



Health Information Technology Advisory Committee Interoperability Priorities Standards Task Force November 13, 2018, 10:00 a.m. - 11:30 a.m. ET VIRTUAL

The November 13, 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, Office of the National Coordinator for Health IT (ONC).

ROLL CALL

Members in attendance

Kensaku Kawamoto, co-chair, University of Utah Health
Steven Lane, co-chair, Sutter 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
Raj Ratwani, Member, MedStar Health
Ram Sriram, Member, National Institute of Standards and Technology
Sasha TerMaat, Member, Epic
Terrence O'Malley, Member, Massachusetts General Hospital
Tamer Fakhouri, Member, One Medical
Victor Lee, Member, Clinical Architecture

Members not in attendance

Andrew Truscott, Member, Accenture
Ming Jack Po, Member, Google
Valerie Grey, Member, New York eHealth Collaborative
Tina Esposito, Member, Advocate Health Care
Sheryl Turney, Member, Anthem
Scott Weingarten, Member, Cedars-Sinai Health System

ONC Staff

Caroline Coy, Branch Chief, Strategic Initiatives
Farrah Darbouze, Public Health Analyst, ONC ISP Task Force Lead
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer

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



Introduction

Steven Lane welcomed the task force and reviewed the agenda. He noted that during today's discussion there will be a continued focus on referrals and care coordination. During the last meeting the task force reviewed the basics of closed loop referrals and how to leverage standards to support that workflow. As part of the scope of this work, the task force will be discussing care coordination which involves communication across the patients care team. Today's meeting will be used to understand how Direct is used for members across the care team.

Ken Kawamoto commented that there is a lot of great work starting in this area, but there is still piloting work that needs to happen. This is different than the work done on orders and results, as much of that work was already mature. There may be a need to identify pilots to meet the functional needs that the task force is discussing around closed loop referrals.

Steven Lane turned the meeting over to Luis C. Maas to share a review and update of the Direct Project.

Direct Project and Closed Loop Referrals - Luis C. Maas III, MD, PhD

Luis C. Mass introduced himself and provided his background. He is the Direct project coordinator and is also a physician and a scientist. He was a practicing radiologist and has now moved entirely into the health IT space to improve the delivery of care. His organization produces software that allows Direct to easily connect to other products. Direct protocols and their associated standards for notification are well established and has been certified since 2014.

Overview of Direct

A standards based secure mechanism was needed to electronically push information from one network to another that was vendor agnostic and reusable, like the fax network that it was hoping to replace. The ultimate decision was to base the mechanism on conventional email using certificates for encryption and integrity protection.

Motivations for Context

Initially, only one use case was defined for Direct, transitions of care. Many implementers built it out in a limiting way, as it was only built for transitions of care. The network has grown substantially to over 1.4 million production Direct endpoints. Once there was the ability to receive, display, and incorporate data from other places, people realized they wanted to do more, as it is a much better option than faxing. Ultimately, automated workflows were designed and it began to go beyond the original use case. People wanted to support different workflows and different payloads.

Challenges

- Early complaint was that some systems were only capable of consolidated clinical document architecture (CCDA) send/receive
- 2015 Edition EHR certification expanded to include a requirement to be able to manage text, PDF, XDM (a Direct standard), and more



- Messages containing PDFs don't have a standardized way to include patient context. The same is true for JPGs and many other content types
- XDM is not universally supported by vendors
- Workflow cannot always be determined from payload type
- Not all CCDAs are for transitions of care

Goals of Direct Project

- Extending Direct use cases beyond transitions of care
- Leveraging Direct networks to encapsulate Health Level Seven (HL7) standard content and other transactions
- Explaining why a message is sent and what response is expected
- Ability to tag non-CCDA attachments (PDFs, images) with patient information

What can we do with Message Context?

- Transaction Type is used to identify the role of the message sender in the transaction sequence
- Patient identifiers are used to identify the patient identifier in a sender's local context
 - Recipients echo this information back in responses and optionally add their own patient identifiers
 - Each party can find itself in its own local reference. Many of these fields are optional, not every communication is about a specific patient.
 - If the patient is not known, patient attributes can be added. Supply what is known and the receiving party will use what it can.

Assembling elements into a complete context

- Example context attachment
- Human-readable, at least mostly (if receiving system not context-aware)
- Mostly looks like an email, the rest of the data has a PDF encoded in the message and the metadata refers to all the attachments

Next Steps

- Direct Project implementers workgroup continues to discuss future steps
- Many are interested in care coordination

Discussion

Arien Malec noted that the Direct protocol was created by design to be transport only and was content neutral, but the content is what defines the user/clinical experience. Provider frustration is formed not by what goes on behind the scenes, but rather by what is going on at the content layer and how their electronic health record (EHR) renders the content layer. Most of that context is defined by how the clinician receives the CCDA. Is it a human readable narrative that contains the essentials or is it 45 pages of "garbage"? Additive context is incredibly useful to address the problem of message content.

Luis C. Mass commented that the CCDA requirements are specific as to what is needed for the certification program. The standard CCDA is not the appropriate payload for every workflow. There are new ways to



present and carry payloads that are more workflow appropriate. There is a catch-up period that is needed as implementers and vendors move from the 2014 Edition workflow specific implementation to the 2015 certified edition that allows for more payload types. The next step is to start thinking about how to handle more payloads, but it is uncertain how long it will take. Some vendors already have a more payload neutral interface.

Arien Malec questioned whether Fast Healthcare Interoperability Resources (FHIR) was discussed as an option? What were the trade-offs?

- **Luis C. Mass** commented that the meta-data was structured after email report types in the email standard. The idea was that this would be renderable in an email client and give the opportunity to be human readable. Ultimately, in the interest of simplicity, email standards were followed. FHIR is discussed a lot. Direct can be used as a conduit for FHIR RESTful application programming interfaces (APIs). Any arbitrary API call can be carried using Direct to carry HL7 v2, http-based APIs, and RESTful FHIR content.

David McCallie noted that it is nice to see the progress that has been made with Direct. He noted that there were debates in the early days about whether Direct would become a general-purpose API between systems. The dominant feeling back then was that Direct was intended to be human mediated like email. Attempts to make it automated for systems to interact may cause trouble, as this was fundamentally a human readable system. David liked the context headers because they are human readable and friendly for deciding what humans should do next. He urged the Direct community to resist doing too much automation with Direct as the channel. Direct security could be used to establish other types of channels. He noted that 360x is on the edge of getting too complicated for a simple email interface.

Steven Lane, co-chair commented that this is one of the challenges for the task force, as the group has a broad range of experience. He noted that a lot of work has gone into optimizing and utilizing the first iteration of Direct. He questioned whether Direct is the only appropriate standard to move forward to support referrals and care coordination?

Arien Malec commented that what worked with orders and results was that there were clinicians involved who practice daily and it was helpful to hear the real-world of orders and results and to compare that to the level of standards development. He liked the process of describing the clinical experience gaps and corresponding that to standards gaps, and then identifying what the appropriate mitigation should be.

David McCallie noted that Steven Lane raised the fundamental tension nicely. He noted that he fully supports expanding the range of moving back and forth with Direct, but making sure there is human interaction. Email doesn't take over the computer and do things when the user is not paying attention, the same should be done with Direct. Deep API automation should be left to a different space. 360x can work to send referrals back and forth, being careful with trying to automate too much.

Holly Miller commented that in the field, one of the beautiful things about Direct is that there is discrete data being exchanged and there is the ability to integrate this from one EHR to another. It helps avoid duplicate testing and adverse drug events. There is much demand in the field for increased automaticity that is enabled by message context that allows for appropriate routing. If the goal is to safely decrease provider burden, there is a lot of possibility and it is quite different from email.



- **David McCallie** shared that he fully agrees with supporting automating routing by parsing the headers if the request is landing in an in box. He noted he was not sure that Direct would be enough to transact the referral. He cautioned the need to be careful how far Direct is pushed.

Steven Lane commented that he is aware of the challenges of attempting to use Direct. There is a whole community of folks that think Direct could support conversational messaging between patients and providers. A lot of work has gone into Direct and there is a lot of opportunity and successes. He commented that he was not sure if this task force is able to push it forward or not and he asked the task force for their thoughts.

Les Lenert commented that Direct is a route to send messages; it was supposed to parallel fax machines and there is only so far it can be pushed. He questioned whether this could be the solution to interoperability.

Sasha TerMaat agreed with Arien's suggested to clarify the gaps that ONC needs to solve. She noted that different circumstances provide different technical next steps and it would help to identify the priority areas of focus.

Arien Malec commented that he likes the framework of looking at the sources of faxes and identifying how to address the sources of faxes in a clinical workflow.

- **Steven Lane** agreed with this comment and noted that Direct can do that but has not been implemented with enough consistency by vendors and providers. He suggested that there may be an opportunity to identify Direct for what it is and what it can be with some modest advances and continued support.

Les Lenert shared that there are only so many types of communication that can deal with the latency inherent in Direct without confirmation of receipt of the message or the action required within a timeframe. Pushing Direct with the current latency is a mistake. He noted a need to move on to something that understands the latency issue and makes this a live interactive process.

Clem McDonald shared that the biggest demand from a clinical perspective is to get stuff from another site with the time it was done. Push is the best mechanism. If all results could be pushed, it would make a difference.

Cynthia Fisher agreed with Clem's comment and supports the need for push as it makes it real-time for the patient.

Steven Lane noted that following today's discussion a consensus document with priority uses of Direct from a clinical perspective will be shared.

Sasha TerMaat commented that she was glad that the consensus document will be shared. She questioned whether the group should review the document and identify the top priorities. She shared that she was envisioning a list of the priority items and then identifying the solution for those, as she was not sure the task force has come to a consensus on what the priorities were for recommendations.

Ken Kawamoto agreed with Sasha and noted that it would be a great next step.



David McCallie noted that one thing discussed is how far to push Direct. Another topic that is important is secure messaging with patients. A final item he noted was that secure text messaging in care settings is on the rise and he wondered if Direct could be extended to support secure text messaging.

Steve Lane shared that after the last meeting, there was an email discussion about the evolving functionality and use of FHIR. One thing that FHIR promises to do is to support messaging. The task force needs to understand what the available standards are and they are working to identify an expert from the FHIR community to discuss this at a future meeting.

He also noted that there is a process flow diagram that will be posted for review. For homework, he recommended that the task force review the process flow diagram along with the consensus document. He noted that based on the discussion today, there seems to be large areas that support care coordination (e.g., secure messaging, secure text). He also noted that there seem to be competing standards in the market place and governance will be an important topic moving forward.

David McCallie also noted that governance is an important topic.

Steven Lane then turned the meeting over to Lauren Richie to open the lines for public comment.

Public Comment

There was no public comment.

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

Holly Miller, MD: "Pull" is always far more time consuming and increases clinician and staff burden compared to "push".

Next Steps

Steve Lane shared that the documents discussed will be available for comments, but not editing. Next steps will be to move from a broad discussion to a framework to review. The chairs will put together a draft framework for the task force to discuss. He noted that he anticipates during the next meeting having an opportunity to comment on the process flow and the prioritization of additional uses of Direct.

He concluded by noting that the task force is working to put together meaningful and helpful recommendations.

The next meeting of the ISP TF is scheduled for November 27, 2018 at 10:00 am.

The meeting was adjourned at 11:26 a.m. ET