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

The September 11, 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
Andrew Truscott, Member, Accenture
Anil Jain, Member, IBM Watson Health
Arien Malec, Member, Change Healthcare
Clement McDonald, Member, National Library of Medicine
Cynthia Fisher, Member, WaterRev, LLC
Edward Juhn, Member, Blue Shield of California
Leslie Lenert, Member, Medical University of South Carolina
Ming Jack Po, Member, Google
Raj Ratwani, Member, MedStar Health
Ricky Bloomfield, Member, Apple
Sasha TerMaat, Member, Epic
Sheryl Turney, Member, Anthem
Terrence O'Malley, Member, Massachusetts General Hospital
Tamer Fakhouri, Member, One Medical
Tina Esposito, Member, Advocate Health Care
Victor Lee, Member, Clinical Architecture

Members not in attendance:
David McCallie, Jr., Member, Cerner
Ram Sriram, Member, National Institute of Standards and Technology
Scott Weingarten, Member, Cedars-Sinai Health System
Valerie Grey, Member, New York eHealth Collaborative

ONC Staff
Caroline Coy, Branch Chief, Strategic Initiatives
Farrah Darbouze, Public Health Analyst, ONC ISP Task Force Lead
Brett Andriesen, Standards Advisory Lead, Office of Technology (ONC)
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.

Steven Lane kicked off the meeting by reviewing the agenda and the Interoperability Standards Priority Task Force (ISP TF) charge. He also reminded the group that through their prioritization process, the ISP TF decided to start with orders and results. The ISP TF collaborated on a document to help identify problems and solutions related to orders and results. He then turned it over to Ken Kawamoto to walk through the shared document.

Review of Orders and Results Document

Ken Kawamoto reviewed a sharable document where all of the ISP TF members were asked to provide feedback.

The document had a column for problems, examples, associated standards/issues (if there are any), proposed remedies, other notes/comments. The task force began by reviewing feedback provided by the ISP TF members.

The initial problem reviewed was that not all results are available for patients to see and the proposed remedy was to expand U.S. Core Data for Interoperability (USCDI) so that most common/important results are available via FHIR APIs, both from resulting labs and EHRs.

- **Arien Malec** questioned whether this represents a standards issue and if there are result types that are not available to the patient.
- **Clem McDonald** clarified that the types not specified in detail in any guidance are EKGs, pulmonary function tests, radiology text reports, etc. Most reports except for labs are not specified in a well-formed fashion. There are some items in CCDA that might hint at being required, but most clinical reports are missing. Labs are incomplete.
- **Arien Malec** clarified that recipients are not looking for raw data, but rather looking for interpretive reports. He clarified his understanding of Clem's point that there are text report types that aren't clarified strongly in CCDA and are not USCDI supported.
- **Sasha TerMaat** noted that ONC 2015 EHR certification does expect that the diagnostic imaging report narrative component would be made available to the patient.
- **Clem McDonald** noted that it is not well specified in any delivery mechanisms.
- **Cynthia Fisher** requested that when information is available, it should be pushed to the patient.
- **Clem McDonald** noted that diagnostic studies need coding to store on a receiving system so that it can be coded as being the radiology chest x-ray report, as an example – without this nothing can be done electronically.

Ken Kawamoto transitioned the group to the next problem, asking for a higher-level review as they go through the remaining problems, as there are subject matter experts on the line who can provide additional insight into the conversation.

Terry O'Malley provided context around his comments into the document. His comments were on issues he encounters when caring for patients. His comments included: not all results available to clinicians; not all results can be used for clinical decision support (CDS), too many results with low value, can't send/receive a series of trended results.

Ken Kawamoto noted that his comments were similar to Terry O'Malley's. His first issue identified that a fair amount of results do not have appropriate Logical Observation Identifiers Names and Codes (LOINC) codes or are missing appropriate units. As an example, for CDS and trending, similar labs need appropriate semantics, without it, there is incomplete decision making.

- **Clem McDonald** emphasized this point, as without the appropriate semantics the usefulness goes down significantly.

Ken Kawamoto noted that smaller labs and some hospital labs don't LOINC code their results. There also is a significant amount of manual entry of labs; it is fairly common for units not to be entered, or the wrong units are chosen. From his system, he noted that approximately five percent of labs have these issues. He suggested that EHRs provide a mechanism for clients to map lab codes to LOINC codes when missing. He also suggested prioritizing which results need to be semantically mapped.

Another problem he identified is that results/observations outside of labs are not interoperable. The next problem he provided was that it is often important to know that something has been ordered and what the status is, which is especially important if recommending that something is done. He noted a lack of standard order catalog.

Steven Lane noted that David McCallie provided comments, but is unable to join the call. He also noted that many of the problems he identified in the document could be combined with the items that others had already discussed. He then transitioned to comments from the task force.

Comments

Ricky Bloomfield commented that it would be helpful to have data regarding what items are not coded to inform the discussion and prioritization.

Clem McDonald noted that there is no regulation at the level necessary to push this along. Most commercial labs are incentivized by insurance, but the smaller independent labs are not. He emphasized that with the right incentive this problem could solve itself within a year.

Arien Malec commented that it might be helpful to classify issues where standards are appropriate but aren't being widely used. Standards are there, but inadequate, and standards are missing. The Health IT Standards Committee, NwHIN Workgroup chaired by Dixie Baker put together a way to identify the status of standards and he recommended leveraging this work.

Discussion of the Orders and Results Standards

Steven Lane transitioned the meeting to Brett Andriesen, Standards Advisory Lead, for a review of the Interoperability Standards Advisory (ISA) as it relates to orders and results. He also noted that the ISA is currently open for public comment.

Brett Andriesen reviewed the Representing Lab Test section of the ISA. Noting that the adoption level for LOINC is flagged three out of five stars. He noted that ONC does not have a scientific way of

identifying the adoption level, it is based on feedback from the field, but there isn't anything quantifiable.

Arien Malec noted that EHR vendors might be able to pull the percent of labs that are or are not LOINC encoded. He also noted that while large academic hospitals are able to LOINC code, smaller hospitals may not have the resources and expertise to code their results.

Steven Lane questioned why SNOMED CT is specified as "feedback requested" on the ISA.

- **Clem McDonald** noted that 95 percent of tests are numeric and SNOMED CT is for the high/low or bacterial named results. He also shared that labs want to be expressive and that is not the type of thing that SNOMED likes to have.

The task force then transitioned to a presentation on lab orders, results and lab test compendium implementation guides from Ken McCaslin, Accenture and Virginia Sturmfels, Quest Diagnostics.

Virginia Sturmfels reviewed the intent of the implementation guides (IGs).

- The guides provide the full function of interoperability between an EHR and the reference laboratory.
- As companion guides, they lay the foundation for a more interoperable solution.
- eDOS provides the test compendium, the components of the test, the requirements for the test, the requirements of the identifiers to be used in the message to order the test from the Lab correctly.
- LOI is a laboratory order message that gathers the appropriate information and submits it to the laboratory based on the requirements established in eDOS.
- LRI is a laboratory result message consistent with the LOI and eDOS from the lab to the EHR/EMR.
    - **Arien Malec** noted that LRI was removed from the 2015 final certification edition.
    - **Steven Lane** questioned that results were not necessarily going through the EHR.
        - **Virginia Sturmfels** confirmed that results are not necessarily going through the EHR. There is an app from Quest that shows results, vocabulary standards are not presented to the patient, but insights into patient reports are presented.

Ken McCaslin noted that related to the earlier discussion, results are not appearing in places because not driving behavior based on an order message. He then provided examples of constraints that include time zone offsets and OIDs that are supported and OIDs that are not.

Virginia Sturmfels reviewed the outcomes from the development of the implementation guides:

- eDOS provides the framework for the requirements of the performing laboratory creating the parameters for the LOI content which drives the LRI reporting process.
- Flexible implementation guides that conform to each other.
- Guidance on conformance between partners.
- Provides path from limited constraints to highly constrained solutions without re-engineering the interface.
    - Even though the LOINC code is sent, the EHR may not be putting it into the patient record.

- Conformance parameters can be extracted and used as conformance validation rules to measure compliance to the IG and profiles.

Discussion

Steven Lane noted that standards exist, but are inadequately constrained, not all of the EHRs can receive all of the metadata elements which impacts the ability to share the data. The task force is dealing with the downstream delivery to the patient or the ability for the provider to share results with the metadata included between systems. He questioned if requirements to share the metadata beyond the initial recipient have been discussed?

- **Virginia Sturmfels** commented that it needs to be more fully discussed and developed. Only have addressed the 'copy to' situation. Virginia noted that she would bring that back to the member laboratories to ensure she is correctly stating.
- **Ken Kawamoto** clarified that there is documentation of who the copy to is, this is provided in a structured way with the ability to send if the lab knows who the individuals are.

Cynthia Fisher thanked the presenters for their feedback and emphasized the need to get results information to patients along with the ability for patients to share this information with their providers.

- **Clem McDonald** noted that Apple Health is helping to solve the data problem as they are providing a way to share the data with the patient.

Arien Malec provided a little history; the LORI guide was a joint effort between the lab community and ONC. The lab orders interface (LOI) was done back in 2012. He noted that there might be additional standards development necessary, such as a hierarchy with LOINC codes, but the task force may find that the standards are sufficient, but inadequately supported in practice on the sending side (versus on the receiving side). The oversight and regulatory mechanisms are very different. CLIA regulates labs from a CMS/HHS perspective. EHR certification is not the appropriate policy lever. In other areas, there may be the technical means to incorporate LOI, but may not be supported end-to-end from a user experience and data flow perspective. LORI the ability to support copy to, ability to support FHIR based API access when the labs are incorporated and to provide access to the patient. There may be incremental efforts needed, but the standards are there. He noted that there are gaps in practice and the task force might want to identify the hooks to make that happen. He suggested that the hooks could be regulatory or simply getting everyone together to discuss the end-to-end user experience.

Steven Lane questioned whether the concept of making the requirement to adhere to the standards could be a prerequisite for labs getting paid to do this work; forcing compliance with standards through the payment mechanism. He suggested as a condition of participation, all metadata sent to the ordering provider's system and maintained by the system, and then subsequently used for interoperability and/or a requirement that result data be made available to patients. If this were a requirement, he wondered if there were risks or unintended consequences that should be considered?

- **Virginia Sturmfels**, with reluctance, commented that she did not see the value in making the metadata available and make the claims submission of payment more complicated than

it currently is, as there are standards that identify what is performed and what is paid for. She could, however, be in favor of making metadata available to patients.

- **Ken McCaslin** questioned whether there is an opportunity for the LOINC community to provide details of what would help the patient understand the data. He suggested identifying the analyte with a LOINC code to have a universal relationship, let's bring in patient-centric information and make it universal so that regardless of the lab, everyone would have the same patient description and make it patient friendly.
- **Steven Lane** commented that patient advocates tell us that they just want the information, they don't want to be protected. He noted that there seems to be a consensus that there is a desire to make the data more transparent and to keep the metadata with the results.
- **Arien Malec** clarified that the notion of direct to consumer has been advocated by the labs, much of the opposition is from the provider community and resultant state laws which forbids labs from being sent directly to the patient, based on concerns that the raw data could do harm to the patient. He noted that there are policy preferences which could get difficult with state regulation.

Steven Lane transitioned to public comment and then asked Sasha TerMaat to clarify her comments in the chat feature of the meeting.

Sasha TerMaat provided links to current certification requirements in regards to diagnostic test reports and lab test results. She noted she shared current lab standards that are in certification, and mentioned that some were in previous certification, but have been removed.

- **Steven Lane** questioned why something would be removed from certification, seems odd that a standard has been removed from certification.
- **Sasha TerMaat** noted that it is a harder question about certification. The question is, is there enough value to merit third-party performance testing of standards for use (certification only covers EHRs, not labs). There is a debate of what is worth paying a third party to test, where is it worth being judicious with spending to receive verification of that item.
- **Arien Malec** noted that this came about because there were certification criteria that weren't tied to MU requirements which were onerous on vendors. Certification should be tightly aligned with MU criteria.
- **Clem McDonald** commented that there was dispute regarding what was topped out. LabCorp disagreed with the decision to remove.
- **Sasha TerMaat -** Does it make sense for certification standard to remain required for EHRs given CMS' decision to remove the measure as being topped out?

Andrew Truscott commented in response to an earlier point, is there a clinical care reason that lab results are not shared with the patient. He questioned if there is policy influence that could be used so that providers can release results to patient. Can a provider make the determination of what results can be shared with the patient?

- **Steven Lane** suggested making it more of an opt-out rather than opt-in.
- **Cynthia Fisher** questioned why set up hurdles for the patient. Patients have the right to their information.

Closing Remarks

Steven Lane closed out the meeting because of lack of time. Will pull together all the input that was provided, do some homework, and put together some specific recommendations for the task force to consider.

PUBLIC COMMENT

There was no public comment.

The following public comments were received in the chat feature of the webinar during the meeting:
Sasha TerMaat: Current certification expectation including diagnostic image reports: https://www.healthit.gov/test-method/view-download-and-transmit-3rd-party#test_procedure

Sasha TerMaat: Cert requirements: https://www.healthit.gov/test-method/transmission-public-health-agencies-reportable-laboratory-tests-and-valueresults

NEXT STEPS

The next meeting of the ISP TF is scheduled for September 25, 2018, at 10:00 am.

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