and "Accelerators"
  - Overall usability and utility for stakeholders
- Expand use cases and track additional standards in the following areas of the ISA:
  - Public Health
  - Health Equity
  - Social Determinants of Health (SDOH)
  - Patient Engagement and Patient Access
  - Care Planning and Care Coordination
  - Provenance
- Expand ISA standards adoption for lab orders and results

The co-chairs alternated while describing the IS WG's Phase 2 Recommendations, which numbered 21 in total. They discussed the WG's specific recommendations around the ISA Structure, Process, and Content, and **Arien** shared a set of Additional Recommendations on Expanding ISA Standards Adoption for Lab Orders and Results the WG created based on earlier work that was brought before the HITAC by previous task forces and workgroups. All of the recommendations were briefly outlined in the <u>IS WG</u>

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<u>Phase 2 Recommendations presentation slides</u> and were detailed in the <u>IS WG Phase 2</u>. <u>Recommendations Report</u>. The co-chairs provided background information and directed HITAC members to the comprehensive descriptions in the report document. They explained that the work of <u>Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) project</u> informed these additional recommendations.

The HITAC co-chairs thanked ONC for their support of the IS WG, members for their dedication and input, and the SMEs for sharing their expertise. They also thanked the WG members for their hard work and precision by which they developed their recommendations. **Aaron** invited HITAC members to share comments or questions.

#### **Discussion:**

- Clem McDonald explained that he shared several comments in the public chat and added that the term "local development test" (LDT) used to be called "laboratory development test." He explained that bigger labs are receiving standard codes for them, though smaller labs may not receive them; however, the situation is not as bad as Arien described.
  - Steven Lane thanked Clem for his contributions to the IS WG and also to
    previous task forces. He explained that learnings from the early days of
    the COVID-19 pandemic showed that there was a need for mapping for
    labs to share data. While bigger labs are doing a better job with this
    process, the recommendation of the WG is that this should be done more
    comprehensively across the board and baked into standards and
    certification requirements for greater consistency.
  - Clem commented that some labs do not send LOINC codes because they have not defined them at all and that the mappings are not always carefully done (about 9% of 180 million mappings are off, and SHIELD's findings suggest that the percentage could be higher).
  - Arien thanked Clem for his comments and added that it is shocking how good a job we do in getting paid relative to the job that we do in ensuring clinical interpretation and broad use of data for health in healthcare.
- Sheryl Turney thanked the IS WG for their work and discussed the importance of the standards that apply to SDOH and the right to request corrections. She noted that the earlier understanding about these standards during the collection process was that this information was static but added that this is not the case. She asked how these standards could be adjusted to reflect the changing nature of this data and the types of issues that are addressed.
  - Arien responded that the HITAC's task forces and workgroups have made recommendations in the past about including the provenance (including the source of information and time of information) of patientgenerated health data. He agreed with Sheryl's comments that any data that relates to a patient's identity must include a provenance history and discussed how the USCDI Task Force's deep dive on gender identity indicated the need for context and time to be recorded with each use of the information.
  - Steven Lane thanked Sheryl for her comments and explained that the IS WG did discuss this topic. He added that SDOH data elements are changeable and context-specific and explained that, with all individually generated health data, different patient answers could come from different situations depending on the collection process. The WG addressed this issue via its recommendations around capturing metadata along with the SDOH data.

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  - Hung Luu thanked the co-chairs and the WG for their work and addressed the comment about the accuracy of coding of laboratory testing versus the billing data. He noted that hospitals have teams of people who specialize in CPT coding, which is a tightly controlled system; CPT codes are simplified because the coding system for billing is different/has different needs than the coding system for interoperability. He described how the SHIELD Project worked to shift the coding away from the laboratories and towards the manufacturers, who would understand their test menu the best and would be able to put the onus on those who could accomplish that most accurately. He emphasized that all stakeholders want what is best for patients and stated that coding is a weakness in the healthcare system that must be addressed to ensure that it is accurate and can support inoperability.
    - Aaron thanked Hung for his comments and his expert contributions to the WG.

Following the discussion, **Steven** referred HITAC members to the 26-page IS WG Phase 2 Recommendations Report document, and he added that because this is an annual, iterative process, HITAC members would be invited to provide additional input next year.

**Aaron** invited members to vote on whether to accept the Phase 2 recommendations from the IS WG and called for a motion. The motion was made by **Hans Buitendijk** and was seconded by **Denise Webb.** 

The HITAC voted to accept the recommendations from the IS WG by voice vote. No members opposed or abstained.

**Aaron** congratulated the IS WG members and explained that the recommendations would then be transmitted to the National Coordinator for Health IT.

#### **PUBLIC COMMENT**

**Mike Berry** opened the meeting for public comment and reminded attendees that written comments could be submitted at <a href="ONC-HITAC@accelsolutionsllc.com">ONC-HITAC@accelsolutionsllc.com</a>.

### **Questions and Comments Received via Telephone**

There was one public comment received via telephone:

**Charles Gabriel:** I have a general question, if that's okay. How do we bring new standards to be discussed, namely maternity, for example? I'm working with a couple of experts on maternity. Is that the right form to bring such topic or domain?

**Steven Lane:** I think what you're asking about is some new changes to the data classes and elements that are included in the USCDI. Is that true? Specific to maternity?

Charles Gabriel: Correct. I would say not changes or add to it or amend or expand.

**Steven Lane:** I will pull up the link in the public chat. You can go to the <u>USCDI page on the website</u> and, from there, you can register and provide public comment directly on the data elements and classes that are included or not included in USCDI.

Charles Gabriel: Thank you so much.

**Questions and Comments Received via Zoom Webinar Chat** 

Jim Jirjis: Jim Jirjis just Joined

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Mike Berry (ONC): Welcome to the HITAC meeting! Meeting materials can be found here: <a href="https://www.healthit.gov/hitac/events/health-it-advisory-committee-46">https://www.healthit.gov/hitac/events/health-it-advisory-committee-46</a>

Katie Campanale- Accel: Federal Register Notice:

https://www.federalregister.gov/documents/2022/06/13/2022-12499/request-for-health-information-technology-advisory-committee-hitac-nominations

Aaron Miri: Please apply for upcoming HITAC terms!!! This is one of the best "families" in all of Health IT.

Wendy Noboa: ONC Standards Hub: https://www.healthit.gov/topic/certification/2015-standards-hub

Aaron Miri: Dr Lane / Arien - it goes without saying. Really appreciate how detailed, thoughtful, inclusive and " easy to understand" you make the entire ISA process

Steven Lane: <a href="https://www.healthit.gov/isa/">https://www.healthit.gov/isa/</a>

Katie Campanale- Accel: All meeting materials can be found here: <a href="https://www.healthit.gov/hitac/events/health-it-advisory-committee-46">https://www.healthit.gov/hitac/events/health-it-advisory-committee-46</a>

Abby Sears: Aaron and Dr Lane's work leading this taskforce was outstanding. Without their leadership and focus we would not have been able to bring such strong, comprehensive recommendations forward. This work will improve the interoperability work in this Country. Thank you for your generous use of your time.

Mark Savage: @Abby +100

Steven Lane: We have learned the hard way that this level of detail will be required to finally make clinical orders and results truly interoperable in a manner that will support semantic interoperability and utility to end users.

Aaron Miri: Dr. Lane - excellent points. Precision (like everything in medicine) matters. Well done to you and the team

Micky Tripathi: More gripping than Top Gun: Maverick!!

Arien Malec: Better acted for sure.

Clem McDonald: Regarding "self developed tests" which are usually referred to as Laboratory developed tests (LDT). Mosst [sic] of the big referral laboratories e.g may, Lab Corp, Quest, ARUP,have [sic] been requesting LOINC codes for their LDT. So there is not a problem here. Suspect to the degree that small labs develop LDT (probably not as common as the big lab. there may be a problem r [sic]

Fillipe Southerland: Appreciate your deep dive in this area. Lab interoperability has been a key pain point within the LTPAC industry.

Denise Webb: Excellent delivery of recommendations Steven and Arien. I commend the great work of the co-chairs and the entire workgroup on behalf of the HITAC. Thank you!!

Arien Malec: We had the same considerations for disability status and accommodations -- these are a time series, and their use needs to be in context and at a point in time.

Steven Lane: Yes!



Wendy Noboa: Download the full Interoperability Standards Workgroup Report to the HITAC: https://www.healthit.gov/hitac/events/health-it-advisory-committee-46

Wendy Noboa: Read more about the new Adopted Standards Task Force on the HealthIT Buzz Blog: <a href="https://www.healthit.gov/buzz-blog/health-information-technology-advisory-committee/onc-launches-new-hitac-adopted-standards-task-force">https://www.healthit.gov/buzz-blog/health-information-technology-advisory-committee/onc-launches-new-hitac-adopted-standards-task-force</a>

Steven Lane: https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

#### **Questions and Comments Received via Email**

No public comment items were submitted via email.

### **FINAL REMARKS**

HITAC

**Mike Berry** reminded members that the next meeting of the HITAC will be held on August 17, 2022. All materials and testimony from today's meeting will be made available at <a href="https://www.healthit.gov/hitac/events/health-it-advisory-committee-46">https://www.healthit.gov/hitac/events/health-it-advisory-committee-46</a>.

**Denise** and **Aaron** thanked everyone for their participation, presentations, and discussion. **Denise** wished everyone a nice break from HITAC meetings and thanked everyone who volunteered to be part of the new AS TF 2022. **Aaron** added that the HITAC Annual Report Workgroup (AR WG) will begin meeting again in July. He reminded everyone that, per the ONC Information Blocking Rule (45 CFR Part 171), healthcare providers must share all electronic health information (EHI) as defined in 45 CFR 171.102 beginning October 6, 2022. As the October deadline approaches, he urged everyone to do their appropriate due diligence.

#### **ADJOURN**

The meeting was adjourned at 11:39 a.m. ET.