# Health Information Technology Advisory Committee Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | April 26, 2022, 10:30 a.m. - 12:00 p.m. ET

# **Executive Summary**

The focus of the Interoperability Standards Workgroup (IS WG) meeting was to work on Charge 2, which is due to the HITAC by June 16, 2022. The WG received a presentation from the Gravity Project on consensus-driven standards on social determinants of health, potential WG recommendation to add the Gravity Project's social determinants of health (SDOH) standards in the Interoperability Standards (ISA), and a high priority use case of advancing maternal health equity. WG members participated in a discussion session following the presentation. Then, the WG discussed the list of suggested ISA topics, which were recently ranked in order of priority, and recommendations added as a result of the previous presentations on the exchange of laboratory data.

There was one public comment submitted verbally, and there was a robust discussion held via the chat feature in Zoom Webinar.

## **Agenda**

10:30 a.m. Call to Order/Roll Call 10:35 a.m. Co-Chair Remarks

10:40 a.m. Gravity Project Presentation

11:40 a.m. Lab Recommendations and ISA Priority Topics Discussion

11:55 a.m. Public Comment

12:00 p.m. Adjourn

## Call to Order

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:30 a.m. and welcomed members and the public to the meeting of the IS WG.

## Roll Call

## **MEMBERS IN ATTENDANCE**

Steven Lane, Sutter Health, Co-Chair
Arien Malec, Change Healthcare, Co-Chair
Hans Buitendijk, Cerner
Christina Caraballo, HIMSS
Steven (Ike) Eichner, Texas Department of State Health Services
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Sanjeev Tandon, Centers of Disease Control and Prevention (Attending on behalf of Adi Gundlapalli)
Hung S. Luu, Children's Health
David McCallie, Individual
Clem McDonald, National Library of Medicine

Mark Savage, Savage & Savage LLC

Ram Sriram, National Institute of Standards and Technology

#### MEMBERS NOT IN ATTENDANCE

Kelly Aldrich, Vanderbilt University School of Nursing Thomas Cantilina, Department of Defense Grace Cordovano, Enlightening Results Jim Jirjis, HCA Healthcare Kensaku (Ken) Kawamoto, University of Utah Health Leslie (Les) Lenert, Medical University of South Carolina Michelle Schreiber, Centers for Medicare & Medicaid Services (CMS) Abby Sears, OCHIN

## **ONC STAFF**

Mike Berry, Designated Federal Officer Matthew Rahn, Deputy Director, Standards Division

# **Key Specific Points of Discussion**

#### **TOPIC: CO-CHAIR REMARKS**

Steven Lane and Arien Malec, IS WG co-chairs, welcomed everyone. Steven described the plan of work and agenda for the meeting. He explained that previous iterations of the IS WG, including the Interoperability Standards Priorities Task Force 2019 (ISP TF 2019), addressed the topics on which the Gravity Project will present. The previous iteration of the WG concluded that the Gravity Project would need to advance its work prior to the WG making any new recommendations to the HITAC and ONC.

Arien thanked the presenters for their patience with the scheduling process and commended WG members who have been adding information to the WG's working Google spreadsheets. He discussed the differences between the WG's prioritization framework documents, which will be used to determine topics where the WG may need to do deeper work and hear panel presentations, and the documents that are being used to track use cases in the ISA and/or include or track a standard or implementation specification in the Interoperability Standards Advisory (ISA). He encouraged WG members to continue to highlight topics in the document.

#### TOPIC: WORKGROUP WORK PLAN

The co-chairs briefly reviewed the charges of the IS WG, which included:

- Overarching charge: Review and provide recommendations on the Draft United States Core Data for Interoperability Version 3 (USCDI v3) and other interoperability standards
- Specific charges:
  - Phase 1: Completed on April 13, 2022, following a presentation to the HITAC and approval by voice vote:
    - Evaluate draft Version 3 of the USCDI 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
  - o Phase 2: 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.

**TOPIC: GRAVITY PROJECT PRESENTATION** 

Mark Savage, Workgroup Member, Savage & Savage LLC, introduced himself and provided background information on the work of the other presenters, who included Evelyn Gallego, MBA, MPH, CPHIMS, EMI Advisors LLC, Senior Advisor of the Gravity Project, and Asha Immanuelle, MAS, BSN, PHM-C, RN, Center for Black Women's Wellness, Member of the Georgia Maternal Mortality Review Committee, Population Health Advisor and Community Liaison for the Gravity Project. They presented on the topic of consensus-driven standards on social determinants of health and made the Gravity Project's presentation slides available. Mark explained that Evelyn would present potential WG recommendations to add the Gravity Project's social determinants of health (SDOH) standards to the ISA, and Asha would summarize the high priority use case of advancing maternal health equity. The presentations were intended to illustrate how the standards and ISA use cases can advance health equity.

Evelyn grounded her presentation by providing definitions for key terms, such as SDOH, protective factors, social risks, and social needs, which were detailed in the Gravity Project's presentation. She recapped the Gravity Project's overall scope of work and recent activities, including defining the coded data concepts for 14 SDOH domains. She described Gravity's conceptual framework, which included four activities and the three overarching use cases that support data around the activities in the framework. She explained that Gravity's work is grounded in the ability to capture/initially use this data within a clinical setting and for exchange outside of a clinical setting. She described how Gravity has convened over 2,000+ participants from across the health and human services ecosystem and invited everyone to join their biweekly public calls on Thursdays from 4-5:30 p.m. ET.

Evelyn presented the Gravity Project's recommendations and next steps and discussed a slide depicting which of their recommendations have already been incorporated in Version 2 of the USCDI and proposed recommendations for the near future. These incorporated items and proposed next steps were organized into the following categories: FHIR (Fast Healthcare Interoperability Resources) implementation guides (IGs) and use cases (UCs), activities/data elements, domains for each activity, and code systems/value sets. She stated that while the next steps fall under Gravity's scope of work and have been proposed, they have not been approved. She shared their visualization of a transaction of a FHIR IG version 2, SDOH Clinical Care IG STU2, which is currently in the balloting stage of many testable system interactions. She stated that Gravity's FHIR IG is designed to meet organizations where they are in terms of adoption and certification. Evelyn described how several national use cases depend on the USCDI with SDOH to serve myriad needs simultaneously.

Evelyn provided a preliminary summary of how SDOH topics are represented in ISA under the two components of vocabulary/code set/terminology for social, psychological, and behavioral data and under specialty care settings. She listed Gravity standards items that are missing in the ISA, which were detailed in the presentation slides.

Asha presented the interoperability use case of how the Gravity standards applied to maternal health equity. She introduced herself and discussed her background, adding that she is a community health nurse specialist who is passionate about advancing maternal health equity in her community and beyond. She described the significance of Black Maternal Health Week in raising awareness about Black maternal health, supporting activism and community building, and amplifying community-driven research and care solutions. She stated that the United States is currently in a maternal health crisis, citing statistics from 2020 that a woman giving birth is 50% more likely to die of childbirth-related causes and that Black mothers are bearing the brunt of the crisis. She emphasized the role of bias, racism, and discrimination play and stated that SDOH data can be used to help solve some maternal health problems through the application of the Gravity standards.

Asha provided background information on the Atlanta-based Center for Black Women's Wellness (CBWW) and its mission and programs, which were detailed in the presentation slides. She described the benefits of each of their programs, including the Alliance For Innovation On Maternal Health Community Care Initiative (AIM CCI), which is a community-oriented approach to standardizing perinatal care. She discussed past work undertaken between the Institute for Health Improvement (IHI) and CBWW, including key goals and findings. She shared a fact sheet on maternal mortality from the Georgia Department of Health and the Georgia Maternal Mortality Review Committee, noting that 87% of pregnancy-related deaths are preventable. She

emphasized that better standardization of post-natal maternal care would make a sizeable impact on the maternal health crisis and shared a slide that compared maternal mortality rates (MMR) in the US compared with other countries.

Asha discussed the connection between SDOH and health equity and the path to achieving health equity by addressing several social and economic factors. She described examples of solutions to improve maternal health outcomes, which included the AIM CCI – a grantee of the National Healthy Start Association (NHSA). She detailed AIM CCI's goal and approach to stakeholder management, which is a community-wide effort with health equity embedded throughout.

Asha described how the Gravity standards could be applied to a number of use cases, which were detailed in the presentation slides and would be additional domains that the Gravity Project would take on. They included:

- Document Chronic Stress (Weathering) Assessment for Black Birthing People
- Document and Track SDOH Related Interventions to Completion
- Gather and Aggregate SDOH Data for Uses Beyond the Point of Care

Asha emphasized the need to discontinue the use of faxing of patient data.

Evelyn thanked the Gravity Project's policy team for their role in developing the recommendations to the IS WG. She explained how Gravity proposed that ONC update recommendations in the ISA across vocabulary/code sets and services/exchange. These were detailed in the presentation slides. She described the current state of race and ethnicity data in federal standards and highlighted Gravity's proposed future recommendations, highlighting the need to capture both the source and method of collection of race and ethnicity data, and noting that this recommendation could have equal merit for other self-reported personal characteristics such as gender identity, sexual orientation, and personal pronouns.

The ISA is located online at <a href="https://www.healthit.gov/isa/isa-document-table-contents">https://www.healthit.gov/isa/isa-document-table-contents</a>. The co-chairs thanked the presenters and invited all attendees to share comments and questions with the presenters.

#### **DISCUSSION:**

- Steven asked about how goals in the Gravity Project's framework were prioritized, and Evelyn
  responded that it includes both patient/person-identified goals and provider-identified goals by
  building from the HL7 FHIR Goals Resource (https://www.hl7.org/fhir/goal.html). Steven thanked
  Gravity for the clear recommendations for how the ISA could be advanced, noting that they are
  in line with recommendations the IS WG sent to ONC in its first phase of work.
- Hans thanked the presenters and commented on the variety of opportunities Gravity and the IS WG have to achieve alignment on their approaches to referrals, which included the recommended services exchange (ServiceRequest, Task) for referrals and Bidirectional Services Electronic Referrals (BSeR) FHIR IG (http://hI7.org/fhir/us/bser/). Evelyn explained how the FHIR IG was built on existing standards and how referral types and responses are acknowledged. She stated that they are differentiated by the use cases and that they have worked closely on this with the Centers for Disease Control and Prevention. She also discussed Gravity's coded terminology work, including 360X (https://oncprojectracking.healthit.gov/wiki/display/TechLab360X/360X+Home). She emphasized the need for additional testing and setting up a glide path. Hans thanked her for the answer and described typical complicating factors in this process.
- Hans asked for recommendations on streamlining the process of using content from the IGs in FHIR US Core during updates to the USCDI and certification process. Evelyn responded that ONC has funded pilots that have been identified to test the FHIR IG, and they have also worked closely with the US Core team to ensure alignment. They have been focused on alignment and have a requirements traceability matrix that supports implementation.
- David commented that slides representing the data flows show both point-to-point interchanges

and centralized coordinating entities. He emphasized that the perfect should not be the enemy of the good with building FHIR interchanges and that Direct can achieve much of the necessary interchange of structured data. Also, he commented that focus on stand-alone coordinating entities and point-to-point interchanges could have the negative, unintended consequence of separating SDOH data from the patient health record. He emphasized the need to not create separate pathways for SDOH data. Evelyn commented that Gravity anticipates a tiered approach to the infrastructure for exchanging this data. Also, she explained that the goal is to incorporate SDOH data with the patient electronic health record (EHR) and discussed examples of how this could be done in a future use case. She discussed the concept of using work on data standards to create a "person record" that incorporates social services as well as healthcare data. David clarified his concern that, by creating new workflows that do not fit into current EHR workflows, there is a chance of diminished success as new workflows are added beyond the API endpoint. Evelyn commented that additional work is needed on better defining workflows. Arien commented that the EHR workflow would be like a clinical referral and that there should not be conflicts between different types of referrals.

- Arien highlighted comments from the public chat that requested clarification on the differences between BSeR and 360X. What roles do they play, and how can the IS WG make recommendations around consolidating/updating operational workflows of the specific SDOHrelated referrals for maternal services. Evelyn responded that Gravity works closely with the BSeR team and that there is a need to better communicate across groups' swim lanes using dedicated resources. She suggested that this could be included as a recommendation of the WG.
- Arien asked about the race/ethnicity domain, noting that in the current state, the CDC code set is the underlying code set used. The WG has recommended expanding the subset of codes used to collect race and ethnicity data. Are there identified subsets that better reflect the lived experience of individuals? Ike asked that the WG consider the consistency of use of these code sets for public health. Arien discussed the example of how social determinants data were used to track the spread of COVID-19 in the Bay Area. Evelyn responded that Gravity has not done a deep dive on streamlining the CDC and OMB code sets used to capture this data but added that there is an opportunity to test this within the context of the Gravity STU2 FHIR IG and upcoming pilots. Asha added that there has been a push in Atlanta to standardize how race and ethnicity data are captured to better understand the disparities that exist in care outcomes (via disparity dashboards).
- Ike emphasized the WG recommendation regarding the need to capture and exchange the provenance (clinical observations, self-reported, other) of the information that is collected for use by downstream users. Secondly, he explained how segregating data could create challenges around ensuring that disclosure and consent to share data occurs appropriately with respect to HIPAA. Finally, he inquired about the role of the patient/individual in controlling data exchange. Evelyn responded that the FHIR IG builds off of other FHIR resources, so it aligns and incorporates the provenance data. Consent is built on the current consent specifications, though this is a topic that is broader than Gravity's scope. She added that individual control is built on the workflow, and she suggested that this should be aligned to the consent piece.

## TOPIC: LAB RECOMMENDATIONS AND ISA PRIORITY TOPICS DISCUSSION

Previously, the IS WG was asked to prioritize the enumerated ISA topics by ranking them in order of importance. Steven explained that several WG members, including Hans, Clem, Hung, and Riki worked offline to include information from the SHIELD/LIVD project and presentation. He briefly explained how these rankings were collected and tabulated and shared the prioritization framework in which WG members compiled information on each of the priority topics, including observations, recommendations, policy levers, use cases, specifications, and more.

Arien stated that just because a topic/use case is lower in the WG's rankings, it does not mean that the WG

will not make recommendations. Rather, their work will not be able to go as deep in these areas due to time constraints. He encouraged members to look for areas where the ISA is not tracking a known use case or standard and to share thoughts about connections between the ISA and the USCDI in the working document.

#### The list included:

- High Priority:
  - Lab Orders/Results: Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care (SHIELD)/LOINC In-Vitro Diagnostic (LIVD) test code mapping tool
  - Social Determinants of Health (SDOH) Standards: Centers for Disease Control and Prevention (CDC) Race/Ethnicity vocabulary subsets
  - Lab Orders/Results: laboratory information system (LIS) to electronic health record (EHR)/public health (PH) systems
  - SDOH Standards: Gravity Project Standards
- Medium Priority:
  - CDC: Electronic Case Reporting (eCR) Standards
  - o Care Plans/Chronic Dx Management
- Additional Priorities:
  - o HIPAA right to request corrections to one's medical records
  - o CDC: PH Data Systems Certification
  - o Portal Data Aggregation Across Multiple Portals
  - o Data Exchange Formats for Price Transparency
  - o Data Sharing Between Federal & Commercial Entities
  - Occupation and Location of Work
- New:
  - Vulcan HL7 FHIR Accelerator supporting clinical and translational research IGs
  - Helios HL7 FHIR Accelerator supporting public health IGs
  - o CodeX HL7 FHIR Accelerator supporting oncology IGs
  - o CARIN work to streamline digital identity and consumer auth/auth to portals
  - Coalition for Content Provenance and Authenticity C2PA New provenance standard from Adobe et al
  - TEFCA standards for consumer access to qualified health information networks (QHINs), RLS
  - o Expand ISA to incorporate information in USCDI Submission Form ISA Federally Required section: note specific federal requirements
  - o Add data classes/elements in USCDI to ISA
  - Communications and referrals between providers and community based social care provider

## **DISCUSSION:**

- Arien explained that a previous iteration of the WG made recommendations on Lab Orders/Results. However, SHIELD and LIVD have made extraordinary progress in this area, so he suggested that the prior recommendations be revised and refocused for ONC, given the current state.
- Hans, Riki, and Hung described and justified updates they made to the wording and content of the previously made ISP TF 2018 Recommendations. WG members made additional suggestions for content and language, which were captured in the shared working document. The recommendations that were reviewed included:

- Orders & Results: Consistent encoding of test and their result values
  - Clem commented that LOINC has been the only standardized code for lab tests and stated that updates to the text could be confusing or misleading. Arien responded that the recommendation referenced the result of the values. WG members discussed the wording and agreed that LOINC should be used as the ordering vocabulary and resulting test identification vocabulary for all tests, orders, and results of tests.
  - Hung explained that he added a new paragraph to describe why the IS WG will propose that the universal device identifier (UDI) be included.
  - Hans commented on how information and recommendation from the SHIELD and LIVD presentations were incorporated.
  - Clem stated that when the specimen is built into the test name, adding a requirement to also collect this information in a separate field will create burdens.
  - WG members discussed why LOINC was developed, noting that local labs used inconsistent naming.

# **Action Items and Next Steps**

Homework for the May 3, 2022, IS WG meeting includes:

- Review the second (new) tab "Full Topic List" in the Google sheet and, under your name, prioritize each topic as High/Medium/Low. The WG leads will utilize this ranking to inform the order in which topics will be discussed and recommendations developed.
- Thank you to all WG members who added topics to the worksheet document prior to our deadline for contributions. Please continue to add your observations, recommendations, and policy levers in the WG's Google Sheet.
- Hans, Hung, and Riki Merrick have reviewed the lab-related recommendations pulled from the 2018/2019 ISP Task Force reports and provided redline comments in this Google document. WG members are invited to please continue to review and add comments.

## **Public Comment**

## QUESTIONS AND COMMENTS RECEIVED VERBALLY

There was one public comment received verbally:

Holly Miller, MD: I actually need to drop for another meeting, but I want to mention that Steve put in a URL (<a href="https://oncprojectracking.healthit.gov/wiki/display/TechLab360X/360X+and+Social+Determinants+of+Health+">https://oncprojectracking.healthit.gov/wiki/display/TechLab360X/360X+and+Social+Determinants+of+Health+</a> %28SDoH%29+Referrals) in the chat with an excellent link to the 360X project regarding social determinants of health referrals. At this time, 360X is only contemplating clinical referrals from a clinical environment to a community-based organization to get those social determinants of health needs met.

This same general workflow that is throughout 360X applies, meaning that there is distinct referral and patient ID that persist throughout the referral process and that the steps of the referral are tracked at all points. The difference is, for the SDOH use case, we have anticipated that there will be community-based organization hubs that will manage some of these referrals, but some community-based organizations will have their own software. For example, Feeding America is building their own software and to include 360X processes in their software. They are very actively engaged in 360X and social determinants of health use case definitions. So, I think, for information, please go to the website that Steve has posted. Thank you.

## QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

From Mike Berry (ONC): Welcome to the Interoperability Standards Workgroup. We will be starting soon. Please remember to change your chat setting to "Everyone" if you would like everyone to see your

chat. Thanks!

Hans Buitendijk: The recommended services exchange (ServiceRequest, Task) for referrals. BSeR also addressed referrals in FHIR. Are there plans to align the two approaches?

Holly Miller, MD: 360X is also addressing the SDOH referral use case

Hans Buitendijk: BSeR is closest to 360X, while there are more variances between SDOH and BSeR, alignment would be helpful.

#### Steven Lane:

https://simplifier.net/guide/bidirectionalservicesereferralfhirimplementationguide?version=current

#### Steven Lane:

https://oncprojectracking.healthit.gov/wiki/display/TechLab360X/360X+and+Social+Determinants+of+Health+%28SDoH%29+Referrals

Hans Buitendijk: And the SDOH Integrated Build that has ServiceRequest / Task is here: https://build.fhir.org/ig/HL7/fhir-sdoh-clinicalcare/index.html

Steven Lane: Thank you for this excellent presentation and discussion. We will transition now to the edited Lab recommendations with Hung and Hans.

Mark Savage: Thanks so much, Evelyn and Asha!

Asha Immanuelle: Thanks everyone!

Riki Merrick | APHL: the first bullet should be renamed - having orders and results twice is always confusing

Riki Merrick | APHL: LIVD and LIVD are reference level - giving information about the kind of test / result values, while the second bullet of the lab orders / results is for exchange of the instance data (patient level data)

Arien Malec: At the same time, we have different issues in the closed loop between EHR to LIS to EHR/PH, and between IVD & DE LIS.

Riki Merrick | APHL: agreed

Riki Merrick | APHL: SHIELD addresses both the kind references (in LIVD and LIDR) as well as the instance exchanges (LOI/LRI and ELR)

#### QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

## Resources

IS WG Webpage

IS WG - April 26, 2022 Meeting Webpage

IS WG - April 26, 2022 Meeting Agenda

IS WG - April 26, 2022 Meeting Slides

HITAC Calendar Webpage

# **Meeting Schedule and Adjournment**

Steven and Arien thanked everyone for their participation, summarized key achievements from the current meeting, and shared a list of upcoming IS WG meetings.

The next meeting of the IS WG will be held on May 3, 2022.

The meeting was adjourned at 12:02 p.m. E.T.