



Health Information Technology Advisory Committee Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | February 8, 2022, 10:30 a.m. – 12:00 p.m. ET

Executive Summary

The focus of the Interoperability Standards Workgroup (IS WG) meeting was to continue workgroup planning, receive a presentation from the HL7 Gender Harmony Project, and to work on Charge 1a, which includes reviewing the new data classes and elements included in draft Version 3 of the United States Core Data for Interoperability (draft USCDI v3). TF members discussed the topics and presentation and provided feedback.

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

Agenda

10:30 a.m.	Call to Order/Roll Call
10:35 a.m.	Workgroup Work Planning
10:45 a.m.	HL7 Gender Harmony Project
11:15 a.m.	Charge 1a Draft USCDI v3 New Data Classes and Elements
11:55 a.m.	Public Comment
12:00 p.m.	Adjourn

Call to Order

Michelle Murray, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 10:32 a.m. and welcomed members to the meeting of the IS WG.

Roll Call

MEMBERS IN ATTENDANCE

Steven Lane, Sutter Health, Co-Chair

Arien Malec, Change Healthcare, Co-Chair

Kelly Aldrich, Vanderbilt University School of Nursing

Hans Buitendijk, Cerner

Christina Caraballo, HIMSS

Grace Cordovano, Enlightening Results

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

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

Adi Gundlapalli, Centers of Disease Control and Prevention

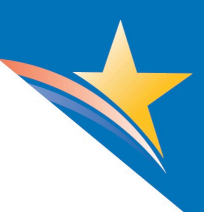
Kensaku (Ken) Kawamoto, University of Utah Health

Leslie (Les) Lenert, Medical University of South Carolina

David McCallie, Individual

Mark Savage, Savage & Savage LLC

Michelle Schreiber, Centers for Medicare & Medicaid Services (CMS)



Ram Sriram, National Institute of Standards and Technology

MEMBERS NOT IN ATTENDANCE

Thomas Cantilina, Department of Defense
Jim Jirjis, HCA Healthcare
Hung S. Luu, Children's Health
Clem McDonald, National Library of Medicine
Aaron Miri, Baptist Health
Abby Sears, OCHIN

ONC STAFF

Michelle Murray, Acting Designated Federal Officer
Carmela Couderc, Office of Technology

Key Specific Points of Discussion

TOPIC: OPENING REMARKS

Steven Lane and Arien Malec, IS WG co-chairs, welcomed everyone. Steven reviewed the agenda for the meeting and invited all attendees to share comments, questions, and feedback in the public chat in Zoom and reminded members of the public that they were welcome to share verbally at 11:55 a.m. during the public comment period.

TOPIC: WORKGROUP WORK PLANNING

Steven 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:
 - Due by April 13, 2022:
 1. 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
 - Due June 16, 2022:
 1. 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 emphasized the need for the IS WG to focus closely on its charges and to add all outside comments and ideas to a parking lot document. He reviewed comments that WG members added to two shared Google documents during offline work and described updates that were made to the documents, including new columns and a list of applicable standards. He thanked Hans and Ricky Bloomfield, of the previous USCDI Task Force 2021 (USCDI TF), for their work on identifying the proposed data elements that were already represented in a Fast Healthcare Interoperability Resources (FHIR) implementation guide (IG), and he invited members to continue this work, which is useful for identifying gaps and working with HL7.

TOPIC: HL7 GENDER HARMONY PROJECT

Arien provided background information on the topic area, which grew from the Health IT Standards Committee (HITSC) recommendations to expand the definition of administrative sex and/or gender to be more inclusive, and he explained that initial work began with the emerging vocabulary standards that were being developed at the time by Facebook and other social media platforms. He welcomed the presenters from the Gender Harmony Project to discuss the progress that has been made since the early work and how it relates to the WG's charge.



Rob McClure, MD and HL7 Gender Harmony Project Lead and President, MD Partners, Inc., and Carol Macumber, Project Co-lead and EVP, Client Services, Clinical Architecture, introduced themselves described their other leadership roles across the industry.

Carol explained that Birth Sex, Administrative Sex, Sex, and Gender Identify are not consistently used or understood and described a use case of a female to male transgender patient (anatomically female but undergoing hormone transition) presenting for imaging and admission. She presented a brief background overview of the Vocabulary Working Group Project, now known as the [Gender Harmony Project \(GHP\)](#), which was detailed in [the HL7 Gender Harmony Project presentation slides on representing sex and gender identity in clinical models](#). The presentation included an outline of their [recent publication in JAMIA: HL7 Informative Document: Gender Harmony – Modeling Sex and Gender Representation – Release 1 \(August 2021\)](#).

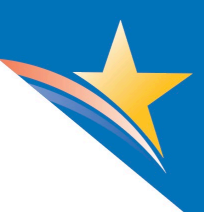
Robert presented the Gender Harmony Logical Model and explained that it is an abstract class model and that each standard will need to map into the specific concrete classes used. It was detailed in the presentation slides, as well as being discussed in the JAMIA article. He reviewed the key aspects of the use of the following GH elements: Gender Identity (GI), Sex for Clinical Use (SFCU), Recorded Sex or Gender (RSG), Name to Use (NtU), and Pronouns. The proposed minimum value sets for each of the elements were included in the presentation slides. He stated that SFCU would be a valuable addition to the USCDI.

Robert shared a project plan of GHP's work, which is currently in Phase 2 with work on a draft underway, and he provided an overview of the changes that need to be aligned. They are specifically targeting FHIR, C-CDA, and HL7 v2. He invited everyone to participate in GHP's work and the balloting process. He reviewed the US Jurisdiction Extension information for GI, including terms, definitions, and applicable vocabulary standards, and provided some cautions, which were detailed in the presentation slides. He cautioned against rolling up more distinct codes into a general code and strongly suggested adding indigenous codes to the list. Canada Health Infoway has requested new SNOMED CT codes for GI, and the GHP is collaborating. He reviewed Sex (Assigned at Birth) (SAAB) which is a type of RSG. He explained how it differs from GI and SFCU and provided some cautions, which were detailed in the presentation slides.

Robert thanked WG members for the opportunity to present and invited them to attend the weekly GHP meetings.

DISCUSSION:

- Arien described commonly held ideas around sex and gender identity and how some of this information has been used in patient matching in systems and clinical workflows. He asked the presenters to comment on how to go from a static healthcare system regarding the concepts of sex, gender, and identity, to a system that is safer and more helpful for patients who do not fit into a binary concept.
 - Robert responded that part of the goal is to transition from the current state to a better system without throwing out preexisting administrative information (important and must be supported but only useful in specific contexts), which includes the use of the elements SAAB and RSG, as well as SFCU and GI. He described an ideal state and stated that the process will include sharing data on administrative sex.
 - Arien summarized various comments made in the Zoom webinar chat, and Arien and Robert discussed the previous use case of a female to male transgender patient. Robert suggested that systems in the future will not just require the entry of “male/M” or “female/F” but that they will be more sophisticated in their use of specified information.
 - The GHP recommended that GI in the USCDI v3 should include at least a four-value value set, where that value set should also accommodate additional values. The USCDI should not imply that a set of hierarchical codes applies. There is a proposal to include SAAB, but Robert stated that, though SAAB is a piece of data that is widely captured, its use is too fluid and driven by jurisdiction; therefore, it should be used cautiously.
 - Carol described work that was done by the U.S. Department of Veterans Affairs (VA) in



which they looked at the many transgender/non-gender-conforming veterans who went back into records to change their “birth sex” information to align with their GI. It turned out that they were making these changes because many felt it was the only way to avoid being misgendered by healthcare providers and staff. However, these changes caused misalignment with other natal sex-based clinical reminders, so the GHP recommends being more consistent and separating these fields so patients do not feel that they need to change them in order to receive respectful care.

- Mark Savage asked the presenters to comment on the use of SFCU as a way to address difficulties related to SAAB. Would they recommend that SFCU is intended to be used in lieu of SAAB?
 - Robert responded that the GHP would rather that SFCU be used instead of SAAB and described how this would be useful in a clinical setting.
 - David McCallie asked if SFCU should be paired with a context to indicate the specific clinical use for which it was captured. Robert responded that GHP’s Logical Model includes a place to capture the context, but when the model is implemented with FHIR, the context will be associated. The idea is that in situations in which clinical assessments are sex-dependent, providers should consider the information that is actually needed to treat the patient. They discussed how to capture this information with the appropriate context and how to avoid creating issues downstream through the use of clinical decision making that may include consideration of hormonal and anatomy-specific observations.
- Steve Eichner commented that behavioral health might have a different definition that is required than physical health. He asked if there is a difference in care delivery.
 - Arien stated that by adding GI to USCDI v3, using at least a four-value value set, would ensure better interactions with patients using their preferred pronouns and identity. He stated that SFCU is an emerging concept that the IS WG should include in its comment on the USCDI v3.
 - Steven Lane explained that the GHP was invited to help the IS WG come up with responses to two of ONC’s original requests: to consider realignment of the USCDI v2 data element of Sex Assigned at Birth with that of GHP’s Recorded Sex or Gender; and to consider realignment of the USCDI Gender Identify value set with that of the GHP. Steven voiced his support and invited other WG members to comment.
 - Arien agreed but stated that the IS WG should keep the GHP’s warnings in mind when making recommendations around realigning USCDI v2 data elements related to sex at birth to ensure that they understand the potential benefits and limitations. Mark agreed with these comments, noting that the GHP has already balanced many considerations and complexities, and suggested that SFCU could be a useful add for future clinical workflows. Members discussed how SFCU could advance through the stages of the ISA process for future inclusion in the USCDI, though it is not currently eligible for inclusion/discussion by the WG.

TOPIC: CHARGE 1A – DRAFT USCDI V3 NEW DATA CLASSES AND ELEMENTS

Steven reviewed Charge 1A and invited WG members to submit feedback on Draft USCDI v3 content and to focus on the following questions:

- Are there any improvements needed in the data classes or elements included in Draft USCDI v3, including:
 - Appropriate and meaningful data class and element names and definitions?
 - Representative examples or value sets used by health IT developers and implementers to fully understand the intent of the data element?
- Are there significant barriers to development, implementation, or use of any of the Draft USCDI v3 data elements that would warrant not including them in USCDI v3?

Steven displayed a version of the New Data Classes and Elements in Draft USCDI v3 that he created in



which he identified the submitters of each new item. He thanked the people who submitted the new classes/elements and invited them to speak about their submissions.

DISCUSSION:

- Grace Cordovano discussed the comments and questions she submitted on the Related Person data element under the Patient Demographics data class. In summary, she stated that this data element needs more clarification to ensure that there is no overlap with the Care Team Members data element. She invited WG members to comment.
 - Mark responded that some of the terms (Related Person's Relationship) were included in draft v3. The co-chairs confirmed, and Grace thanked them for addressing her concern.
- Mark shared several comments on Related Person's Name and Related Person's data elements under the Patient Demographics data class and asked the WG to discuss whether they are already included under the Care Team Member data class. Do the data elements provide any additional information, and should they be removed or reincorporated elsewhere?
 - Hans commented that the definition of Care Team Member is inclusive but asked if Related Person is a subset. He stated that, in FHIR, there is a distinction that is not necessarily a subset, but it is distinct. He suggested that the WG should review the FHIR model and definitions.
 - Steven agreed and suggested that Hans/the ONC team share the definitions in FHIR. He suggested that Care Team Members may be viewed as a subset of Related Person. David agreed and stated that there is confusion in the definitions as to which is more inclusive. Grace described specific contexts of chronically ill patients and patients injured in an accident. Steven asked for links to specific value sets, and Hans included them as links in the chat via Zoom. Mark asked if the intended use of the information is key to identifying and if there are any value sets for the relationship types. Steven suggested that the WG members review the links Hans shared in the chat as homework. The links were added to the spreadsheet used to record comments.
- Mark shared the comments he made on the Disability Status, Functional Status, and Mental Function data elements under the Health Status data class. He recommended adding to these data elements the source and method of collecting the value and the capability to track changes and a history of the value. For example, was the value patient/self-reported or observer-collected? This information may be added to these data elements or to the Provenance data class with a requirement that they be collected and recorded as part of these three data elements.
 - Mark explained that the Gravity Project has been looking at standards for source and method of data collection (in relation to Race and Ethnicity). He added that this information is also important to address noting self-collection for disability, functional status and mental function and asked if these are considered part of the provenance of these data elements.
 - Steven thanked Mark for his comments and asked WG members to respond to them within the document or later in the meeting, pending the amount of available time.

Action Items and Next Steps

IS WG members will be asked to capture their thoughts and recommendations between meetings in two Google documents that will inform the WG's recommendations and streamline the conversations. Members should share a Google email address with ONC's logistics contractor at onc-hitac@accelsolutionsllc.com to be set up with access to the documents. Once WG members have gained access, they may input recommendations and comments into the appropriate documents:

- IS WG Member recommendations regarding Draft USCDI v3 and Level 2 Data Elements (members have full edit access to this document)
- Draft USCDI v3 data elements sheet for recommendations on changing or removing data elements (charge 1a) (members may add comments but may not add lines), consider these questions



- Are changes warranted to these data elements, including definitions, examples, value sets? Should some of these not be included? If so, why (including significant barriers to adoption)?
- Are there significant barriers to implementation that warrant removing these data elements from consideration?

IS WG members will be prepared to engage in conversations with presenters to better inform the WG recommendations. WG members may enter comments on this topic into the Google documents to keep track of individual thoughts.

As homework for future meetings, IS WG members should:

- Follow up on Gender Harmony (GH) Presentation
 - Work group to document decision to align USCDI birth sex with GH recorded sex or gender, and to align the USCDI v2 gender identity value set with the Gender Harmony gender identity value set
 - Sex for Clinical Use (SFCU) considerations – any further discussion necessary? Should WG specifically recommend ONC support for the advancement and/or future inclusion on SFCU in USCDI.
- Review material for Related Person and Care Team Members – links documented in WG spreadsheet
 - Reminder: discussion about possible overlap, opportunity to clarify and/or distinguish the definitions
- All are invited to support Hans in the mapping of USCDI v3 proposed elements to C-CDA and FHIR
- February 15, 2022, Focus: Patient Address
 - Patient Address – Discussion scheduled for Feb 15 (with ONC's Project US@ lead Carmen Smiley, PhD, presenting)
 - Review the [published specification for Project US@](#)
 - Review ONC's current specification for Patient Address (Current and Past Addresses) in Patient Demographics
 - Note: a use case to discuss is related to historic addresses
- February 22, 2022, Focus: Functional/Disability Health Status
 - Consider who should be an invited guest presenter?
- Members are invited to consider areas of interest for future meetings' focus on specific USCDI topics/domains
 - Specific ONC requested topics that you have a particular interest in and/or would be willing to dig a little deeper into.
 - ISA related topics to consider
 - TEFCA standards enablement
 - FHIR roadmap, standards from FAST, patient access leveraging QHINs for national access

IS WG members are asked to consider and identify any personal interest in ISA-related focus areas in which they are willing to dig deeper, perhaps in parallel with the Workgroup focus on USCDI over the coming months, for example:

- TEFCA standards enablement
- FHIR roadmap, standards from FAST, patient access leveraging QHINs for national access
- Additional exchange purposes that are contemplated in CURES but not perfectly enabled via initial TEFCA
- Potential standards/IGs for HIE certification



- SDOH / Gravity data standards
- Race/Ethnicity vocabulary subsets, e.g., CDC
- Lab Orders/Results standards including SHIELD/LIVD, LIS to EHR/PH SYSTEMS
- Public Health (PH) data standards and potential PH Data Systems Certification
- eCR Standards
- Other ISA topics of interest

Public Comment

QUESTIONS AND COMMENTS RECEIVED VERBALLY

There was one public comment received verbally:

Clair Kronk: Hi, can you hear me? Great. This is just one consideration with HL7 and one of the reasons we added the extension functionality to be able to add other things. My question revolves around whether there are Native American reservations that have specific terminology that they would like to use, or, for anyone in Hawaii, if they want to use Māhū, or specific terms in the Northern Mariana Islands, or other indigenous terminologies. Will USCDI allow for those to be extended from whatever gender identity they consider and, if so, have they considered how that might interface places that don't have it? Would it be filled in as a string for additional gender identity or something of that sort?

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Hans Buitendijk: Will be starting that review this week using both latest published and going through ballot process.

Mark Savage: Diversity helps!

Grace Cordovano: Could someone share the link to the use cases that are highlighted on this slide? Would love to take a deeper look and learn more please.

Clair Kronk: I believe it's this link: <https://confluence.hl7.org/display/VOC/Cross+Paradigm+Use+Cases>

Robert McClure: It is a link off the main page here <http://hl7.me/GHP>

Robert McClure: Yes, Clair has it

Grace Cordovano: Thank you!

Robert McClure: We are building more use cases

Steven Lane: There is a bit of background noise. Anyone who is able to mute please do so.

Mark Savage: Welcome, Clair! So glad to have your help.

David McCallie: given the cautions about avoiding “roll ups” and given the continual cultural evolution of gender identity, maybe we should just be capturing text instead of codes?

Steven Lane: Is SFCU intended to be time-bound and/or context specific? Asked another way, should an individual have a single permanent SFCU for use in all situations?

Mark Savage: I think the suggestion was no, SFCU is not permanent over one's life.

Mark Savage: *not necessarily



Steven Lane: Thanks @Clair.

Carol Macumber: SFCU has a cardinality of 1 to many and therefore more than one can exist in a record at any time and be valid for varying periods.

Steven Lane: Key question for Gender Harmony: Would you recommend that ONC include ALL of the 5 GH data elements, as defined and specified in the coming IGs, in USCDI V3?

Leslie Lenert: Are there use cases that this representation has difficulty with?

Steven Lane: I do not see SFCU listed in the ISA web site at level 2, for potential inclusion in USCDI, or at the lower levels for future advancement. Am I missing this? It seems that this would force ONC to potentially embrace some but not all of the GH standards recommendations. Is this a valuable step forward without implementing the full set all at once?

Arien Malec: I don't believe you are missing this — my interpretation of the clear sense of GH WRT the WG charge of contemplating SAAB is "don't"

Leslie Lenert: Without adding Sex for Medical Use? Does that make sense?

Steven Lane: Les - That is not an option if it is not a Level 2 data element.

Mark Savage: Thank you so much Carole and Rob and GHP team! Both for this presentation and help but also all the work behind it and the learnings to come.

Mark Savage: *Carol

Hans Buitendijk: <https://build.fhir.org/relatedperson.html>

Hans Buitendijk: <https://build.fhir.org/careteam.html>

Mark Savage: Maybe better to drop "subset" and think of Venn diagram and amount of overlap.

Hans Buitendijk: For related Person relationships: <https://build.fhir.org/valueset-relatedperson-relationshiptype.html>

Hans Buitendijk: And to get an idea of the roles of a care team participant to compare "relationships" <https://build.fhir.org/valueset-participant-role.html>

Steven Lane: @Grace - I agree that the current presentation is confusing. It would be helpful to at least *[sic]* flag the items in Level 2 that are also in Draft V 3

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

Resources

[IS WG Webpage](#)

[IS WG – February 8, 2022 Meeting Webpage](#)

[IS WG – February 8, 2022 Meeting Agenda](#)

[IS WG – February 8, 2022 Meeting Slides](#)

[HITAC Calendar Webpage](#)



Meeting Schedule and Adjournment

Steven and Arien thanked everyone for their participation and shared a list of upcoming IS WG meetings. Mark commented that the WG should work on distinguishing between exchange standards and terminology standards going forward.

The meeting was adjourned at 12:00 p.m. E.T.