



Health Information Technology Advisory Committee Interoperability Standards Workgroup Virtual Meeting

Meeting Notes | March 22, 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 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 Plan
10:40 a.m.	Draft USCDI v3 IS WG Member Recommendations
11:50 a.m.	Upcoming Chare 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

Hans Buitendijk, Cerner

Christina Caraballo, HIMSS

Grace Cordovano, Enlightening Results

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

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

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

Jim Jirjis, HCA Healthcare

Hung S. Luu, Children's Health

David McCallie, Individual

Clem McDonald, National Library of Medicine

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

Kelly Aldrich, Vanderbilt University School of Nursing
Medell Briggs-Malonson, UCLA Health
Thomas Cantilina, Department of Defense
Kensaku (Ken) Kawamoto, University of Utah Health
Leslie (Les) Lenert, Medical University of South Carolina
Abby Sears, OCHIN

ONC STAFF

Mike Berry, Designated Federal Officer
Al Taylor, Medical Informatics Officer
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. 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 the WG members for their work on specific recommendations and urged members to be judicious in their use of time, given the WG's schedule. Arien invited members to review the updated recommendations in the WG's spreadsheet working document because the co-chairs edited them during offline work.

TOPIC: WORKGROUP WORK PLAN

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.

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:

- Clinical Notes data class (submitter: Hans Buitendijk)
 - Discharge Summary data element



- Procedures data class (submitter: Hans Buitendijk)
 - Reason for Referral data element
- Health Insurance Information data class (submitter: Hans Buitendijk)
 - Coverage Type
 - Coverage Status
- Patient Demographics
 - Related Person Name and Relationship
 - Tribal Affiliation
 - Reason for Referral
- Clem McDonald's submissions
- Complete review of Health Status (Disability, Functional Status, etc.) –renaming and redefining
- 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

DISCUSSION:

- Hans presented his recommendations for several data elements and classes and invited WG members to share feedback. He explained that the key challenge to consider is the timing of standards necessary to support the elements and classes in the certification process.
- Hans reviewed the recommendation that he submitted to add the data element of **Discharge Summary** to the **Clinical Notes** data class and shared his recommendation to the HITAC not to include specifications for specific data in a narrative note.
 - Hans stated that the recommendation, as written, suggests adding unstructured text to a discharge summary document, which is currently a structured C-CDA document. He asked if the WG wants to recommend the use of a different data element type to hold unstructured information and added that some health IT systems do not use discharge summary type notes. Arien distinguished between the discharge summary that is a clinical note and the summary that is a structured document type, which has an implementation guide (IG) attached to C-CDA or a Fast Healthcare Interoperability Resources (FHIR) specification. Arien asked for feedback on the option to amend the language of the recommendation to reflect the distinction between the narrative/ unstructured (Discharge Summary Clinical Note) and structured data element (Discharge Summary Document Type), and Hans commented that the Discharge Summary is the narrative noted, in this context in the USCDI. Ike commented that there is a need for structured and unstructured notes for disability data.
 - WG members agreed that, for this element in the USCDI, there is a need to clearly emphasize that it is an unstructured document which is meant to be added to the other specific Clinical Note types already specified in USCDI v2.
 - Mark asked if there was an intersection between this recommendation and another previous recommendation from the Centers for Medicare & Medicaid Services (CMS) from an earlier workgroup to include the Discharge Medication List in the USCDI. Arien discussed the differences between a discharge medication list and a discharge note, noting that both would typically be included in a discharge summary (structured document type). Al described what is already required to be included in a discharge summary ("A synopsis of a patient's admission and course in a hospital or post-acute care setting. Must contain admission and discharge dates and locations, discharge instructions, and reason(s) for



hospitalization.”) as part of the transition of care certification criteria and commented that this recommendation already aligns and does not add any new requirements for electronic health record (EHR) systems.

- WG members discussed what is intended to be included in the USCDI to ensure interoperability specifications and how to include both structured and unstructured data in the discharge summary. They discussed how to best avoid confusion downstream, and AI commented that ONC wants to preserve the free text/narrative piece, though the content should include the components listed in the recommendation. Ike asked how to make information that is not codified “findable” for relevant, high-priority patient care and described a use case related to his personal care. Is there a way to prioritize data to ensure that critical information is not overlooked?
- Steven shared a new ONC clarification to the recommendation, which WG members discussed, with Hans commenting that there is no standard way to validate that specific structured data elements are contained within narrative/unstructured notes within USCDI. Steven commented that this recommendation was based on a straightforward suggestion from the Electronic Health Record Association (EHRA). WG members determined that the final recommendation is that this data element is specific to the unstructured narrative portion of a Discharge Summary and does not include any specification or requirement of discrete data elements.
- Hans explained that the **Coverage Status** data element under the **Health Insurance Information** data class was a medium priority, so the WG did not discuss it. Then, the WG determined that the comments Hans submitted on the **Coverage Type** data element (under the same data class) were already included in Mark’s recommendation, which was discussed at a previous meeting.
- Hans reviewed the recommendation he submitted to change the name of the “**Reason for Referral**” data element (under the **Procedure** data class) to indicate that a request for something is being made. He explained that not all health IT would support the use of this element, so the USCDI must be stratified, or the purpose of the element must be adjusted to be that solid library that drives standardization.
 - Hans commented that it would be helpful to clarify what the request is for, in addition to the clinical concern or diagnosis. Arien described similarities with e-prescribing and suggested that it should be attached to an order for service request, where this is a clinical indication for a service, procedure, or referral. If the WG is referring to a procedure that really happened in the past, the reason must be included. AI responded that the ONC was trying to capture the intent of the referral, and he explained that it is listed in this data class because the referral is a type of procedure as a requested service. He stated that this is a specific requirement in transitions of care, but because ONC has not previously identified a clear value set, it would be reasonable for the WG to suggest that ONC list some examples in the final version of USCDI v3. Arien emphasized the need for consistent terminology.
 - Hans asked if a more general name for the data element, e.g., Reason for Request, would be a better, clearer option, noting that it could then be used in a wider range of areas. Clem commented that this could create new, undue burdens. Hans commented that this would be an optional item for collection, and Clem stated that this should be stated explicitly. Ike commented that justification is required on the payer/billing and prescribing side.
 - The WG agreed to recommend clarity regarding whether the collection of this data element would be required by all certified health IT and noted that there is a generic need for this kind of clarification across the USCDI.
- Clem reviewed the recommendation that he submitted to allow LOINC as an applicable standard for the Smoking Status data element to the Health Status data class in USCDI v3. He stated that there are several sensitive and broadly collected questionnaire items that should be added as a package with a set of answers. He described several that have additional LOINC terms associated.
 - WG members discussed the number of validated instruments for Capturing Smoking



Status. AI commented that the current requirement in the USCDI is to capture smoking status using SNOMED codes but that it does not specify which particular codes could or should be used. He explained that because there was not agreement from providers about how to best use the captured codes, the specific codes were removed.

- WG members discussed Clem's suggestion to capture assessments, and AI explained that there has been push back against the idea that EHRs must capture more specific assessments. Steven stated that if nothing has been specified, all options are valid for use. Clem asked for examples to be included, and David suggested that this seems to be another case in which selecting the appropriate assessment based on clinical context creates a standard way to capture potentially complex information if the context warrants it.
- WG members agreed to the recommendation that ONC clarify that the data element could use a number of assessment instruments and include a set of examples.
- Mark and Arien reviewed their updated recommendations around including the data elements of **Disability Status**, **Functional Status**, and **Cognitive/Mental Status** under the **Health Status** data class in USCDI v3. Arien provided an overview of their detailed recommendations, which were discussed at the previous WG meeting, and explained that the data element that was previously called "Mental Function" should be retitled as "Cognitive/Mental Status." They also recommended that "Health Status / Assessments" be inclusive of patient generated data, including self-assessments, and shared a number of recommendations related to all previous related discussions.
- Arien reviewed the recommendations around renaming the "Health Status" data class as "Health Status/Assessments" with LOINC as the applicable code set and clarified that the intent is not for every EHR to be able to produce every possible assessment but to make all assessments available for the purpose of interoperability. He added that the WG is recommending that the Social Determinants of Health (SDOH) Assessments data element should be moved into this data class in USCDI v3.
 - Hans supported the recommendations but asked if LOINC is the applicable code set for all assessment tools. Arien reviewed the detailed recommendations, noting that a multi-stakeholder collaborative group should be asked to establish a core LOINC code set. Clem emphasized the need for a starter code set. AI explained that some of the recommendations were included in the USCDI Task Force 2021 recommendations to the HITAC and added that the Gravity Project has now associated all SDOH assessments, panels, and subsets with LOINC codes. Additional work is being done on value sets, which will likely be pointed to as the minimum value set. Clem commented that a health status could be specified using a SNOMED code and an assessment using a LOINC code and that the list should be thinned down.
- Mark reviewed the updated recommendations regarding the **Pregnancy Status** data element within the **Health Status** data class which the ONC has proposed to include in USCDI v3. He explained that it is a critical data element for numerous use cases, and WG members discussed the several use cases that were outlined in the recommendations.
 - Clem inquired if there is a specific list of data element definitions, and AI responded that it includes "Yes," "No," and "Do Not Know" and that "Intent to Become Pregnant" could be added as part of a value set encoded in SNOMED. Contraceptive status was not included.
 - All WG members agreed to the updated recommendations.
- Clem reviewed his recommendation that the **Specimen Type** data class under the **Laboratory** data class should be optional in USCDI v3 due to the additional burden that its requirement would place on laboratories.
 - AI commented that even though the data element is not relevant to all tests, it was added as it is critical for some labs and available for most. It was added as a component of the COVID-19 pandemic response. If it is added to the USCDI, it would require that certified health IT modules be *able* to capture this element and make it available for exchange.
 - WG members discussed the implications of requiring this element and potential associated



burdens. Arien commented that the **Medications** and **Laboratory** data classes are highly formally specified in interoperability requirements that are in certification. He described how EHRs and certified health IT systems have a content model that is inclusive of multiple elements. He suggested using the content model for interoperability that is specified in the C-CDA and FHIR IGs. He discussed how different interoperability specifications may or may not require specific data elements. Hung asked Arien for clarification on his recommendation, noting that the two that are included now are inadequate for discrete lab result data interoperability, and he added that many of the elements that would make the USCDI more inclusive are not even leveled at the Comment Level. Hans described the roadmap discussion about what standards must be included and stated that while some may be in the general places that support workflows, they are not yet included in C-CDA or FHIR US Core.

- WG members agreed that harmonization is needed here, and Arien agreed that the WG should request ONC support to work on this topic after completing its Charge 2 ISA-related work. Arien suggested employing the USCDI in the content model that is already required by the IGs that are in certification. The controlling content model is the US Core FHIR model, as well as the Consolidated US Core model. The WG will work to formalize this recommendation and will propose adding to USCDI in conjunction with adding to US Core Standards. Hans commented that, to date, the USCDI has only referenced vocabulary standards. WG members agreed that this recommendation would be for subsequent work (not the current Charge 1 recommendations to the HITAC).



- Clem asked if the **Reference Range** and **Normal/Abnormal Flag** data elements could be recommended for inclusion in USCDI v3. AI responded that they are not at any level of the USCDI, so they are out of scope for the WG to recommend at this time. Any WG member or member of the public is at liberty to suggest these data elements for consideration for future inclusion in USCDI.
- Hung discussed his recommendation to move the **Instrument Unique Identifier** data element in the **Laboratory** data class from Level 1 to Level 2. He also provided an overview of the WG's previous discussions and justifications around including the **Specimen Source Site**, **Test Kit Unique Identifier**, and **Values/Result Status** data elements (under the **Laboratory** data class) in the USCDI v3. He recommended including SNOMED-CT under applicable standards.
 - WG members discussed the recommendations, noting that these have some of the same issues as previously discussed for other elements, including that some are already specified in FHIR US Core but are not currently in the USCDI. Hans asked how to pull in knowledge from standards other than FHIR US Core that already have regulatory requirements for data elements.
 - Arien commented that the WG should recommend adding to USCDI the obvious data elements that are already included in FHIR US Core before focusing on the less obvious elements. He suggested adding SNOMED-CT as an applicable vocabulary standard because it is already required. WG members discussed where it was required.
 - AI asked who manages the list of test kit unique identifiers and if the LOINC codes that are associated with test kits are unique. WG members agreed that the FDA manages the list and that many test kits may be coded to a single LOINC code, though not all are identifiable. Clem described the complexities around test kits and the associated LOINC codes. AI described how ONC inferred the use of qualitative versus quantitative tests through the recommendations. The test kit includes the device used. Hung commented that his recommendations to add the Unique Test Kit Identifier data element to USCDI were intended to reduce burden on labs.
 - Following a discussion, the WG recommended that USCDI v3 note SNOMED-CT be included as an applicable vocabulary standard for qualitative Lab Values/Results. (LOINC still used to specify test, UCUM used to specify units.)
 - The WG discussed the recommendation about the **Specimen Type** data element. Clem commented that SNOMED is used to specify Specimen Type in the Laboratory In Vitro Diagnostic (LIVD) specification, and that SNOMED is the code set used. The WG recommended that the USCDI v3 similarly note SNOMED-CT as an applicable vocabulary standard for Specimen Type.
 - The WG discussed the recommendation to include **Test Kit Unique Identifier** in USCDI v3 and FDA Test Kit Unique Identifier as applicable standard or value set. This would not constitute a requirement to capture this data discretely, but rather a requirement that the data should be exchanged if systems have it.
 - Arien reinforced his comments that the WG should recommend adding more obvious items to the USCDI and, in response to a question from Clem, discussed complexities around Medications and Labs and the applicable core specifications.

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).
- 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 to 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:

Laura King: Hi, thank you so much. My name is Laura King, and I'm the Director of Public Health of the American Heart Association. My background and training is as a registered nurse, and I worked in public health for over 25 years. I want to thank the Interoperability Standards Workgroup and ONC for their efforts to advance and expand United State Core Data for Interoperability. High blood pressure impacts more than 129 million people in the US and it is the leading modifiable risk factor for preventing death from cardiovascular disease. The accurate measurement and interpretation of blood pressure is vital for diagnosing high blood pressure and assessing effectiveness of treatment. Access to a common set of data, health data classes, and elements will help physicians, health care practitioners, and public health professionals diagnose, treat, and care for individuals with high blood pressure and ensure that they are engaged and empowered with data and much needed information and support across the healthcare community. The clinical evidence and guidelines outline the importance of the proper estimation of an individual's blood pressure requires multiple blood pressure readings and measurement readings, meaning the blood pressure should be diagnosed after two or



more blood pressure readings and have obtained at separate intervals and then averaged. This is a case, regardless of where their blood pressure is taken, such as in an office setting or a patient measuring their own blood pressure at home. Thus, consistent communication of average blood pressure is critical for addressing hypertension nationwide. Including the average blood pressure in the USCDI class would make it easier for physicians and other healthcare providers to diagnose and treat blood pressure and access blood pressure control more accurately. Practitioners need health IT systems that can store and exchange average BP, separate and apart from individual readings. This would assist with improved documentation, enabling physicians to utilize more accurate and appropriate information in the clinical decision-making and help solve one of many interoperability issues that have challenged systemic uptake of BP reporting. The Centers for Disease Control and Prevention, the American Medical Association, and National Association of Community Health Centers agree with the American Heart Association and support a set of standardized Average Blood Pressure data element. The AHA asks for the Interoperability Standards Workgroup to include the Level 2 Average Blood Pressure data element in the USCDI v3.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Jim Jirjis: Good morning

Grace Cordovano: Great points Hans! Here's a great piece defining EHI for everyone:
<https://www.healthit.gov/buzz-blog/information-blocking/say-hi-to-ehi>

David McCallie: Please don't lose the narrative

Steven "Ike" Eichner: Thanks for the language, Hans!

Andrea Pitkus: If data are received in structured format in EHR from other information systems, don't want to lose discrete data, encoding, etc. indicated in other USCDI data elements/classes too.

Arien Malec: (Re-sending to "Everyone") Right — nobody is saying that, but the place to put that is in the implementation guidance for the interoperability specification.

David McCallie: @Arien, USCDI prioritizes interop IGs, but you could have an interop standard for something that's not part of USCDI (right?)

Arien Malec: You could have an IG for something that's not part of USCDI, but you don't have a certification hook for the data elements.

David McCallie: Capturing the "reason for" something like an order or a medication opens a can of worms. Might need to scope this to "services?"

Arien Malec: I would formalize that as the "indication"

David McCallie: My point is to scope it away from medications or other routine orders

Ram Sriram: @David: Encoding Rationale into EHRs is an interesting topic. Lots of work has been done in other areas, such as Engineering Design.

David McCallie: (I believe that we should capture "intent" for things like medications, but the community has pushed back against that, when studies have been done. To Clem's point - lots of new work)

Ram Sriram: @Clement: Rationale should be encoded automatically. This is probably a research topic.

Arien Malec: Most eRx systems have the ability to capture indication, but they are usually not captured.



David McCallie: @Ram - yes, very interesting problem for routine medical care - it "ought" to be there, but it does impose more work

Jim Jirjis: Often there are multiple reasons a person is on a med: For example Calcium channel blocker may be for HTN, A fib, Migraine, etc

David McCallie: Gordy Schiff has the best thoughts on medication "indication" - <https://www.nejm.org/doi/pdf/10.1056/NEJMp1603964>

David McCallie: Do we know if any of the listed example assessments are proprietary and would require a license?

David McCallie: @steven +1 - excellent practice

Terrence O'Malley: Agree entirely with Arien, the choice of assessments on our part was limited by our interests and in no way represents the breath of assessments required in clinical care. Thanks.

Holly Miller: Agree with Arien, and in fact, this was our intent.

Arien Malec: Thanks Holly & Terry!

Arien Malec: Intent & contraceptive status also applicable for REMS, etc.

Andrea Pitkus: Re Pregnancy status, I believe the HHS required question / answers for COVID reporting differs slightly

Mark Savage: @Steven, the others on "Health Status" (26-36) were consolidated in entries 4 and 26 already discussed.

David McCallie: Smoking Hx is "just another assessment", which could be encoded the same way as all the others. Makes sense to me.

David McCallie: There could be multiple smoking assessment instruments, depending on clinical context. Can't we just specify to use the appropriate assessment tool?

Andrea Pitkus: It is important in chemistry.

Andrea Pitkus: Spm Type is required by law for COVID reporting requirements. It's not in the LOINC code for every test either.

Andrea Pitkus: It's part of ELR, eCR, HAI, regulations. Also required as part of CLIA

Andrea Pitkus: Need it especially from those ordering/collecting lab tests.

Arien Malec: There are a bunch of things required in CLIA, FHIR, etc, that are *not* formally specified in USCDI.

Andrea Pitkus: Also many pathology / cancer orders as the lab may not know what specimen arrives in the specimen container, especially if an aliquot, a paraffin block, etc.

David McCallie: "able to capture and exchange" does not mean it's required for all labs

Andrea Pitkus: One cannot tell complete meaning of a lab test by name alone. Also why Spm info is needed.



Andrea Pitkus: Testing naming is highly variable. Some include the specimen name, but often it is not listed for lab and other procedures that are most common and where it's assumed (i.e. K is assumed on serum, and appendectomy is assumed open) unless otherwise specified per medical vernacular

Andrea Pitkus: Also if information systems in between hops don't support, downstream users may not receive SPM data too. Including in functionality for all helps ensure data get where needed most.

Andrea Pitkus: Hans is correct that FHIR US Core Lab examples are missing specimen type / source info and lab test names.

Andrea Pitkus: Specimen Type is encoded with SCT Spm Hierarchy codes, with qualifiers (convalescent specimens, post transfusion reaction specimens) from SCT qualifier codes.

Andrea Pitkus: reference range is part of CLIA, but Clem is correct not all information systems support them and they should for accurate interpretation of lab results

Hans Buitendijk: FHIR US Core does actually not include as a Must Support a Specimen reference for a test result. That would have to be addressed if Specimen Type would be included into USCDI v3 beyond its current "optional" status.

David McCallie: Amazed that we don't include reference range

Arien Malec: This has been my basic point on both Medication and Labs.

Arien Malec: There are so many things that are obvious and not included that I'd rather specify the obvious and not included *then* specify the non-obvious.

Andrea Pitkus: "interpretations" and "flags" for lab results are also used for interpreting Antimicrobial Susceptibility testing (by about half of laboratories in the US)

Arien Malec: This LOINC/SNOMED split has been a frequent comment by HITAC and HITSC before that.

Andrea Pitkus: Susceptible result interpretations include S for Susceptible, R for Resistant, I for Intermediate where numeric result values are utilized. Needed for EHRs for HAI reporting VRE (vanc resistant enterococcus), eCR, etc.

David McCallie: USCDI doesn't feel like a very strong "lever arm" for changing these behaviors

Andrea Pitkus: LRI has been part of MU2

Arien Malec: Has been, but was removed if I recall.

Andrea Pitkus: For eligible Hospital labs to send and EHRs to receive.

Andrea Pitkus: Correct. LRI was removed for MU3.

Dan Rutz: It may be necessary to specify exactly what the test kit identifier should be (UDI?)

Andrea Pitkus: Test kits don't automatically get a LOINC.

Andrea Pitkus: LOINC does not go to specificity of test kit

Arien Malec: Sadly so — was removed because the associated MU measure was removed, before we realized that certification should be associated with interoperability.



Carmela Couderc: UDI - unique device identifier

Andrea Pitkus: Clem is correct in that multiple UDIs may be needed for a single test result and its value.

Arien Malec: The reason I keep bringing this up is that if there were any reference standard for content, it **should** be encoded in LRI.

Hans Buitendijk: Agreed with Andrea. Test Kit identifiers are mostly assigned by manufacturers. They may have UDIs, but not necessarily yet.

Andrea Pitkus: @arien. Agree. Would love to see lab standards for eDOS, LOI, LRI, EHR-S functional guide for receipt of lab results to address many of these gaps needed by downstream users (PH, providers, federal agencies, etc.)

Andrea Pitkus: Please include SCT organism codes where result values are organisms

Hans Buitendijk: FHIR US core does not yet support test results referencing the device used (e.g., test kit). You only see that in the operational workflow implementation guides that are HL7 v2 based.

Hans Buitendijk: Not to say that FHIR does not support that linkage, it is just not put into guidance yet.

Arien Malec: @Hans — remind me — does LRI require test kit if available?

Andrea Pitkus: HHS also requires UDIs for test kit/platform for COVID results reporting

Hans Buitendijk: Yes, in the context for ELR. LRI encompasses ELR, but not limited to it.

Andrea Pitkus: Most vendors unable to support multiple code systems for result values (to add LOINC answers would cause issues since SCT is in the standard currently prescribed)

Hans Buitendijk: @Andrea: That is their preference, but still hard to obtain for all. Hence the flexibility we had to allow in ELR to enable it, but not require it.

Arien Malec: As I noted, if I had to pick a data model to be the reference data model, I'd pick LRI, because it's already been mapped to CLIA/CAP, ELR, e tc. *[sic]*

Andrea Pitkus: @hans. It's correct some information systems / labs reporting cannot yet support UDIs or other codes especially those reporting via paper, fax methods.

Hans Buitendijk: Agreed that we can go to LRI (latest version going through ballot wrap-up) that would cover CLIA, ELR, and COVID related requirements. When we do that, we should not expect that all needs to go into a C-CDA always/ever, and various CHIT would not need to support that.

Andrea Pitkus: The only lab test where UDIs are requested are for COVID

Andrea Pitkus: FDA wants for all though

Arien Malec: Likewise, if I had to pick a reference model for Medications, I'd pick the NCPDP SCRIPT implied model, because it defines the requirements for "semantic" interoperability, in the sense that the medication as expressed in the EHR is the same medication as dispensed to to *[sic]* the patient.

Hans Buitendijk: And for lab orders LOI.

Arien Malec: Agreed @Hans.



Dan Rutz: A standardized domain for the test kit IDs would be important, it's currently not well-specified (HL7 & industry folks invented a syntax to generate an ID but it's not ideal)

Hans Buitendijk: And for referrals 360X/Gravity/Bidirectional

Dan Rutz: "FDA Test Kit Unique ID" may not be sufficiently specific for this to be implementable.

Hans Buitendijk: USCDI could have a rapid expansion, but we have to discuss how the chain of USCDI=>Standards/Implementation Guides => Certification Criteria does not create a monolithic approach to all CHIT having to support everything, which is the current approach in flight.

David McCallie: Does the missing "reference range" actually cause people to NOT include it?

Andrea Pitkus: Agree w Dan Rutz. Also for certain lab results like CBC WBC count may involve multiple UDIs for reagents and another for platform

David McCallie: (old man mode - we were exchanging reference range in the 1980's)

Arien Malec: @David — it's included de facto, but not de jure

Arien Malec: (Slightly less old man mode: same, but in the 00s)

David McCallie: USCDI isn't really de jure is it? It's all optional

Arien Malec: It's the ought WRT interoperability, yeah?

Mark Savage: Not USCDI v1

Al Taylor: There is no "reference range" submission in ONDEC. There is a "test interpretation (abnormal flag)" submission which is Level 1

Grace Cordovano: <https://www.healthit.gov/isa/taxonomy/term/1391/level-2>

Arien Malec: It is required, however, for FHIR CORE.

Andrea Pitkus: Has ONC assessed what lab items are required by CLIA regs and not supported by information systems to identify all these "gaps"?

Arien Malec: So it's certified against.

Hans Buitendijk: Reference ranges are accommodated in operational workflow implementation guides, not necessarily in FHIR US Core.

Arien Malec: Conformance for FHIR US Core is "Preferred" for reference ranges.

Arien Malec: Which makes sense, because not all tests have applicable reference ranges.

Andrea Pitkus: Some FHIR implementations lack too

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.



Resources

[IS WG Webpage](#)

[IS WG – March 22, 2022 Meeting Webpage](#)

[IS WG – March 22, 2022 Meeting Agenda](#)

[IS WG – March 22, 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 to work on Charge 1 will be held on March 29, 2022.

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