Meeting Notes

Health Information Technology Advisory Committee
Interoperability Standards Priorities Task Force
February 5, 2019, 10:00 a.m. – 11:30 a.m. ET
Virtual

The February 5, 2019, meeting of the Interoperability Standards Advisory Task Force of the Health IT Advisory Committee (HITAC) was called to order at 1:02 p.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Roll Call

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
Leslie Lenert, Member, Medical University of South Carolina
Ram Sriram, Member, National Institute of Standards and Technology
Sasha TerMaat, Member, Epic
Sheryl Turney, Member, Anthem
Terrence O'Malley, Member, Massachusetts General Hospital
Victor Lee, Member, Clinical Architecture

MEMBERS NOT IN ATTENDANCE

Andrew Truscott, Member, Accenture
Ming Jack Po, Member, Google
Raj Ratwani, Member, MedStar Health
Ricky Bloomfield, Member, Apple
Scott Weingarten, Member, Cedars-Sinai Health System
Tamer Fakhouri, Member, One Medical
Tina Esposito, Member, Advocate Health Care
Valerie Grey, Member, New York eHealth Collaborative

ONC STAFF

Denise Joseph, Public Health Analyst, ONC ISP Task Force Lead
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer

Call to Order

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

Opening Remarks

Steven Lane welcomed the ISPTF members. He shared that Ken Kawamoto will need to leave today's meeting early for a conflicting meeting. He reviewed the agenda, sharing that the prioritization topics will be reviewed and then they will pick up where the ISPTF left off during the last meeting reviewing the Orders and Results Draft Recommendations. He noted that additional input was provided from Victor Lee and a large vendor to help with this discussion.

Prioritization of Topic Areas

Steven Lane shared that five areas have been identified for prioritization to help the ISPTF decide the order of future work. Twenty-two of the task force members have voted and six people have not voted at all (one member only with her top priority area). Members who haven't voted and were in attendance were asked to share their votes.

Arien Malec shared his ranking:

1. Evidence-based Disease Management
2. Medication & Pharmacy Data exchange
3. Prior Authorization

Ram Sriram noted that he was not able to vote due to the government shut-down. He shared his vote which was the same priority as Arien's (noted above). As the group continued the discussion, he realized he misinterpreted some of the items and changed his vote to:

1. Evidence-based Disease Management
2. Prior Authorization
3. Social Determinants of Health

Steven Lane shared the prioritized results based on the voting.

1. Medication & Pharmacy Data Exchange
2. Evidence-based Disease Management
3. Social Determinants of Health
4. Prior Authorization
5. Price Transparency

Ken Kawamoto commented that medication and pharmacy data exchange seems to clearly be the priority item based on the voting. He also shared a discussion that he had with Steve Posnack around aligning

some of these items. Evidence-based disease management, prior authorization, and price transparency have alignment as the delivery of point-of-care guidance. He suggested starting with medication and pharmacy data exchange and then approaching the other three as a group.

Clem McDonald questioned the need to discuss medication and pharmacy data exchange.
- **Steven Lane** shared what was discussed during that last meeting around discrete sigs and the value this data brings to patients and providers for clinical decision support.
- **Clem McDonald** noted that it would be burdensome on physicians to have to enter discrete sig information**.**
- **Ken Kawamoto** shared that when physicians enter discrete sig information today, it can be lost in the process of pharmacy dispenses and subsequent renewal requests.

David McCallie commented that he thought there would be work done to determine where things are in each of these domains and then highlight gaps to identify where work by ONC should be focused.

Steven Lane transitioned to the next agenda topic.

Review of Orders & Results Draft Recommendations

Steven Lane reviewed a spreadsheet with recommendations, walking through the spreadsheet one row at a time. He picked up the review where the ISPTF left off during their last meeting.

Please note: Each priority item was given a letter to help follow the discussion in the notes.

PRIORITY 1B (row 3 in the spreadsheet)

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

Discussion
Members agreed with the changes made to this item.

PRIORITY 1C
Priority 1C: Observation
- Not all results available for patients/proxies to effectively view, receive, and utilize.

Priority 1C: Recommendation
- Make all results (including textual reports) in the EHR available to patients via APIs, free of charge, as allowed by state law, whether or not results are mapped to standard code sets.

Discussion
Arien Malec verbally shared the additions he had offered during the prior task force meeting. He commented that the Office on Civil Rights (OCR) had provided guidance around these areas that he

believes addresses the concerns regarding patient access charges. He highlighted the following points from this guidance:

1. Patients have a right to access
2. Patients have a right to request a preferred form and format
3. If form and format available, must be provided to the patient
4. Cost to provider is limited to the direct costs of the covered entity

When taken together, in the case when the covered entity has access, the covered entity is required to provide to the patient, and the cost to the patient must align with the direct costs to the provider.

The ISPTF agreed to keep "free of charge" in this recommendation which caused significant discussion during the previous meeting.

David McCallie asked to clarify result, as some may interpret this to mean more than lab results. He noted that APIs don't cover all results in the EHR. The expectation is that the data available to patients will be expanded through the U.S. Core Data for Interoperability (USCDI) as things progress. As is, the language is ambiguous.

- **Steven Lane** clarified that the intent is for all results to be available.
- **David McCallie** shared that APIs are needed for some result types which are not in place yet.
- **Sasha TerMaat** agreed with David McCallie that this is contingent on API development for all results.
- **David McCallie** commented that the policy lever/responsibility should encourage that the USCDI have a staged approach to eventually cover all data.
- This discussion resulted in the additional bullet under policy lever: Expand the scope of API requirements to include access to all results, through the USCDI process, to eventually include "all data" as required by the 21st Century Cures Act.

Sasha TerMaat noted that "as allowed by state laws" needs to be added as it wouldn't be feasible to release results that are prohibited due to state law. This change was agreed to by the group (included above).

Priority 1C Recommendation

- Encourage and eventually require resulting agencies to make results available electronically, directly to patients, as allowed by state laws, via APIs, free of charge. This could initially be encouraged via CLIA regulations. As necessary, this could be required as a condition of payment for resulting agencies.

Discussion

Arien Malec when labs are covered entities, access requirements apply. What isn't there is that every lab hosts an API (the readily available form and format is not there).

Terry O'Malley suggested adding "electronically" to the recommendation and the group agreed to this change (included above).

Steve Lane suggested adding "via APIs" to the recommendation. This change is included above.

Priority 1C Recommendations

- Encourage and eventually require the use of standard "patient-friendly" order and result display names for patients based on LOINC standards (This work is in process; https://loinc.org/download/loinc-display-name-file/).
- Recommend alignment of state and federal policies to assure consistent and predictable data accessibility to patients. This should begin with the development of a catalog of varying state and territorial requirements, followed by specification and promulgation of national standards to promote maximal sharing of data with patients in both human and machine-readable formats.

Discussion

There were no concerns with the small tweaks to these recommendations.

PRIORITY 2A
Priority 2A Observation

- There is currently no standard way to differentiate the Type of result (e.g., Radiology, Microbiology, Pathology) sent in a C-CDA document.

Priority 2A Recommendations

- Create a C-CDA standard component that identifies the different Result Types included in the Results section of a document and add it to current exchange specifications.
- Assure that FHIR specifications for test result components include the exchange of Result Type metadata to allow filing and integration of results by Type in receiving systems.

Discussion

David McCallie expressed concern with getting this detailed, as it might go beyond ISPTF's level of expertise.

There were no objections with including this in the recommendations from other members.

Based on the discussion from Priority 2B (below), the ISPTF decided to add the policy lever: ONC & HL7 should convene stakeholders to advance the C-CDA standard to address clinical content and usability of received results data.
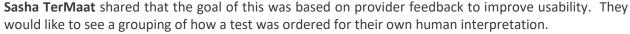
PRIORITY 2B
Priority 2B: Observation

- The C-CDA standard does not prescribe whether to send result components individually or grouped by ordered procedure.

Priority 2B: Recommendation

- The C-CDA standard should be updated to require that result component sent with documents be grouped by procedure in order to keep the necessary context for interpretation on the receiving side.

Discussion

Sasha TerMaat shared that the goal of this was based on provider feedback to improve usability. They would like to see a grouping of how a test was ordered for their own human interpretation.

- **David McCallie** questioned whether perhaps the C-CDA permits the grouping and people don't take advantage of this capability.
- **Sasha TerMaat** comment that it permits but does not require so some vendors .
- This discussion resulted in adding the policy lever for ONC & HL7 to convene stakeholders to advance the C-CDA standard to address clinical content and usability of received results data.

PRIORITY 2C

Priority 2C Observation

- Need standard interoperable methodology to specify and identify what has been ordered, and what is the Status of an order.

Priority 2C Recommendations

- Include Order Status as required component of interoperable metadata.
- Include in scope all orderables.
- Map priority orderables to standard codes. LOI standard could be useful. Potentially use LOINC for orderables, SNOMED for values.

Discussion

Steven Lane shared that the problem this is trying to solve is that there is no ability to know what orders have been placed, only completed procedures and resulted orders. This is about the interoperable nature of the order and its status before it is completed.

There initially was a suggestion to remove, "Map priority orderables to standard codes. LOI standard could be useful. Potentially use LOINC for orderables, SNOMED for values", but the group decided to leave this recommendation in (included above).

There was a suggestion to move this to priority one, but the discussion resulted in keeping it a priority two.

David McCallie suggested that this seemed to be a functional requirement, not a standards gap. He was concerned that there were bigger gaps than this.

- Other members disagreed (Steven Lane and Clem McDonald).
- David McCallie agreed to keep it, as no others shared his concerns.

PRIORITY 2D

Priority 2D Observation

- Existing standard code sets utilized for order, and result metadata are frequently not unique or sufficiently granular to accurately determine the clinical equivalency of tests ordered or performed at multiple organizations.

Discussion

Sasha TerMaat shared that the goal is to improve the ability of disparate systems to exchange discrete results data. Sometimes code sets are insufficiently granular. This is a problem that impacts order and results interoperability, and this may be not a role for this group.

SNO-MED, LOINC, and CPT were initially included as examples. Based on the discussion, these examples were removed.

PRIORITY 2E

Priority 2E Observation

- There is a need for a standard methodology to integrate external decision support, for clinicians, patients, and other stakeholders, into the full range of order and results workflows.

Priority 2E Recommendation

- Support the advancement of standards such as CDS Hooks.

Discussion

David McCallie suggested adding "such as" because there are multiple standards, including NCPDP, that may be necessary (noted above).

Clem McDonald suggested not including NCPDP and the group agreed.

Priority 2E Recommendations

- Support the development of Hooks that can be activated/utilized when a provider or patient receives and/or is reviewing a result.
- Support the development and use of standards to determine and expose/display net pricing and suggested alternative order information to relevant stakeholders including ordering providers, clinical support staff, payers, and patients.

Discussion

The group agreed to the suggested modifications to these recommendations.

PRIORITY 2F

Priority 2F Observation

- There is a need for standards to support the integration of Prior Authorization into EHR-based ordering workflows.

Discussion

Steven Lane suggested changing to standards (plural versus singular which is how it initially appeared) and the group agreed (noted above).

PRIORITY 2G

Priority 2G Observation

- Result data exchanged between HIT systems may not include sufficient Provenance Metadata for the recipient to understand the source of the data.

Discussion

The ISPTF members agreed to the addition of this item.

PRIORITY 2H

Priority 2H Observation

- Many vendors do not consistently send unique Reference IDs for discrete results data. This makes it difficult to identify and accurately update data already received.

Priority 2H Recommendations

- All systems should generate, use, and send unique and consistent Reference IDs for all orders, procedures and result components.
- Require interoperability of order/result Reference ID metadata with orders and results such that receiving systems can recognize a specific order or result as having been received previously.
- Internal identifiers must be persistent and not change over the life cycle of an order or result.
    - **Clem McDonald** suggested the inclusion of "persistent" (included above).
- Internal identifier data inclusion should be independent of a transport mechanism (e.g., HL7 V2, LOI, LRI, C-CDA, FHIR) and it should not matter if, e.g., an initial result arrives via an LRI and a correction arrives via FHIR – the duplicated or modified result should be obviously detectable.

Discussion

Clem McDonald commented that the recommendation was too complicated. To help simplify, a recommendation was removed that was deemed unnecessary.

PRIORITY 1D

Priority 1D Observation

- Orderable tests are not standardized between systems and lack mapping to standard terminologies, limiting the portability and interoperability of both orders and results.

Discussion

Victor Lee shared that he felt the recommendations needed more information; therefore, he suggested clarifications to the recommendations.

Steve Lane commented that due to the time, he would work with Victor Lee to add his comments into the recommendations.

Priority 2I

Priority 2I Observation

- Results and other externally-source observations may pass through many systems including consumer and unregulated app vendor-controlled systems where tampering or other data modification may occur.

Discussion

Steven Lane shared that this was not discussed in detail but wanted to be sure it was okay to add this into the list of recommendations. The ISPTF members agreed to adding this item.

Public Comment

There was no public comment.

Comments in the public chat

Chris Baumgartner: Can we get a copy of the final scoring for prioritization of topics discussed at the start of the call?

Next Steps and Adjourn

The next meeting is February 19, 2019, at 10:00 a.m. ET to review the recommendations on closed loop referrals.

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