Health Information Technology Advisory Committee
Interoperability Priorities Standards Task Force
Meeting Notes, October 9, 2018, 10:00 a.m. - 11:30 a.m.
VIRTUAL

The October 9, 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 Seth Pazinski, 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
Cynthia Fisher, Member, WaterRev, LLC
Edward Juhn, Member, Blue Shield of California
Ming Jack Po, Member, Google
Raj Ratwani, Member, MedStar Health
Ram Sriram, Member, National Institute of Standards and Technology
Ricky Bloomfield, Member, Apple
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
Clement McDonald, Member, National Library of Medicine
David McCallie, Jr., Member, Cerner
Arien Malec, Member, Change Healthcare
Sasha TerMaat, Member, Epic
Tina Esposito, Member, Advocate Health Care
Leslie Lenert, Member, Medical University of South Carolina
Sheryl Turney, Member, Anthem
Scott Weingarten, Member, Cedars-Sinai Health System

ONC Staff
Farrah Darbouze, Public Health Analyst, ONC ISP Task Force Lead
Seth Pazinski, Acting Designated Federal Officer

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

Steven Lane welcomed the task force and reviewed the agenda. He noted that during today's discussion there will be a review of orders and results recommendations. The task force will also discuss the next domain to review which the chairs are proposing to be referrals and care coordination.

Review Draft of ISPTF Orders & Results Recommendations

Ken Kawamoto walked through the draft recommendations which had been prioritized.

Priority 1A

Priority 1A: Laboratory and other test results are not consistently encoded with appropriate standard codes.

Recommendations for Priority 1A:
- Standardized Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine - Clinical Terms (SNOMED-CT) coding must be provided by resulting agencies (e.g., labs, imaging centers, providers) as a CLIA requirement. If this is ineffective in delivering data, this could be made a CMS condition of payment.
- Identify and prioritize the most common/important results of each order type (including but not limited to lab, imaging, cardiac, pulmonary, neuro-muscular).
    - The examples noted above were updated during the meeting due to feedback from the task force.
- Consider the priorities of multiple stakeholders/use cases, e.g., patients, clinicians, population health management, payers, quality, safety, public health, research.
- Require and enforce the use of information models and terminology standards for all test orders and results. Priority should be on the test identification, numeric test results, and free text results.
- Mapped codes must be included with results as they are maintained in and exchanged between HIT systems.
- EHRs and LISs should provide a mechanism that allows clients to map internal result codes to standard vocabularies.
- Implement mechanisms to support and ensure proper LOINC encoding by resulting agencies, such as auditing or certification by CLIA.
    - This recommendation was refined per **Terry O'Malley's** comments below.
    - **Ming Jack Po** noted that it would be great if these mappings are transparent for knowledge sharing.

Policy Lever(s) / Responsibility for Priority 1A:
- ONC
    - Use available electronic health record (EHR) data sources to assess current compliance with Laboratory Results Interface (LRI) specs and LOINC and SNOMED encoding to identify areas for additional focus
    - Work with Health Level 7 (HL7) and industry stakeholders to create a LRI companion guide for HL7 Medical Document Management (MDM) and associated content and terminology standards to allow standards-based exchange of textual reports

- o Continue work with Centers for Medicare & Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC) and associated industry stakeholders to harmonize information models and terminology standards to Electronic Clinical Quality Measures (eCQM) definitions and reportable disease requirements
  - o Continue coordination with Food & Drug Administration (FDA), Clinical Laboratory Improvement Amendments (CLIA) and National Library of Medicine (NLM) to establish mapping between the output of analyte devices and LOINC terms.
- FDA
  - o Continue to promote use of LOINC in diagnostic device approval and oversight
- CMS
  - o Establish safe harbors or fast lanes for achieving CLIA quality obligations through delivery of HHS-endorsed standard-based results (e.g., LRI with LOINC encoding) electronically to certified EHRs
  - o Require certification under CLIA to HHS-endorsed standard-based results (e.g., LRI with LOINC encoding).
  - o Work with NIST to develop and provide testing program to assure compliance.
  - o Should above steps be insufficient to promoting standards-based interoperability, require certification as a condition of payment.
  - o CMS establish safe harbors (e.g. LOINC coding). Require certification under CLIA. Require certification as a condition of payment.

Discussion Comments

Terry O'Malley noted in regards to the recommendations that there should be ways to make it easy to do the right thing.

Priority 1B

Priority 1B: Not all results sent to clinicians in codified format with necessary metadata to allow integration and utilization in EHRs.

Recommendations for Priority 1B:
- Utilize USCDI to assure that prioritized results are interoperable via HL7 v2 messages (where applicable), C-CDA, and FHIR.
- Prioritize complete and accurate coding at the data source (e.g., LIS) rather than trying to code or correct externally sourced data downstream.
- Require that resulting agencies provide standardized metadata, (e.g., methodology, units, normal range) to ordering and copy to providers.
- Standard metadata must be maintained as result data is transmitted between systems (e.g., LISs, Imaging systems, EHRs, PHRs, HIEs, Payers, Public Health).

Policy Lever(s)/Responsibility for Priority 1B:

- ONC
  - o Work with HL7 and industry stakeholders to map and harmonize US Core Data for Interoperability (USCDI) to LRI, Laboratory Order Interface (LOI) and associated implementation guidance, and Argonaut-profiled FHIR (Fast Health Information

Resources) and support end-to-end stakeholder testing of discrete lab result and report transmission to providers and patients.

- CMS
  - o Establish guidance promoting use of standards (LRI, LOINC and others) with certified health information technology to address laboratory requirements for accurate reporting.
  - o Include laboratory and other result transmittal requirements in Advanced Alternative Payment Model (APM) program requirements (e.g., require Medicare Shared Savings Program [MSSP] applicants to specify how provider participants will receive standards-based electronic laboratory results).
  - o Reconsider "topped out" nature of electronic laboratory receipt in the Merit-based Incentive Payment System (MIPS) program. Previous requirements addressed receipt or entry of electronic laboratory information but not the structure, content and terminology associated with such receipt which should be re-introduced as a requirement.
  - o Work with NIST to develop and provide testing program to assure compliance.
    - ▪ This comment was added due to **Ram Siram's** comment below.
- Other Federal Agencies
  - o Require use of standards-based laboratory receipt in VHA, DoD MHS, IHS, and other applicable Federal provider organizations (e.g., DOJ, DHS).

Priority 1B Discussion:

Ram Sriram questioned how it is known that things will work the way they are supposed to work? How do you test the conformance of the standard? He recommended adding NIST as a collaborator to assist with testing.

Priority 1C

Priority 1C: Not all results available for patients/proxies to effectively view, receive, and utilize (this was updated due to **Ricky Bloomfield's** comments below).

Recommendations for Priority 1C:
- Require that ordering providers make results available to patients/proxies within a reasonable timeframe, as allowed by state laws, assuring that, where appropriate, providers have an appropriate opportunity to review and comment on results to facilitate patient interpretation.
- Make all results in the EHR available to patients via APIs, whether or not results are LOINC encoded.
- Develop and require the use of standardize "patient friendly" result display names to patients based on LOINC standards (in process).
  - o This recommendation was updated due to **Ricky Bloomfield's** comments below.
- In the future consider requiring resulting agencies to make results available directly to patients. This could initially be required via CLIA regulations. As necessary, this could be required as a condition of payment for resulting agencies.
- Recommend alignment of state and federal policies to assure consistent and predictable data accessibility and interoperability. This should begin with a clear articulation of varying state

requirements, followed by specification of national standards to promote maximal sharing of data in both human and machine-readable formats.

- o This recommendation was updated during the meeting due to the feedback provided by **Sasha TerMaat** noted below.

Policy Lever(s)/Responsibility for Priority 1C:

- CMS
  - o Make patient access to data via APIs a required measure for relevant programs.
  - o Augment program requirements to include receipt of information in other standardized structured formats (e.g., C-CDA) similar to API requirements.
  - o Continue to promote patient access and API requirements using certified health information technology.
- ONC
  - o Facilitate completion and maturation (with relevant stakeholder feedback) of ongoing LOINC work to define patient friendly result display names.
    - ▪ This was updated due to **Ricky Bloomberg's** comments noted below.
  - o Encourage and facilitate use of these terms for patient-facing purposes.

Discussion for Priority 1C:

Steven Lane shared comments from **Sasha TerMaat** that she shared prior to the call as she was unavailable during the call. She shared that she thought it would be helpful to see if there are steps that could be taken to standardize policies across states regarding what is permitted to be released electronically. She also suggested that a strong recommendation that states could be pushed to adhere to or a clear mapping of what each state expects would be helpful.

- **Cynthia Fisher** questioned how to have a standard across the country?
  - o **Ken Kawamoto** noted that he believes that there are not state specific requirements, it is more around disclosure requirements.

Ricky Bloomfield commented in regards to patients receiving data and the need to align around consumer-friendly titles. Getting buy-in would be helpful for consumers. He noted that LOINC published a draft of patient friendly terms that could be leveraged, but it is still an early draft.

- **Ming Jack Po** noted that at Google they use Schema.org used to edit and dump mappings, not traditionally in a health care setting. This could be helpful if ONC or someone else is willing to maintain it. There is a need to facilitate getting things together, even without regulatory power.
  - o **Ken Kawamoto** noted this might be a higher-level comment about how to better crowd source mappings. He thought this might go into another document that the chairs are using to brainstorm ideas that should be shared.

Priority 1D

Priority 1D: Orderable tests are not standardized between systems and lack mapping to standard terminologies.

Recommendations for 1D:

- Develop and eventually require the use of standards-based catalogs of orderable tests with consistent mapping to associated code sets (e.g., LOINC) for all order types.
- Utilize consensus development process to develop standard orderables for the most common/important tests of each order type, including the orders that link to prioritized results.
- Standardize commonly used order panels, building on the ~2,000 order panels currently cataloged by LOINC.

Discussion
Cynthia Fisher commented on how difficult it is to get price transparency and it would be helpful to lay the groundwork.
- **Steven Lane** shared that there is support for the ordering provider, scheduler, consumer, and it might be helpful to expand on clinical decision support to call this out.
- **Ken Kawamoto** commented that the standards are there, but questioned if it could be tackled across all orderables, not just test orderables.
    o **Cynthia Fisher** noted this would be fantastic to cover across all orderables.

Priority 2A

Priority 2A: Need standard methodology to integrate external decision support, for clinicians, patients and other stakeholders, into orders workflow.

Recommendations for Priority 2A:
- Leverage and advance CDS Hooks standard, e.g., define and support a CDS "Hook" that can be activated when a provider or patient is reviewing a result.
- Develop and support the use of standards to determine and expose net pricing information to relevant stakeholders including providers, payers, and patients.

Priority 2B

Priority 2B: Need standards to support Prior Authorization workflows

Recommendations for Priority 2B:
- A number of Prior Authorization standardization efforts are underway, including DaVinci, NCPDP, and CMS AUC requirements. These efforts should be harmonized into a consistent approach.
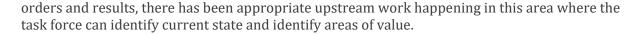
Discussion
Cynthia Fisher provided comments about concerns related to pricing. After some discussion, it was agreed to come back to this topic and harmonize it with the recommendations that are presented to the HITAC at a later time.

Next Domain Focus: Closed Loop Referrals & Care Coordination

Ken Kawamoto shared that based upon the work from the laboratory results domain, the chairs thought it would make sense to move on to closed loop referrals and care coordination. Similar to

orders and results, there has been appropriate upstream work happening in this area where the task force can identify current state and identify areas of value.

Steven Lane noted that during the prioritization process there was interest in all of the domains and this one was close to the top. A lot of work done by others that can be leverage. This is a great opportunity for clinicians and patients to streamline the processes to ensure referrals are well informed and managed efficiently. There will be benefit from working on this domain as a full task force, rather than breaking up into smaller groups.

He shared that the plan will be similar to what was does for order and results by having Brett Andriesen from ONC join a task force meeting to share the Interoperability Standards Advisory work. There will also be experts available to present the work from 360 Exchange Closed Loop Referral (360X) to share their expertise and experience to inform task force deliberations and recommendations.

He also shared a recent tweet that revealed frustration around closed loop referrals. The tweet acknowledges that the technology exists, but it is not used. This tweet helps emphasize that this is a relevant, lively topic.

To conclude, **Steven Lane** shared that care coordination was included in the title for the next domain because it is more than just closing the loop, often times there is a need and desire for ongoing care coordination from multiple members of a care team. Issues that arise in closing the loop bares on ongoing care coordination, specifically technologies for coordination of care.

Public Comment

There was no public comment.

The following public comments were received in the chat feature of the webinar during the meeting:

Dheeraj Pal - NYeC: I think there might be the grey area. How does the patient understand the service quality of $300 vs. $ 3000? Does the patient have to inform the insurance and employer or is it completely the patient's decision to go for the service and inform later?

Next Steps
The chairs will be presenting the orders and results recommendations at the HITAC committee on October 17, 2018. The next meeting of the ISP TF is scheduled for October 23, 2018, at 10:00 am ET.

The meeting was adjourned at 11:18 a.m. ET.