



Health Information Technology Advisory Committee Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | March 17, 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 to work on Charge 1, which included reviewing the new data classes and elements from draft Version 3 of the United States Core Data for Interoperability (Draft USCDI v3) and considering data classes and elements in Level 2 that might be appropriate to add to USCDI v3.

There was one public comment submitted by email, 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 Plan
10:40 a.m.	Draft USCDI v3 IS WG Member Recommendations
11:50 a.m.	Upcoming Charge 1 Meetings
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 10:31 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

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

Sanjeev Tandon, Centers of Disease Control and Prevention (*Attending on behalf of Adi Gundlapalli*)

Kensaku (Ken) Kawamoto, University of Utah Health

Hung S. Luu, Children's Health

David McCallie, Individual

Clem McDonald, National Library of Medicine

Mark Savage, Savage & Savage LLC

Abby Sears, OCHIN

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

Ram Sriram, National Institute of Standards and Technology



MEMBERS NOT IN ATTENDANCE

Kelly Aldrich, Vanderbilt University School of Nursing
Medell Briggs-Malonson, UCLA Health
Hans Buitendijk, Cerner
Grace Cordovano, Enlightening Results
Thomas Cantilina, Department of Defense
Christina Caraballo, HIMSS
Rajesh Godavathi, MCG Health, part of the Hearst Health network
Jim Jirjis, HCA Healthcare
Leslie (Les) Lenert, Medical University of South Carolina

ONC STAFF

Mike Berry, Designated Federal Officer
Al Taylor, Medical Informatics Officer
Carmela Couderc, Branch Chief, Terminology Content and Delivery, Standards Division
Matthew Rahn, Deputy Director, Standards Division

Key Specific Points of Discussion

TOPIC: OPENING REMARKS

Steven Lane and Arien Malec, IS WG co-chairs, welcomed everyone and noted that several WG members were not in attendance due to their concurrent involvement with the Healthcare Information and Management Systems Society (HIMSS) Conference 2022. Steven reviewed the agenda for the meeting and invited all attendees to share comments, questions, and feedback in the public chat in Zoom. He reminded members of the public that they were welcome to share verbally at 11:55 a.m. during the public comment period. Steven thanked Hans for his work on mapping the new submissions to the C-CDA and HL7 implementation guides (IGs).

TOPIC: WORKGROUP WORK PLAN

Steven highlighted areas of focus, which were detailed in the [March 17, 2022, IS WG presentation slides](#), and 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.

TOPIC: DRAFT USCDI V3 IS WG RECOMMENDATIONS

Steven invited the submitters of specific recommendations to present on the following draft USCDI v3 data classes and elements and asked WG members to share feedback:

- Laboratory data class (submitter: Hung Luu)
 - Instrument Unique Identifier data element



- Specimen Source Site data element
- Test Kit Unique Identifier data element
- Values/Result Status data element
- Provenance data class (submitter: Mark Savage)
 - Author data element
- Health Status data class (submitter: Terry O'Malley)
 - Health Concern data element
 - Disability Status data element
 - Functional Status data element
 - Mental Function data element
 - Pregnancy Status data element
 - Smoking Status data element
 - SDOH Assessment data element?
- Complete review of Health Status (Disability, Functional Status, etc.) – consider renaming and redefining
- Add Immunization Status

Hung Luu [presented recommendations for Laboratory data elements](#) and invited WG members to share feedback. Hung thanked the WG for the opportunity to present, noted that his suggestions were based on personal experiences with the Food and Drug Administration's (FDA) Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care (SHIELD) Initiative, and highlighted personal experiences related to personal protective equipment (PPE) related needs and mapping patient decision support to the EHR during the early days of the COVID-19 pandemic. He described how information was mapped from external locations to the EHR, including the decision-making process and how information was tagged in the system. He described clinical interoperability issues that were identified with 80% of the external results due to their lack of necessary information and variations in the ways in which data were represented. He described the challenges he encountered and explained that these issues could be solved up front if these results were mapped to a standardized ontology, such as SNOMED.

Then, Hung described how quantitative results from differences in devices and test kits are used to grade performances across peer groups. He stated that these differences are related to differences in instrumentation across laboratories which must be accounted for in the results. He described an example of how one LOINC code could be used to report the results of several different tests within one class and highlighted how using just one LOINC code for this data class is inappropriate without the inclusion of information around instrumentation and kit information. Without adding this information to USCDI v3, laboratories will lack the data necessary to determine equivalency. He discussed how instrumentation at his institution, Children's Health, is technically "off-label," as they were not cleared for use for children (as a protected population). He described how the FDA is using real-world evidence to perform post-market surveillance and expand initial indications to populations that have not been evaluated for clearance. He stated that this is a health equity issue that also has ramifications for clinical interoperability.

Hung described how issues could arise related to information that is suppressed in the chart or through mistakenly mapped external results. He emphasized how patients could undergo unnecessary or incorrect treatments, imaging, and other testing, based on these laboratory mistakes. He proposed that in order to make clinical interoperability available to everyone, the information should be available to the laboratory and must include not just the name of the test but also information on the specimen, source, and type, as well as the instrument platform and test kit utilized. His recommendations were included in his presentation slide deck.

Mark Savage presented the items he submitted for draft USCDI v3, which included Health Status, Sex and



Gender, Health Insurance, and the Provenance data class/Author data element. He described each and invited WG members to share feedback.

DISCUSSION:

- Arien discussed the complexity of data elements within the Medications and Laboratory data classes and the applicable vocabulary standards. He asked AI to comment on whether individual elements should be added iteratively to Laboratory, just as was previously discussed for Medications and how the USCDI measures and manages these very complex objects effectively.
 - Steven explained that the WG had previously discussed how to meaningfully display the current medication lists and commented that Laboratory was different, though there are challenges exchanging and integrating discrete lab data into systems. Because the WG made a decision to defer adding new data elements to the Medications data class, it does not mean that they must make the same decision on Laboratory. Arien asked AI to comment on the level of specificity the WG should use in its recommendations.
 - AI responded that ONC revisits the level of complexity needed for the core set of data in electronic health records (EHRs) and each data class and element with each review and versioning cycle of the USCDI. Previously, they considered expanding these data classes but did not choose to do so.
- Hung reviewed his recommendations to update/add data elements under the Laboratory data class and explained how they would benefit hospitals with fewer resources and reduce mistakes and patient harm.
 - Arien commented that there are no numeric or qualitative results and no reference range as a data element under Test Result in USCDI. He suggested that the WG should make recommendations to point the USCDI towards making the underlying ontologies more specific (for defining results) instead of adding additional specific data elements without associated reference ranges.
 - Steven commented that he shared his thoughts in the public chat, noting that Reference Range is not a submitted data element anywhere in the USCDI at this time, and he asked the WG to keep this discussion brief in the interest of discussing it further at a future meeting.
 - Clem asked why COVID tests (that had specimen information attached) that were entered into the LOINC In Vitro Diagnostic (LIVD) mapping tool were not helpful in the process Hung described. Also, he asked how Hung differentiated the tests. Hung explained that there is insufficient functionality in EHRs for laboratories to capture, transmit, and support some of the information (considered vital by the Department of Health) included with those tests. He stated that the government requires the inclusion of data that is not currently supported in the ecosystem.
 - Ike commented that the process of transmitting laboratory results and reporting between labs, hospitals and public health must be reexamined and reconciled. Also, the relationship between the USCDI and USCDI+ (use cases or otherwise) must be defined to avoid confusion. He cautioned them to consider any additional, unintended burdens labs could face as a result of the WGs recommendations around what data are necessary.
 - Steven thanked everyone who submitted feedback on this topic in the public chat and noted that all comments would be reviewed and compiled as soon as possible, ideally before the WG's next discussion on this topic. He reminded everyone that ONC included two additional data elements in Draft USCDI v3: Specimen Type and Result Status. He asked the WG to consider which data elements that ONC identified as Level 2 should be brought forward into the final version of USCDI v3.
- Mark reviewed the recommendation that he and Abby submitted that recommended alignment with the Gender Harmony Project's (GHP) framework and the five data elements (Gender Identity, Sex for Clinical Use, Recorded Sex or Gender, Name to Use, Pronouns) and the value



sets which work together to represent sex and gender diversity and improve patient care outcomes. He explained that fields from the USCDI that add critical data should be kept (“Additional Gender Category or Other, Please Specify” and “Choose Not to Disclose”) and added that the GHP is currently drafting a supporting proposal (work underway following their presentation to the WG). He specified where the GHP recommended including these elements and recommended tracking the source of the value and method of capture.

- Arien asked if the data element Sex for Clinical Use was included in Mark’s recommendations, noting that the USCDI might not be ready to include it now. Mark responded that this recommendation has always included the data element and explained that he has found LOINC codes and HL7 Fast Healthcare Interoperability Resources (FHIR) specifications for Sex for Clinical Use and for Recorded Sex or Gender. He shared links to the GHP’s articles as justification for including these data elements. Arien asked if interoperability resources are in place to support these elements, noting that though Sex for Clinical use may be the same for many patients, it could be malleable and context-specific for others. Mark responded that the GHP stated that though these values might differ, they could be supported for interoperability.
- The WG agreed to accept and include the recommendations to the HITAC, pending updates to the wording during offline work.
- Mark reviewed the recommendation that he submitted to add the Level 2 data element of Author to the Provenance data class in USCDI v3 and shared his recommendation to the HITAC and justification. He emphasized the particular importance of noting whether values are self-reported or clinically observed to address issues related to health equity and how patients self-identify. He explained that the Social Security Administration (SSA) submitted this element initially, and they asserted that over 3 million disability applicants need to use it. He invited the WG to share feedback.
 - Steven commented that there are EHRs that could face challenges in adding this element by specifying the author individually (e.g., Who was the original author? Who was the last person to modify the data?). He suggested adding the element to simply specify if the data source was patient, caregiver vs. clinician, or other care team member.
 - David stated that the class of the author might be known, while the exact author is unknown, so he suggested that “Source” could be used instead of “Author.” Steven responded that ONC has leveled “Source” as Level 1, “Author” as Level 2, and “Author Role” as Comment Level and that all were suggested by different stakeholders with different supporting use cases. He asked AI to comment on ONC’s perspective on whether the WG could recommend including the Level 1 or Comment Level elements in USCDI v3. Mark emphasized that “Author” is clearer regarding self-reported data and that the GHP presentation showed that the birth certificate could be a source while someone else is an author. WG members discussed differences in the terms.
 - AI commented that ONC has made changes to given definitions for data elements to make them more applicable across multiple, broader use cases, which could involve changing the scope of any of the data elements the WG discussed. He discussed several options that could inform the WG’s recommendations, and Steven captured feedback from AI, WG members, and the public comments entered in Zoom. Arien asked if Author/Source could be used, but AI stated that this would have to be a separate recommendation, as the specific term was not shared through ONC’s submission system. Author/Organization has been in place since USCDI v1.
 - The WG agreed to draft a recommendation to add Author to the degree necessary to differentiate and identify data that is sourced from the patient or caregiver (separate from the healthcare provider/team).
- Mark reviewed the recommendation that he submitted to add data elements of Disability Status, Functional Status, and Mental Function to the Health Status data class in USCDI v3 and shared his recommendation to the HITAC and justification. He explained how he pulled together recommendations shared by presenters to the WG at a previous meeting, including adding the



source and method of collecting the value and invited members to share feedback. He noted that the recommendation would include work soon to incorporate five other categories of questions and a data element that are leveled lower or not yet supported.

- Mark commented that the presenters affirmed that “Disability Status” is the correct term but recommended the use of the terms “Cognitive Status” and “Functional Status,” rather than “Mental Function,” as the wording for the other two data elements.
- Arien explained that, at its previous meeting, the WG discussed adding “Disability Status” as an assessment, which would have a minimum vocabulary that is the inclusion of the ACS Washington Group value set. Also, he summarized a previous discussion that “Disability Status” is similar to a vital sign (observations that can and do change over time) than a demographic data element (semi/permanent characteristic). He stated that he prefers the assessment approach. Mark responded that the presenters preferred that it be included as (and works better as) a demographic element because it even has implications for clinical workflows. He raised the issue of including different elements as static or changeable could have implications for other elements.
- Steven encouraged WG members to focus on getting the data elements into the USCDI, as their location could be updated later. He commented on the WG’s discussions around the importance of including metadata on the provenance of data. AI commented that the WG could make a recommendation to specify the collection method.
- Ike shared several comments, including that the terms evaluation and status should be reviewed. He suggested that these elements should not be included in the demographics class in the USCDI; all reasonably related data elements should be aligned within the same data class. He discussed the real-world use case of his health condition, noting that it is a particular diagnosis code for a particular disease, not a disability. The disease can impact his disability status, but it is not his disability status. Coding statuses do not support or reflect the progression of the disease through different values or levels that would be useful/relevant to include in the medical record. He suggested that both structured and unstructured data should be included in the recommendation to better capture information in a patient’s medical record to improve care outcomes.
- WG members discussed wording options and decided to recommend adding “Mental/Cognitive Status” as a data element. They acknowledged the discussion around under which data class the elements should be added, noting the issues they identified, and they will encourage ONC to make the determination. The WG also recommended capturing the method and source of collection.
- Mark reviewed the recommendation that he submitted to add Pregnancy Status as a data element under the Health Status data class in USCDI v3 and shared his recommendation to the HITAC. He explained that the USCDI Task Force 2021 recommended its inclusion as a high priority within its recommendations to the HITAC. Mark discussed two levels of terminology, including capturing the intent to become pregnant, and explained that he learned from subject matter experts that there are important value sets for Pregnancy Status that have critical implications for care that have not been included.
 - Steven explained that several related data elements have been submitted but that have only been leveled by ONC at the Comment Level. AI reminded WG members that the original intent of Pregnancy Status was to capture the impact of other conditions on pregnancy or pregnancy on other conditions. The use case that led to this submission was a screening necessary to evaluation for Zika. He stated that some of the recommendations would alter the initial scope of the recommended data element and that other elements could provide a closer use case to the intent of the new recommendation.
 - Steven suggested that the recommendation of an additional value set should be added as a public comment, and AI explained that ONC did not define the value set, as there is a wide range of options around pregnancy status (any possible complications, pregnancy progression, etc.). He stated that the WG’s recommendation could include mentions of specific value sets, and Steven invited WG members to share feedback on whether they



wanted to recommend specific value sets or to wait for additional public comments to guide their suggestions. Arien commented that the WG must choose whether to confine their recommendations to the specific use case of Pregnancy Status screening in relation to Zika or to make a broader recommendation while leaving the industry to make decisions on value sets/ontology.

- WG members discussed options and decided to recommend that, even though this data element was recommended by the CDC for a specific reason (Zika), the WG is not limiting its support for the element to that use case. The WG will not point to a specific value set or ontology (currently unknown) and will suggest that Pregnancy Status be added. In the period between USCDI v3 finalization and inclusion in the ONC Standards Version Advancement Process (SVAP), the industry should coalesce on a recommended ontology and list of values sets. Mark offered to help ONC in the future and to work on the wording of the recommendation.
- Steven reviewed the overarching recommendation to add the Health Insurance Information data class and data elements (Coverage Status, Coverage Type, Relationship to Subscriber, Member Identifier, Subscriber Identifier, Group Number, and Payer Identifier) in USCDI v3.
 - All WG members agreed to recommend including the data class and elements. Arien highlighted comments Hans shared on Coverage Type and suggested that the WG's recommendations reflect ONC's need to work with other industry organizations to reconcile the vocabulary for coverage type. All members agreed.

Action Items and Next Steps

IS WG members were 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 document. Once WG members have gained access, they may input recommendations and/or 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), and consider these questions:
- For homework for the March 22, 2022, meeting:
 - The WG will continue to work on individual recommendations as recorded in the IS WG Draft USCDI v3 Member Recommendations (Editable) Google document.
 - Clem will review his highest priority recommendations from the following Entries 2, 3, 5, 6, 9, 11-13, 15, 21-25, 28, 29, 39, 41, 52, 54, 60, 62, 66, 68
 - Hans will review his highest priority recommendations from the following Entries 7, 18, 20, 56, 59, 63, 64, 67
 - Complete review of Health Status (Disability, Functional Status, etc.) – Entries 26-36, 70
 - Complete review of Hung Luu's Laboratory recommendations – Entries 38, 40, 42, 43
- The WG will continue to use the Draft v3 Data Elements for ISWG Review Google document as a reference to inform any recommendations that pertain to any Draft USCDI v3 data elements.
- Friday, March 25, 2022, is the cut-off for new recommendations on the editable spreadsheet, but WG members were encouraged not to wait until the last minute share input.
- The WG will not be able to work through and discuss every one of the 70 recommendations, so WG members were asked to please review other lines to identify which should be prioritized by the WG.
- Individual WG members were reminded that they can submit public comments on the Draft USCDI v3 or Level 2 tabs on www.HealthIT.gov/USCDI for those recommendations the WG is



unable to include but that members would like to advance to ONC.

- The WG will try to work through the whole spreadsheet of recommendations over the next meetings, reserving the March 29, 2022, meeting for recommendations that came in that week, followed by prepping the recommendations transmittal for review and finalization on April 5, 2022. The WG must deliver the recommendations letter to the HITAC co-chairs the week of April 4, 2022.
- Members are invited to consider more ideas on the WG's Task 2 work on the Interoperability Standards Advisory (ISA) Standards, which should start in early April 2022, following the completion of the WG's Task 1 recommendations to the HITAC. ISA related topics to consider include:
 - 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
 - Social Determinants of Health (SDOH) / Gravity data standards
 - Race/Ethnicity vocabulary subsets, e.g., CDC
 - Lab Orders/Results
 - 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:

Ulrike Merrick: Hello, this is Riki Merrick with the Association of Public Health Laboratories (APHL), and I wanted to thank you for considering adding those lab data elements. I've been trying to get those in for a while because they are essential to making lab data interoperable. I just wanted to share that aloud, and I have left many comments in the chat.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Steven Lane: Welcome everyone. We encourage the public to contribute to the discussion and the public record here in the Chat.

Raj Dash: Agree with Arien Malec's statement. There is no single coding scheme to capture complex laboratory tests. Multiple data elements are required to meaningfully compare results. Looking forward to Dr. Luu's proposal (Raj Dash, MD from Duke Health)

David McCallie: USCDI feels like a powerful priority setting service, but should stay away from details of encoding complex content domains

Ulrike Merrick: Specimen source site is a CLIA requirement; instrument and test kit unique ID are important to figure out if laboratory results are comparable - so if you want to be able to aggregate results across the patient's record over time, or across different patients for population these values are critical. (Riki Merrick, Association of Public Health Laboratories)

Steven Lane: Great public comments. Keep 'em coming!



Andrea Pitkus: Multiple data elements and codes are required for lab data (many by law for public health reporting, cancer reporting, etc.). Andrea Pitkus Laboratory Informaticist

Arien Malec: Conceptually, a Test/Result is an object that has the required and optional data elements specified in the HL7 LRI specification.

Andrea Pitkus: Specimen Type and/or Source is vital as public health reporting criteria differs based upon them. (i.e. MRSA is usually not reported on skin/non sterile site, while it is a reportable condition from a sterile site like CSF or Blood)

Steven Lane: The key question for this Workgroup, HITAC and USCDI is whether meaningful iterative changes can be made by adding a modest number of specific data elements to the laboratory data class so as to facilitate more robust discrete result interoperability. We should not expect to make a final WG decision on this today, but will within the next week or so.

Andrea Pitkus: A number of test result interpretations vary based upon specimen type and/or source. Sensitivity / Specificity varies for COVID depending on specimen site (oropharyngeal, nasal, oral)

David McCallie: The standard already accommodates these fields (I think.) So this is about making certain fields required that are now optional? Does USCDI have the power to do that?

Andrea Pitkus: Specimen Type, Source, their qualifiers; result values-qualitative, organisms, for lab data were part of MU requirements and implementation guides.

Ulrike Merrick: specimen type is a required element in LRI - BUT that is for exchanging the data; LRI (and other data exchange specifications have no authority in telling the receiver what to do with the data once received); USCDI will ensure that lab data receivers retain that information in a discrete fashion.

Al Taylor: @David Yes, when a Health IT module adopts a new version of USCDI through voluntary update using Standards Version Advancement Process, the Health IT module certifies to the ability to capture and exchange all data elements in the new version of USCDI.

Andrea Pitkus: Specimen Source isn't always provided (especially during pandemic), thus labs or providers cannot report to public health. Adding to USCDI will help ensure the data are needed across the health continuum.

David McCallie: @Al, thanks. But making certain fields required would cause potential rejection of lab sources that don't have that information. Too restrictive if mandatory?

Al Taylor: @Andrea, this is precisely why ONC added specimen source data element to Draft USCDI v3.

Arien Malec: For full disclosure, I'm on team "whole hairball" — either we treat USCDI as an ontology with the specificity that implies, mapped to interoperability specifications like LRI, *or* we don't. I really don't know why/how to pick specific data elements out as important for USCDI. Why instrument, but not reference range?

Raj Dash: @David McCallie, @Al: to my knowledge there is no single standard that accommodates the variations in results that determine equivalency of results. Dr. Luu is spot on that specific data elements such as test kit and instrumentation are critical. If the goal is interoperability then such data elements must be required. (Raj Dash, Duke Health)

David McCallie: I'm of the "ought to" camp - USCDI should say what OUGHT to be included, but not reject messages that don't or can't That's a CLIA issue?

David McCallie: @Raj - thanks. Is this data always available at the source?



Andrea Pitkus: CLIA Test Report requirements: <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-K/subject-group-ECFR9482366886d579f/section-493.1291>

Steven Lane: As always, USCDI simply says, if you have it send and receive it as a part of this element. None of these require collection or rejection of data.

Raj Dash: @David, yes, at the source.

Ulrike Merrick: I thought USCDI is not necessarily just about what is in a message - I though USCDI is about data elements the EHR-s needs to support in a structured manner.

Ulrike Merrick: Yes the data is available at the source - the IHE LAW specification, that is for data exchange between instruments and LIS supports reporting of instrument and test kit information

Andrea Pitkus: HHS COVID required elements include Device Identifier (test kit/platform), source, result values, etc.: <https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html>

Steven Lane: Adding data elements to USCDI will, in time, require certified EHR systems to be able to manage and exchange these data elements discretely.

David McCallie: I certainly agree that this information ought to be present (when available.) But I'm unclear on whether USCDI is the way to accomplish this.

Raj Dash: If USCDI can capture all of these data elements, and EHR's support them, then the effort we require to bring in external results will diminish tremendously. Important for patient safety! Very nice and to the point Dr. Luu.

Adam Davis: I'm curious how we reconcile that in the same EHR there is a results console where a provider can manually enter results from a faxed lab sheet that has none of this specificity of information and those results will act as local results. It seems we're holding labs obtained through CCD's or HL7 feeds to a much higher standard than 1 that is typed manually by a provider.

What impact do we think that adding these fields to will allow easier or make mapping more challenging. The biggest challenge of lab interoperability today is the intense labor needed for individual health systems to map.

Ulrike Merrick: LRI already requires these elements to be sent, if available - instrument/test kit data is RE

David McCallie: @Arien - ontologies are good, but can be too static for the dynamic issues here, where new tests and categories are emerging in real time

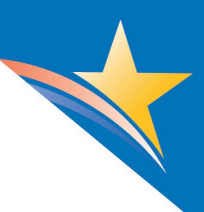
Andrea Pitkus: Currently there are developers omitting some of these key lab data elements necessary for interpretation and use of lab data by many users/scenarios. This can be a patient safety issue.

Arien Malec: The "Values/Results" element says "Documented findings of the analysis of a tested specimen. Includes both structured and unstructured (narrative) components."

Arien Malec: It's a sort of handwave at an implied ontology.

Ulrike Merrick: the SHIELD LIVD document encodes all the allowable specimen types and then picks a LOINC that covers most of them

Andrea Pitkus: The challenge with some LOINCs is they are XXX specimenless [*sic*] LOINCs and lack needed detail for many scenarios in pathology and infectious diseases. Thus the specimen type and source need to be provided and not rely on LOINC.



David McCallie: @al - where does CLIA intersect with USCDI, in terms of required data about a lab test?

Raj Dash: USCDI is not compliant with CLIA 493.1291 if that remains. COVID results are very simple compared to most others so not the best use case. If the goal is interoperability then I don't see how we can get away with not including the relevant data elements to determine result equivalency / comparability. (Raj Dash, Duke Health)

Raj Dash: @David, specifically 493.1291 line item d speaks to reference intervals (Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.)

AI Taylor: @David, USCDI is standards agnostic, meaning that outside standards do not necessarily directly apply to USCDI, except to the extent those outside standards inform existing data elements in USCDI or submissions for new ones. It was in this way that LIVD codes (value sets) informed the additional data element of specimen type.

David McCallie: historical results have to be interchanged as well, so you can't really require a field that isn't historically present. You can "ought" it, and put pressure on the originating labs to include it when present. but hard to require it?

Arien Malec: To be clear, I'm **not** opposed to better specifying the underlying ontology for medications or lab data, but I'd rather do that by pointing USCDI at an underlying ontology or model, where one exists, or at the implied model defined by interoperability specifications, where one does not exist.

Andrea Pitkus: Ideally, all lab data should have the same level of standards adoption. Keep in mind most labs have not been required to adopt standards, but some have voluntarily (messaging, terminology) as they were not eligible for MU incentives (except eligible hospital labs). Pandemic magnified impacts. CLIA doesn't specify the how (created in paper, fax, electronic)

Ulrike Merrick: @ Carmela - lab results are quantitative or qualitative - which has several different types: ordinal (there is an order to the results), nominal (a list of organisms for example), narrative (free text, not easily codable)

Ram Sriram: @Scott: Right now we seem to focus on additional data elements. It would be interesting to see how semantic interoperability can happen within this context. Will require some ontological reasoning.

Adam Davis: Do CLIA regulations apply when you are getting labs from another health system that were not ordered by your providers? When we're talking about lab interoperability we are talking about a fundamentally different relationship than when we're talking about lab ordering and resulting within a health system or between a health system and a reference/specialty lab. Since *[sic]* the beginning of time providers have seen "outside" labs and made decisions based on them and those labs were often analog. I think one could think of lab interoperability as trying to replace that type of sharing rather than the type of sharing between labs and the ordering provider/system which CLIA applies to.

Andrea Pitkus: USCDI is helpful with more consumer based testing and devices where these data may be collected or exchanged too.

David McCallie: @AI - CLIA is a regulation, not a standard so what I meant was where the regulatory pressure can best come from

Arien Malec: CLIA applies to transmission from a CLIA regulated clinical lab; it does not apply to secondary interoperability from a provider to another entity.



Andrea Pitkus: Here's a link to the CLIA regulations: <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#subject-group-ECFR9482366886d579f>

Ulrike Merrick: @Adam - as Dr. Luu pointed out not knowing the details resulted in their healthcare system re-testing patients, because they couldn't be sure, if the results they came with could *[sic]* be treated the same *[sic]* as their own.

David McCallie: @Arien, right but CLIA could ensure that these data fields are always "produced" for downstream consumption. Perhaps it already does that.

Andrea Pitkus: fyi, there are CLIA requirements where testing is sent to a referral lab that the receiving lab can't modify the results data.

Adam Davis: @arien. That's right, and I think we do a disservice to lab interoperability to hold interoperability to those standards.

@Ulrike I understand those concerns, but there's a bunch of labs that providers could act on with a lot less specificity. HgbA1c, Lipids, no provider is checking which test kit it was run on. We're throwing out a ton of potential benefit here.

Andrea Pitkus: Other CLIA requirements such as a corrected report (including errors, amendments, etc.) apply to the "individual using the results" which can be the patient and take a path "hopping" through multiple systems. [https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#p-493.1291\(k\)\(2\)](https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#p-493.1291(k)(2))

Mark Savage: <https://loinc.org/loinc/99501-9/>

Steven Eichner: Is there a need to re-analyze USCDI vs. public health laboratory results reporting vs. LR1?

The outputs of the analysis would confirm if/what gaps exist. If a gap does exist, and the element is in PH data reporting it, it should be relatively easy to evaluate the data element's maturity.

Ulrike Merrick: @Adam - that is why SHIELD is trying to identify test types where "intermingling" of results has no patient risk - specifically where the tests all are calibrated to an international standard

David McCallie: @ike +1

Andrea Pitkus: It would be helpful to get CLIA folks to offer clarification with expanded electronic use as to which parts of the regulation have specific "end points" and which do not. Especially in consideration of consumer / device receivers.

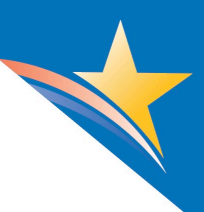
Ulrike Merrick: @Steve: LRI already has that "gap analysis" - it has the LRI_PH profile component - that shows what is different for PH reporting

Steven Eichner: A potential risk in maturity evaluation is that test kit information may be available and/or more complete ONLY for specific conditions.

Clem McDonald: Every COVID test approved under emergency use by the FDA was incorporated into the LIVD platform within 3 days (supported by the IVD industry, CDC, FDA and Others. and these codes include the specimen Thewhole *[sic]* list is Here <https://loinc.org/sars-cov-2-and-covid-19/>

Clem McDonald: Apologize-- I have to leave for another meeting.

Andrea Pitkus: CDC also has HIV LIVD tests/codes: <https://www.cdc.gov/hiv/xls/guidelines/cdc-hiv-diagnostic-tests-loinc-map.xlsx>



David McCallie: @mark - is "source" different from "author"? Sometimes author is not known, but perhaps source = patient would be adequate?

Steven Eichner: @Ulrike Great! so if we compare LRI and draftV3, the gaps can be identified. We'd need, as I laid out above, a method for determining if any element is in LRI and is NOT in USCDI, is the element mature enough for inclusion in the USCDI.

Ulrike Merrick: Thanks Clem - yes - each row in that spreadsheet represents a test-kit / instrument combination that is then mapped to LOINC for both order and performed test = the test that reports the result value; it also includes the SNOMED CT codes for codifiable result values as well as the SNOMED CT codes for all allowable specimen types

Clem McDonald: I think steven's suggestion is GREAT

Clem McDonald: also this item has been worked heavily in FHIR, and we should be sure to look at what they say

Ulrike Merrick: I agree with @Steven - but the elements for consideration should be R, C or RE (meaning "Must Support" for those who speak FHIR better).

Clem McDonald: This definitely needs more research and work, but starting simple would be most successful

Ulrike Merrick: Actually the lab work in FHIR is not up to the level of detail in LRI

Rita Torkzadeh: I would think self-reported data applies to other USCDI data classes such as SDOH Goals and Problems, and Clinical Tests for an individual collects from home (e.g. nasal swab)

Clem McDonald: The other problem is that *[sic]* we are unlikely to have an ID for all possible "authors"

Andrea Pitkus: concur w Riki. Much work is needed to get FHIR lab data ready for daily reporting needs (including CLIA elements as specimen type is missing from US Core example currently)

Ulrike Merrick: I agree that we need to differentiate between source and author - personally I think source is more important than author

David McCallie: Source is sort of like "authority" and author is more like "identifier" So maybe we combine them, when both are known

Ulrike Merrick: I don't like mixing author and source

Andrea Pitkus: There's different trust between health professional and non health authors/sources

David McCallie: The more you talk about these examples, the more it makes sense to focus on "source" rather than specific "author"

Steven "Ike" Eichner: What of the use of the label/term "editor?" That may be a helpful term if we are expecting change (e.g. there was an original report and the value is now changed. Or is that a new report with an new author

Steven "Ike" Eichner: I'm suggesting again an alternative term to "status." How about "evaluation?"

David McCallie: @arien - I agree that these "statuses" can rapidly change, and are more like observations than like demographics

David McCallie: Ideally nothing in the record is static, but existing systems may make that distinction



Arien Malec: The note on

Arien Malec: The note on malleability here is that one expects a single GI to be reflected in demographics (representing the current GI), whereas one might want to see functional status or disability status as a time series — the change in time is material/important.

Rita Torkzadeh: What Mark is recommending with regards to Disability status makes sense with regards to helping patients make appointments (In scheduling my last med appointment I was asked whether I had accessibility issues which should be common practice)

Arien Malec: To @steven's point, USCDI makes no implication on EHR workflows; my point is about cardinality and time series (the same point that @ike is currently making).

Steven "Ike" Eichner: Have substance abuse concerns been considered explicitly? Do they need to be today?

David McCallie: part of the problem about which class these elements go into is that we have use-cases for a summary of the issue, versus use-case for time-series of more granular data (e.g. PT/OT and range of motion improvements)

Andrea Pitkus: For laboratory specimen collection, the specimen collection procedure (i.e. biopsy, resection, urine clean catch vs catheter, venipuncture vs fingerstick / heelstick) [*sic*] should be included as well. Many collection procedures are precoordinated with specimen types and/or specimen sources such as Breast Fine Needle Aspiration or Urine Clean Catch. (Procedure can be encoded with SCT too)

Ulrike Merrick: + 1 @ Andrea

Ulrike Merrick: During zika knowing that the woman was post-partum was also an important aspect PH wanted to know

David McCallie: I agree with the expanded value set. Useful to more circumstances

Andrea Pitkus: Pregnancy status has been a HHS COVID required data element

Ulrike Merrick: HHS COVID answers only included pregnant, not pregnant and unknown - coded to SCT

Arien Malec: We also have screening for teratogens where intent, use of contraception is important.

Steven Lane: See CDC comments on Pregnancy Status @ <https://www.healthit.gov/isa/taxonomy/term/1651/level-2>

Arien Malec: It's interesting that we have elements that come into USCDI based on a specific use case — because something came in for Zika does not mean that we shouldn't seek to generalize.

Ulrike Merrick: I agree with generalizations

Abby Sears: I highly recommend that we use a broader approach

Mark Savage: For women, pregnancy status is not just about Zika.

Carmela Couderc: HL7 FHIR International Patient Summary has defined a value set limited to the 3 values yes, no, unknown.

Arien Malec: I was intentional about "value sets" b/c pregnancy status may include future intent, history, current status.



Andrea Pitkus: Concur with Riki.

Ulrike Merrick: @ Carmela - using yes / no / unknown limits possible value set members and also it may not be recorded that way, which is why HHS value set uses the pregnant, not pregnant from SCT

Carmela Couderc: @Riki - agree its a very limited value set.

Carmela Couderc: The binding strength is also.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There was one public comment received via email:

Andrea Pitkus, PhD, MLS(ASCP)CM, Laboratory Informaticist, shared the following presentation resource to support the inclusion of laboratory terms in the USCDI: https://www.healthit.gov/sites/default/files/facas/2022-03-17_Andrea_Pitkus_Public_Comment.pdf

Resources

[IS WG Webpage](#)

[IS WG – March 17, 2022 Meeting Webpage](#)

[IS WG – March 17, 2022 Meeting Agenda](#)

[IS WG – March 17, 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 March 22, 2022.

The meeting was adjourned at 12:01 p.m. E.T.