Health Information Technology Advisory Committee

HTI-1 Proposed Rule Task Force 2023 Virtual Meeting

Group 3: ONC Health IT Certification Program Updates- Insights Condition, Standards Updates, and RFIs

Meeting Notes | May 18, 2023, 10:30 AM – 12 PM ET

Executive Summary

The focus of the Group 2 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Task Force session on May 18 was to review and discuss the Laboratory Data Interoperability Request for Information (RFI). Carmela Couderc, ONC, reviewed the RFI and members from the public, Riki Merrick, Craig Newman, Eric Crugnale, and Erin Holt, presented their recommendations to the ONC and the Task Force.

Agenda

10:30 AM	Call to Order/Roll Call
10:35 AM	HTI-1 Proposed Rule Task Force Charge
10:40 AM	Laboratory Data Interoperability Request for Information
11:50 AM	Public Comment
12:00 PM	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 AM.

Roll Call

Members in Attendance

Steven Eichner, Texas Department of State Health Services, Co-Chair
Steven Lane, Health Gorilla, Co-Chair
Hans Buitendijk, Oracle Health
Fillipe Southerland, Yardi Systems, Inc

Members Not in Attendance

Elaine Johanson, FDA
Hung Luu, Children's Health
Meg Marshall, Department of Veterans Affairs (VA)
Clem McDonald, National Library of Medicine
Naresh Sundar Rajan, CyncHealth

ONC Staff

Mike Berry, Designated Federal Officer, ONC
Johnny Bender, ONC
Dustin Charles, ONC
Carmela Couderc, ONC
Michael Lipinski, ONC
Sara McGhee, ONC
Michael Wittie, ONC

Key Points of Discussion

HTI-1 Proposed Rule Task Force Charge

HTI-1 Proposed Rule Task Force (Task Force) co-chairs, Steven Eichner and Steven Lane, welcomed Group 3 attendees. Steven Lane reviewed the meeting agenda and charge detailed in the May 18 meeting presentation materials.

Laboratory Data Interoperability Request for Information

Carmela Couderc, ONC, provided background on the Laboratory Data Interoperability RFI from 2015. She explained ONC did not adopt the 2.5.1 Laboratory Order Interface (LOI) Release 2, Directory of Services (eDOS), and Laboratory Results Interface (LRI) Release 2 Implementation Guides after considering public comment from the 2015 Edition Proposed Rule. ONC seeks comment on health IT standards by clinical laboratories and whether ONC should adopt additional standards and laboratory-related certification criteria as part of the ONC Health IT Certification Program. Riki Merrick, Association of Public Health Laboratories, provided recommendations on which implementation guides ONC should adopt in certification criteria, discussed the maturity of existing Health Level 7 (HL7) version 2 (v2) and Consolidated Clinical Documentation Architecture (C-CDA) standards to support laboratory interoperability and the impact of moving to Fast Healthcare Interoperability Resources (FHIR)-based data exchange. Riki also reviewed barriers to additional health IT certification criteria for laboratory interoperability and how it impacts adoption of the technology. Craig Newman, Altarum, reinforced that the focus on Orders and Results should be the priority and implementation guide regulations need to be specific to functionality. Craig also noted laboratories are still learning about FHIR and all it has to offer. Eric Crugnale, Sonic Healthcare, discussed barriers labs have when they are required to support all data elements. Eric supports laboratory certification, but there should be incentives for labs to adopt these systems. Erin Holt, Tennessee Department of Health, said her agency operates a public health lab and 56 primary care clinics. Erin stated that lab related standards-based interoperability is critical, and discrepancies in exchanging information can lead to missing data, the inability to trend, and result in a lack of data reporting.

Discussion

- Steven Eichner said there is a wide range of parties interested in lab data and information exchange. A lot of these parties are looking not just at exchange with hospital systems but also exchange between hospitals, public health reporting, and disease control.
- Steven Lane, on behalf of Susan Clark, a member of the public, asked if this Proposed Rule is inclusive of genetic lab data.
    - Carmela said yes.
- Riki Merrick noted the Association of Public Health Laboratories will be submitting comments

separately from the Task Force.

- Steven Lane said as a clinician he has challenges getting comprehensive data from labs. Would FHIR make this possible in the future?
    - Eric Crugnale noted his organization has seen that type of request. He said that data could be displayed in a portal where viewing rights could be granted. He noted it could also be displayed through a health exchange and FHIR could be beneficial for that specific use case.
    - Steven Lane noted labs are providers under the Information Sharing Requirements, so they should be able to respond to data in the format requested. As a provider, he wants to send a query and download all results for a patient.
- Hans Buitendijk recommended ONC focus on vocabulary, data quality, and targeted adoption of laboratory order interface (LOI) and laboratory results interface (LRI) profiles. In the most recent ONC Final Rules, there was a lack of incentives for labs. All parts of the workflow need to be examined because both electronic health records (EHRs) and labs are sources of information. What should be focused on? What are the biggest challenges?
- Steven Eichner said it might not be useful to use FHIR for all lab results. United States Core for Data Interoperability (USCDI) includes some data element components related to lab results. What is the relationship between the two? Should the Task Force investigate supporting data access through supportive technology? He also noted the Task Force should discuss patient access to lab results.
    - Erin Holt said the intent of the case report is to notify the public health department of a potential suspect, not a potential case. Depending on the condition, the public health department might get to the report earlier in the workflow based on something in the problem list. Lab information might not be immediately available.
- Eric said the greatest incentive for labs to adhere to this change would be to achieve interoperability. It would be great to get to a point where version endpoint updates are not needed for workflows. He noted from a vendor perspective, there is revenue that needs to be generated. Labs spend large amounts of money to pay for licensing and transactions associated with connectivity to EHRs. If those revenue opportunities go away for vendors, they may not be supportive.
    - Hans agreed and noted it may be on a case-by-case basis. It will be an ongoing evolution.

PUBLIC COMMENT

Mike Berry opened the meeting for public comments.

QUESTIONS AND COMMENTS RECEIVED VERBALLY

- Luis Palacios noted he works with multiple specialties. When information is received from an entity, how much information needs to be passed forward? For example, radiology does not find lab results relevant. Is it required for this information to be passed forward?
    - Steven Lane noted that this is an ongoing question in the community and encouraged Luis to add it as a public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Welcome to the HTI-1 Proposed Rule Task Force. Please feel free to use Zoom chat and tag "Everyone". Thank you.

Susan Clark: Is this RFI inclusive of genetic/genomic lab data?

Susan Clark: 👍

Luis Palacios: Maybe outside scope of this general meeting. One of two questions...This may have been answered in the past I don't know. When sending lab data how much lab data should be sent in the record.

Thinking about all population, We have Peds that have 21 years of information. while most specialties do something in the order of seven.

Luis Palacios: question two: When I get data from other providers am I responsible to forward those labs that have nothing to do with my specialty or do I need to filter to what I do.

Luis Palacios: I am new to this topic and learning quickly.

Hans Buitendijk: Full disclosure on my roles where I am involved in these topics, whereas my comments today are from an EHR implementation perspective. I am also Co-Chair of the HL7 Orders & Observations workgroup and editor of a number of the standards referenced (HL7 v2, LOI, LRI, FHIR LIVD) since HL7 v2.3/2.3.1. Suitability of standards will be a different perspective vs. what certification should focus on.

Hans Buitendijk: An additional consideration is that one need not declare support for the base LOI/LRI, but pre-adopt a specific profile that can be used with an older/custom transaction to minimize change, yet support current, targeted requirements.

Hans Buitendijk: C-CDA is used for documents that include laboratory results, but not for workflow management. HIEs use Hl7 v2 to feed their repositories, and receive/manage C-CDA documents that include lab results as well.

Hans Buitendijk: FHIR US Core is not well suited to manage the workflow where it would be responsible fo the results reporting to an ordered test. FHIR FOE would need to be available for that, not just the remaining CLIA data elements. FHIR US Core is well suited for general queries for data.

Steven Lane: We anticipate that all of these recommendations will be submitted to ONC as part of the public comment process. As a workgroup/taskforce we must consider whether any/all of these recommendations should also be submitted as recommendations to HITAC, or whether we perhaps have complementary or conflicting opinions worth submitting as recommendations.

Luis Palacios: backward compatibility is appreciated so I like profiles without the need to mapping is great idea.

Carmela Couderc: The deadline for comment submission is June 20.

Riki Merrick: in IHE we also are taking the step of breaking our profiles into smaller chunks/options

Riki Merrick: I agree with moving to the OML, mostly because the ORM was not updated when the more use case specific message structures like OML were introduced in V2.5; one of the elements that is not supported in the ORM is information about the next of kin, which is important for lab results of minors, so making OML the expected order message structure would be beneficial

Craig Newman: The Public Health WG has an item on their agenda for today's work group call (4PM Eastern) to discuss HTI-1. All are welcome to join.

Hans Buitendijk: Having Labs provide portals/APIs for providers/patients to augment flows would emphasize at that point targeted certification opportunities to subsets of USCDI.

Riki Merrick: LOI and LRI have profiles that support privacy indications around specific aspects of the order and results :)

Craig Newman: Definitely agree with Riki and Erin about support Public Health programs to exchange data rather than relying on work arounds such as labs reporting data (e.g. race and ethnicity, sexual orientation and gender identity) which is not a requirement for performing the lab test

Riki Merrick: LRI also has guidance around how to implement micro, how to do reflex testing and the other more use case specific cases like newborn screening (additional data elements), clinical genomics (complex data structures)

Riki Merrick: LOI also has profiles that helps the provider identify those results that should be held back from patient disclosure

Hans Buitendijk: Agreed it is not a question of eCR vs. ELR, rather eCR and ELR supporting collectively the right data through the right data stream.

Steven (Ike) Eichner: I'm withdrawing additional questions. Thanks!

Erin Holt: Yes, agreed, Hans. And both greatly benefit from codes/vocabulary in place, like LOINC and SNOMED.

Hans Buitendijk: A combination of advancing data through USCDI (covering all relevant CLIA data as a minimum), having FHIR/CDA as general data sharing mechanisms (queries) and targeted focus on vocabulary across the workflow chain (analyzer-LIS-EHR-etc.) and targeted profile advancement rather than a wholesale replacement of all existing v2 messages.

Riki Merrick: Ensuring getting the data we need - like specimen information in orders

Steven Lane: Thank you everyone for your participation today.

Erin Holt: Thank you!

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

No comments were received via email.

Resources

HTI-1 Proposed Rule Task Force 2023 Webpage
HTI-1 Proposed Rule Task Force 2023 – May 18, 2023 Meeting Webpage
HITAC Calendar Webpage

Adjournment

The meeting adjourned at 12:00 PM.