



Health Information Technology Advisory Committee Interoperability Priorities Standards Task Force Meeting Notes, September 25, 10:00 a.m. - 11:30 a.m. VIRTUAL

The September 25, 2018, meeting of the Interoperability Standards Priorities (ISP) Task Force of the Health IT Advisory Committee (HITAC) was called to order at 10:02 am ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

ROLL CALL

(Members in attendance, representing)

Kensaku Kawamoto, co-chair, University of Utah Health

Steven Lane, co-chair, Sutter Health

Anil Jain, Member, IBM Watson Health

Arien Malec, Member, Change Healthcare

Clement McDonald, Member, National Library of Medicine

Cynthia Fisher, Member, WaterRev, LLC

David McCallie, Jr., Member, Cerner

Edward Juhn, Member, Blue Shield of California

Ram Sriram, Member, National Institute of Standards and Technology

Ricky Bloomfield, Member, Apple

Sasha TerMaat, Member, Epic

Sheryl Turney, Member, Anthem

Terrence O'Malley, Member, Massachusetts General Hospital

Tamer Fakhouri, Member, One Medical

Valerie Grey, Member, New York eHealth Collaborative

Victor Lee, Member, Clinical Architecture

Members not in attendance:

Andrew Truscott, Member, Accenture

Leslie Lenert, Member, Medical University of South Carolina

Ming Jack Po, Member, Google

Raj Ratwani, Member, MedStar Health

Scott Weingarten, Member, Cedars-Sinai Health System

Tina Esposito, Member, Advocate Health Care

ONC Staff

Farrah Darbouze, Public Health Analyst, ONC ISP Task Force Lead

Lauren Richie, Branch Chief, Coordination, Designated Federal Officer

Lauren Richie called the task force meeting to order, conducted roll call, and then turned the meeting over to the co-chairs.



Ken Kawamoto kicked off the meeting by reminding the task force of their discussion during the last call on September 11, 2018, where they discussed orders and results, focusing on labs. Following that meeting, he explained that a few subject matter experts (SMEs) were gathered to inform a shared Google document which was organized into problems, examples, associated standards and issues, and proposed remedies. He noted that once a recommendation is identified, there still needs to be a consideration of what should happen next. With that in mind, the next steps will be to review the document and prune the list to come up with a prioritized list of recommendations and approaches.

Steven Lane added that the goal is to trim down the list of recommendations that have come out of the discussions in the task force, while also trying to develop a methodology that can be applied to the other domains identified as priorities.

David McCallie questioned whether once a problem is identified, are solutions also identified?

Ken Kawamoto noted that the solutions are the trickiest. At this point there is no clear major lever that ONC controls in some of the areas identified; therefore, there needs to be a discussion of how a problem that is identified is solved. He noted that Arien Malec has a lot of expertise in this area and has helped inform a lot of those items in the document.

Steven Lane noted that the charge for the group is to provide recommendations for action. The task force is also charged with identifying the standards needed for each priority.

Ken Kawamoto noted that today's discussion would start with a presentation about Logical Observation Identifiers Names and Codes (LOINC) with Dan Vreeman from Reigenstrief. In his presentation, Dan will attempt to answer questions that came up in the task force in regards to LOINC.

LOINC Presentation - Dan Vreeman, Reigenstrief

Dan Vreeman shared a presentation on advancing interoperability with LOINC. He noted that LOINC is focused on solving one part of the interoperability puzzle. LOINC is the universal standard for identifying health measurements, observations, and documents. LOINC terms have the specificity to distinguish between clinically important differences. Trying to create codes that reflect the level of precision needed for exchange and action. The scope of LOINC is broad.

LOINC is designed for identifying observations and works equally well for in HL7 v2, CDA, FHIR, or CDMs. Need a consistent way to identify variables across data and LOINC has codes for individual observation.

LOINC has a major release twice per year. LOINC is known for lab test content, but there is a full spectrum of variables that LOINC has that includes: newborn screening, genetic reporting, orders, public health.

There are orders sets or panels in LOINC; there is a set of additional order panels and a vetted list of common order codes. That subset is available in LOINC and had significant community input.



Also in collaboration with:

- Radiological Society of North America (RSAN) on a robust set of terms for radiology procedures to be used for diagnostic imaging.
- CMS to represent the question and answer assessments in LOINC.

LOINC HL7 v2 Lab Standards Quartet includes:

- Lab results implementation guide (LRI)
- Lab order interface guide (LOI)
- Public health electronic lab reporting guide (ELR)
- Definition of communication of a directory of service (eDOS)

LOINC is the code identified for the test or order set. It can also be linked to what the test is. If there isn't an appropriate LOINC code, a local code can be used. This is necessary because things continue to change.

Consolidated CDA 2.1

- FDA has been moving towards using real-world evidence.
 - Made a requirement for using lab test studies requiring LOINC for lab test data in studies starting after 2020.
 - Strong support of LOINC to identify in vitro diagnostic device (IVD) tests; helped inspire LOINC for IVD tests (LIVD)
 - Also recommended by Clinical Laboratory Improvement Advisory Committee (CLIA)
- CDC has been a long-time user of LOINC for electronic lab reporting, case reporting, immunization messaging, National EMS Info System, National Trauma Data Standards, vital statistics, and more.

LOINC in the real world

- All reference labs have mapped observation codes to LOINC codes and are working on the orders side (still a work in progress).
 - Research networks use LOINC in their common data model
 - Diameter Health reports 51% LOINC lab results
- There is an emerging ecosystem of knowledge products leveraging LOINC SMART on FHIR apps, Infobutton-powered decision support (UpToDate®, MedlinePlus)

Recommendations

- Standards grow because users make requests. It is an ongoing process because testing keeps evolving and needs change.
- Low hanging fruit
 - Diagnostic imaging reports C-CDA, FHIR, DICOM, and FHIR all support LOINC/RSNA Playbook. (It's also in ISA).
 - Other clinical measurements and observations
 - Clinical notes (Argonaut is working on this)
 - Patient-reported outcomes measures, surveys, assessments
 - Lab orders
 - These are harder because of order set proliferation, but LOI and eDOS exist.
 - No MU requirements/incentives to use.
 - Upstream standardization is the best approach



- When IVD vendors identify standard codes, all the downstream consumers benefit
- Policy decision to standardize could cause trouble
 - Want to be closest to the source to be the most accurate
- LOINC and SNOMED CT Together
 - Use LOINC for observations (orders and results). Use LOINC to identify the question.
 - Use SNOMED CT for observation values and assertions (e.g., problem list)
 - Use together, but for distinct purposes
 - Caveat: Use LOINC Answers for observation values in standardized assessments (nursing, PRO, etc.) and other specialized/required strings.

New tools for data aggregators

- LOINC Groups Roll-ups of equivalent LOINC codes for a specific purpose
 - Download and FHIR API based access available
- Better display names for lab tests
 - Improved, unique, and more “user-friendly”

Discussion

David McCallie thanked Dan for the clear presentation. He then questioned what percentage is coded in LOINC?

- **Dan Vreeman** responded that the closest he knows is what Diameter Health reported, 51%. He noted that this data was from approximately one year ago. He noted that the codes exist and the mappings may be done, but it doesn't mean that the information is in the transaction.
- **Arien Malec** noted that his analysis was about the same, but there seems to be a lack of progress over the last five years.

Steven Lane thanked Dan for the presentation. He noted alignment with the gaps shared in the presentation with what has been identified by the ISP TF. He shared that one idea discussed in the ISP TF was that LOINC coding should be a requirement for payment of a test. The coding should be maintained with the result and when shared with systems. He questioned if Dan had any concerns with those ideas.

- **Dan Vreeman** responded that in general, he believed that was the right direction. Some insurers have it required in their plans that providers include LOINC coded data. He shared that a broad approach to move forward is a good one. The benefit of standardization has when applied at the source, as it is more error-prone to try to do standardization anywhere else. He noted that the upstream part is important.

Terry O'Malley mentioned that in the USCDI work, an issue around local codes and the lack of mapping them to a standard was identified. He questioned whether there were other examples where interoperability is being held up?

- **Dan Vreeman** noted that the proliferation of local codes that exist is the largest issue. He highlighted the need to get the incentives right to make standardization happen. In regards to interoperability, he noted that there are some kinds of information that are organized more loosely than users would like. He also noted that additional structure within HL7 that pulls out the key items in a discrete fashion is very useful. The problem of local codes is a prevailing problem.



David McCallie reinforced the importance of the work done on equivalence classes. There is excessive granularity that is not necessary for the clinician and doesn't make for easy use, and the equivalence classes are a huge value. Mapping is complicated and can be fraught with error. Local codes mapped to a LOINC code requires a lot of judgment; therefore, we end up with mappings that are not perfectly accurate. The lab originator should assign the LOINC code and is the best source. He noted that there are thousands of observations that are coded to LOINC that are not necessarily lab tests.

Arien Malec noted his pleasure that some of the recommendations are in the process, in particular, FDA embracing LOINC for IVDs. He questioned how many IVDs are issued with LOINC codes. He also questioned if there is any retrofit work.

- **Dan Vreeman** commented that nearly all companies have mapped their internal codes to LOINC codes and many have made available to customers in a variety of ways. Some were more cautious about making the mappings available because waiting for assurance that they wouldn't have an issue with FDA.
- **Arien Malec** mentioned that the full ecosystems in the line of FHIR of getting results include IVDs, lab system vendors, intermediaries, EHR vendor, and EHR implementation. Ideally, everything would be perfect at the source and then flow through the ecosystem and out of the box mapping lowers the effort there.

Arien Malec questioned whether the LRI and associated mapping has been recommended. What else can Clinical Laboratory Improvement Amendments (CLIA) do to encourage CLIA regulated labs to adopt a standard?

- **Dan Vreeman** mentioned that he spoke to the CLIA committee in April, where they made a series of recommendations which he can share. He noted that they didn't specifically identify the need for local tests to LOINC codes. They did, however, make recommendations for implementation guidelines for IVD and LIS manufacturers.

Ricky Bloomfield commented, in relation to Steven's comment around reimbursement, what appetite is there to require LOINC as a specific standard. Noting that there is hesitation around requirements because new standards could arise and the old standard could be limiting. How can this group best help?

- **Dan Vreeman** commented that it is a reasonable participation requirement which is why the payment route is a good one. The direction of payment-based is a good one, but there is hesitation thus far.

Steven Lane questioned if they are successful in creating the requirement for payment with appropriate LOINC coding. Would that be problematic for Regenstreif or LOINC because of demand? Is there a risk if people inaccurately code and how to avoid that?

- **Dan Vreeman** noted that he wasn't sure if they can keep up with demand or not. The landscape is evolving, codes requested early in the process are manageable, particularly when it is the person who knows the test the best. This is much easier than working with interpretations from stakeholders. He also noted that there are ways that things could be short-cut, but wouldn't serve the intended purpose. There probably is another layer, maybe certification around mapping which is something that can't be automatically tested, an SME is needed to identify if good mappings or not.



Ken Kawamoto commented that orderables are done by LOINC and not SNOMED.

- **Dan Vreeman** there is no model for connecting an order with a set of things that would come back from it in SNOMED. Within the US there are different paradigms for ordering, other places use general codes. In the US there is a tighter connection between what is ordered and the results.
 - The idea of procedures can have a variety of meanings; procedure can be every action. That isn't the same a diagnostic test or laboratory measurement, LOINC doesn't have codes for procedures, only items that are ordered as a collection.
- **Ken Kawamoto** noted that the ISP TF may need to come back to this.

Ken Kawamoto noted to make sure LOINC codes are implemented above stream.

Steve Lane noted that a lot of good work has been done and thanked Dan for his presentation. He noted next steps would be to narrow in on what the recommendations will be and begin to shrink down the recommendations. He noted that the co-chairs would appreciate feedback from all of the ISP TF members to incorporate and discuss at the next meeting. There are a number of other domains that will soon need to be discussed.

Ken Kawamoto reviewed the shared Google Document and walked through some of the recommendations.

- Many of the results in practice are not LOINC coded the 50% discussed earlier was sobering.

Arien Malec articulated a number of the policy recommendations that have been discussed.

- There is good guidance and standards for lab delivery, but don't have good document delivery.
- Need to extend the LRI to appropriate standards of textual documents.
- Some work has been done, but just need to make sure that harmonizing from LRI, LOI, SMART, FHIR, all the rest of the standards to make sure that a test generated upstream is available to the patient downstream.
- Need to address where we are and gather better data about where we actually are.
- FDA coordination is happening, but need to do a better job of making sure standard mapping is available to labs.
- EHR connectivity, many cases have trenches already dug for gas lines to the house, but the trench may need to be dug again.
- Need to work with CLIA and College of American Pathologists (CAP) to remove obstacles.
- CMS has a lot of levers, including underutilized levers with CLIA.
 - Include lab requirements in more programs (conditions of participation, promoting interoperability, bundled payments)
- He provided history on the Meaningful Use measure which was topped out because it was a measure of EHRs that could receive labs, there was no tie to the standards. There may be a need to reconsider the certification requirement to address the full lab experience.
- Other federal agencies Veteran's Health Administration (VHA), Department of Defense, Indian Health Services, Homeland Security, many organizations receive electronic labs. Many do this for in-person labs. VHA could be a lever for standardization for receipt of the results.



- Better certification criteria in CLIA. A lab has an obligation to verify that the receipt of the lab is clinically valid. If the EHR is certified and can certify to the LRI guide using LOINC, it can remove some of the requirements. CLIA is focused on removing the burden.

Ken Kawamoto noted that he would put together a strawman, highlighting that the biggest issue is that LOINC codes are not provided upstream, in particular at local hospitals. He shared that behind the scenes there will be work on recommendations that will be made available to ISP TF members and reviewed at the next meeting.

Terry O'Malley questioned if the current recommendations are pulling the same policy levers for everything.

- **Ken Kawamoto** noted it would be useful.

David McCallie questioned whether items are going from good to better and just want to be sure that this is the primary thing that should happen.

Ken Kawamoto noted that he is prioritizing items and the ISP TF will go back to those items if there is more time. He suggested that members can help identify areas that should be moved up to a higher priority.

Priority Uses Survey Results

Ken Kawamoto questioned whether the items prioritized should be done as a group or be broken into smaller groups going forward. He expressed concern about the bandwidth for members to break into smaller groups and leaned toward keeping the discussion at the ISP TF level. He also questioned whether medications should still be the next item for the ISP TF to work through.

- **Arien Malec** noted that usability of the basic fundamentals hadn't been addressed.

Closing Remarks

Ken Kawamoto closed out the meeting noting that the ISP TF is trying to focus on clinical use cases. During the next ISP TF meeting, the group will follow-up to decide how best to proceed going forward.

Public Comment

There was no public comment.

Next Steps

The next meeting of the ISP TF is scheduled for October 8, 2018 at 10:00 am.

The meeting was adjourned at 11:30 a.m. ET