ASTP | Health IT Advisory Committee

Health Information Technology Advisory Committee

HTI-2 Proposed Rule Task Force 2024 Virtual Meeting

Group 1: Public Health

Transcript | August 27, 2024, 11 AM – 1 PM ET

Attendance

Members

Bryant Thomas Karras, Washington State Department of Health, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Steven (Ike) Eichner, Texas Department of State Health Services
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Gillian Haney, Council of State and Territorial Epidemiologists (CSTE)
Joel Hartsell, Association of Public Health Laboratories (APHL)
Erin Holt Coyne, Tennessee Department of Health, Office of Informatics and Analytics
Jim Jirjis, Centers for Disease Control and Prevention
Mary Beth Kurilo, American Immunization Registry Association (AIRA)
Kikelomo Oshunkentan, Pegasystems
Thomas M. Wilkinson, U.S. Department of Homeland Security

Members Not in Attendance

Steven Hester, Norton Healthcare
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth

ASTP Staff

Seth Pazinski, Designated Federal Officer
Maggie Zeng, Staff Lead
Molly Prieto, Group 1 Co-Lead
Rachel Abbey, Group 1 Co-Lead
Sara McGhee, Overall Task Force Program Lead & Group 2 Lead

Presenters/Discussants

Jeffery Smith, ASTP
Aaliyah Parker, ASTP

Call to Order/Roll Call (00:00:00)

Seth Pazinski
Good morning, everyone. Welcome to the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule Task Force Group 1 meeting. I am Seth Pazinski with the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP). I will be serving as your designated officer today. As a reminder, this meeting is open to the public and public feedback is welcome throughout the meeting. Comments can be made in the Zoom chat feature and there will be time for public comment towards the end of the agenda today. We will get started with roll call. When I call your name, please indicate that you are present. I will start with our co-chair, Bryant Thomas Karras.

Bryant Thomas Karras
Present.

Seth Pazinski
Shila Blend.

Shila Blend
Good morning.

Seth Pazinski
Hans Buitendijk. I see him on.

Bryant Thomas Karras
We cannot hear you.

Hans Buitendijk
It should work now. Can you hear me?

Seth Pazinski
That is great. Good morning. Steven Eichner.

Steven Eichner
Good morning.

Seth Pazinski
Lee Fleisher. Rajesh Godavarthi.

Rajesh Godavarthi
Present.

Seth Pazinski
Thank you. Gillian Haney.

Gillian Haney
Present.

Seth Pazinski

Thank you. Joel Hartsell.

Joel Hartsell
Present.

Seth Pazinski
Steve Hester. Erin Holt Coyne.

Erin Holt Coyne
Good morning.

Seth Pazinski
Jim Jirjis. Mary Beth Kurilo.

Mary Beth Kurilo
Good morning.

Seth Pazinski
Kikelomo Oshunkentan.

Kikelomo Oshunkentan
Good morning.

Seth Pazinski
Zeynep Sumer-King. And I did get a message that Naresh Sundar Rajan will not be able to join us today. Thomas Wilkinson.

Thomas Wilkinson
Good morning. I am here.

Seth Pazinski
Thank you. Is there anyone I missed or if you have just joined us that would like to announce themselves? I will turn it over to our co-chair, Bryant Thomas Karras to get us started.

Opening Remarks (00:02:30)

Bryant Thomas Karras
Everybody, hold onto your hats. This is going to be a fast one today. We have got a ton to get through. Although with a quick scan, there were still some people who had not finished their homework assignments. I am hoping you have them in another document and you will be able to drop them in when we get to your section of the spreadsheet. We are hoping to go through and approve, as a group, final text that will get transmitted forward and that the staff can assemble into a document that will get reviewed in the three days of next week. They will need time to assemble all of that, so we need to get this finalized today. Also, without further ado, I think we should jump right into it because we want to have every moment of time to get through the document. I will caution everybody that we may need to avoid wordsmithing and make sure that we have the meat of the comments or our recommendations for each of these with the exception. The details that do matter are when we reference specific Implementation Guides (IGs) or specific releases of Health Level 7 (HL7) guides. We want to make sure that we get that right.

Let us jump in. How do we want to do this? Are we operating from the spreadsheet, I believe. And Maggie, are you driving? Who will be doing this?

Task Force Recommendations Worksheet (00:04:31)

Aaliyah Parker
I will have the spreadsheet. This is Aaliyah.

Bryant Thomas Karras
Thank you so much. Apologies in advance. It will be a lot of jumping around, I am imagining or sliding back and forth. Is it possible to use your entire screen to spread the spreadsheet out further to the side? Excellent. It is getting better. I still have black space on either side of the spreadsheet. I do not know if that is accessible to you. Is it just because of the shape of my screen?

Steven Eichner
It might be your screen. Mine is edge-to-edge. And real fast, as a reminder for folks, at the top of the screen, you can zoom in and make it larger by going up to Your Viewing and there is a zoom ratio button to make it bigger if you need to on your own screen.

Bryant Thomas Karras
For aging eyes, it can be very advantageous. Mary Beth, F1 is up first. How are you doing distilling all of the comments into a succinct recommendation?

Mary Beth Kurilo
We think fairly well. We added all the comments into Column J. I know folks have gone in and edited those slightly. I would be happy to walk through those if that would be helpful.

Bryant Thomas Karras
Column J is where the finals are going to go. The next Column K is blank. Perfect. I wanted to confirm there was not anything hiding there. Which paragraph should we focus on?

Mary Beth Kurilo
If we shift over to Column J and zoom in on that one, I think Column G is conversational, but Column J is where the main comments are. Some of them are really straightforward and some may require some discussion. At the top, we recommend that F1 criteria focus on the 2018 update to the HL7 Version 2.5.1 Implementation Guide as the implementation guide under development will likely not be published until late 2025, early 2026. That was in response to a question that ASTP had about where should they focus in on the final rule. We met with our Centers for Disease Control and Prevention (CDC) colleagues and they confirmed that it will likely go to ballots at likely the September 2025 meeting. Comments will need to be resolved, so it is likely to be early 2026 before that one is on the street.

Bryant Thomas Karras
It is implicit that the community era is still in favor of sticking with the HL7 Version 2.5.1 Implementation Guide standard because by that time, early 2026, one could imagine that a Fast Healthcare Interoperability Resources (FHIR) IG could be ready as well. Is that on the horizon or not even in discussion?

Mary Beth Kurilo
Probably not to replace submission and query. I think we are having a lot of conversations about a bulk FHIR query IG for the immunization community but unlikely to have one to replace the mission query for B2.

Bryant Thomas Karras
Let us change the first paragraph to green. Next.

Mary Beth Kurilo
This is really about terminology. We recommend the term bidirectional be replaced and that the actors in each use we had put senders and responders. Hans made the modification to say providers and immunization registries be better identified in each individual requirement. Specifically, we propose replacing the term bidirectional exchange with immunization registries, submission and/or query. The F1 section is highlighting the certification expectations for certified electronic health record (EHR) technologies. It is helpful to center them as the actor in this portion. That is really about making sure we are being clear or the rule is being clear in who they are referring to when talking about who is submitting and who is responding to a query. I will just mention that we support Hans' recommendation to rather than say sender and responder to say provider and immunization registry since that is who we are referring to in this section.

Bryant Thomas Karras
And immunization registry is a consistent term across all 57 jurisdictions?

Mary Beth Kurilo
Yes. And I think that is worth a brief conversation. The rule uses immunization registry and immunization information systems interchangeably. I think they are both referenced throughout the document. I think as a community, we lean in a little bit more to the term immunization information systems because we feel like it is more representative of the broader functionality of our system. But we would love to hear the group talk about that. I see Hans has his hand up as well.

Bryant Thomas Karras
I will turn to Hans in a second. But the last clarification is I wonder if we should put Public Health Assessments (PHA)'s immunization registry just to differentiate because some EHRs or some health systems may operate a registry internally. I am just clarifying that we are talking about the gold standard jurisdictional registry.

Steven Eichner
I am not sure it makes a difference. If private registry wants to use the standard, I do not think there is anything prohibiting them.

Bryant Thomas Karras
There are several local jurisdictions that operate immunization registries even within a state, New York City for example. All right. Let us stay neutral on that.

Hans Buitendijk
Quick clarification. The intent of my comment was, and I am not sure whether it came clear, but if we go at some point back to Row 2, it might be more clear that F1 would be renamed to immunization – provider and F21 would be renamed to be the immunization registry or PHA immunization registry. It is not that F1 would be renamed to provider and immunization registry.

Bryant Thomas Karras
Got it. Thank you for that clarification.

Hans Buitendijk
I think that was the intent. Again, it might not totally come across. At some point in time, you go back to F1.

Bryant Thomas Karras
We did not parse your sentence correctly.

Hans Buitendijk
It is totally correct **[inaudible] [00:13:06]**.

Steven Eichner
Technically, it is more than providers because if something like this rule is using the same interface to pull data to **[inaudible] [00:13:19]**, immunization status, it may or may not be acting as a provider per se.

Bryant Thomas Karras
Provider, care site.

Hans Buitendijk
It is another way to indicate that you are performing the immunization because that is really what we are focusing on, if the school does the –

Bryant Thomas Karras
The school might be entering an historic –

Steven Eichner
That would still be the provider. But if they are creating the registry for the vaccination status to validate if the student has vaccines to go in, they are not the healthcare provider at all at that point. They are a requester. They are a user.

Hans Buitendijk
It might become a different rule that says that that rule, if we are focusing on the query ability.

Steven Eichner
Absolutely.

Bryant Thomas Karras
Thinking of ONC's authority, I do not think ONC is going to have authority over school-based systems like they would with EHR systems.

Steven Eichner
It is looking at the user. We are worrying a little bit too much about the wordsmithing here. There are other entities other than providers that they are likely to use the query function.

Hans Buitendijk
And at that point in time, I would be more inclined to create a new criterion for just a query capability if there is interest in certifying that because, here we are trying to say that you need to support as part of this both the submission and the query ability. That is what the provider's system is supposed to be capable of, not one or the other.

Bryant Thomas Karras

Just to move things along, can we scroll over to the title column. I think it is A or B. Hans, what you are saying is change name to immunization registries bidirectional, we are wanting that to be change name to immunization registries provider?

Hans Buitendijk
Or it could be good to add the immunization registry submission and query – provider. And then, for F21, it is the immunization registry receipt and responding to queries. You want to keep it shorter but we are looking at whatever the Immunization Information Systems (IIS) is supposed to do on their end, receiving and responding to queries.

Steven Eichner
Do we need the provider there because you left it off? But it does not matter if you are a provider or not, you are focused on the function. And I agree with you on the big scope. It probably should be broken out into sending and receiving as two separate components because, particularly looking at specialized EHRs. It is perfect if the provider is never giving an immunization but they may be querying for immunization status. They do not need the function of submission, so why should they necessarily have to pay for it?

Bryant Thomas Karras
Can we turn this next paragraph green, or do we need to wordsmith it a little bit more and come back to it?

Mary Beth Kurilo
I am scanning questions just making sure we are identifying the actors correctly and also, coming back to that immunization registry versus immunization information system. And I do see a comment from the chat. But immunization registry does feel like a step backwards because I think we really socialize the IIS terms as representative of broader functionalities. How about I do some final wordsmithing on this following the meeting and folks can go in and take a look?

Bryant Thomas Karras
I think the discussion that is there around replacing bidirectional with actors in the body of the text seems clear, with the exception of immunization registry versus IIS or maybe you do both. What I am looking for is do we need a specific paragraph or replacement text for what the title change should be.

Steven Eichner
I think we are better off, rather than labeling provider, if we look at labeling system type, it is better off as IIS or whether it is EHR system or whatever you want to call it in that sense, rather than the user because there may be a bunch of different users of the different technologies. What is being certified here is the technology, not the user.

Hans Buitendijk
Fair point on the last. Other than that, the light of the role is the thing that the Health IT (HIT) are doing that, whether it is in EHR or whether we are splitting it up and dividing it into different roles. A school system or a specialty EHR or an all-purpose whatever. The variety of HIT is so much that we use HIT and EHR as not always applicable. But it is the HIT in support of the provider to enable immunization capabilities.

Steven Eichner
It was a user, actually.

Bryant Thomas Karras

We are over time for discussion on this one. We will have to come back to see, Marybeth, what you have crafted. We can turn to some of the other points that we did not get to it sounds like you found inconsistency of 2028 versus 2027. I am assuming you want 2028.

Mary Beth Kurilo
Before we get to the big discrepancy, I am wondering if we can briefly discuss the third recommendation down on the potential removal of the requirement for EHR to develop functionality to support United States Customs and Border Protection (CBP) Reimbursable Services Program (RSP) as a receiver of the query message. I think both Hans and I put in a recommendation to consider removal there given that we really call a need for FHIR-based query in G10 and G20. It seems like it may make sense not to ask EHRs to build in a V2 capability to respond to queries. But I would love to see if we have the group support of that.

Bryant Thomas Karras
Did you field that to your membership as well?

Mary Beth Kurilo
We did and we discussed it briefly. And we will be discussing it again at the start of September but our committee is supportive of that.

Bryant Thomas Karras
I imagine the community but maybe more importantly, the vendor community would have their hands full either way. But it makes a lot more sense to be building toward something that is going to last longer.

Hans Buitendijk
The thing is that immunizations are already in G10 and G20 may be adding. I do not have the exact data on the G20 has the immunization. But that seems the more logical path for queries, otherwise we are building a new capability that EHRs otherwise have no need for that there is a question of who is going to use it on a V2 environment, which means that it is one thing to go to a limited number of IIS. It is another thing to go to thousands upon thousands of provider systems with V2 queries. It is not scalable. That is why from an EHR perspective on that side, implementing and being able to respond to V2-based queries is going to have limited opportunities versus FHIR-based access to immunization data is going to have a much easier to scale approach.

Bryant Thomas Karras
And we may have bulk. It is a different topic, I know, but maybe it will supersede the need. I am really worried now. We are well over time. Let us get on to the next one and we will come back and hopefully have some green text to approve. Scroll down to F2, please. Ike and Gilliam, you are on deck to turn some things green or get ready to turn some things green. Do you want to walk us through your recommendations? Hans had some friendly amendments.

Steven Eichner
After you, Gillian.

Gillian Haney
I will be really honest here; I have not been in the office so I have not had ample opportunity to spend as much time as I would like on this. I think Steve's comments around the actual standard are appropriate. And I would agree with that. I think the thing that might require some conversation is in response to Hans' comment around alignment with case reporting. And I just wanted to state that syndromic surveillance data and electronic case reporting data serve two extremely different purposes. And I would not make that recommendation.

Steven Eichner
I would agree very much with that, as well as Erin's comments looking at there is not really a FHIR guide to shift you at this point. Public health does sometimes link, especially where surveillance data may have personal identifiers, some jurisdictions do not like that. They may link that with substantive data but as Gillian says, there are much different purposes for collecting surveillance data and electronic case reporting (eCR) data. If we delete collecting data, we are getting more syndromic surveillance to eCRs. We would not be able to take advantage of the timing of the data that is coming in for most syndromic surveillance data. Looking at the dates, January 1, 2027, is a Friday. One of the things we need to cognizant of and we have elaborated on a little bit is things like the CDC reporting week ends on Thursday. We want to make sure that is aligned. We did provide a little bit of an explanation as to why because otherwise, we are running into some challenges about why pick January 1 for a transition versus December 31 as being the last day. It seems a little weird, quite frankly, across-the-board to have the expiry date be the first across-the-board for any of these pieces.

Bryant Thomas Karras
Yeah. Midnight or 11:59 on the 31st.

Hans Buitendijk
I might be able to help shortcut this part. On a future section, A was meant to be for the future, not for the current HTI-2. That would be impossible. I have no problem that this is not included in the recommendation in a future consideration. That can be addressed later. But I do want to clarify that the proposal is not that syndromic surveillance is replaced by case reporting. Understand that that cannot work. Rather, that the format and technique that is used and the use of FHIR to use for the transmission syndromic surveillance would be extremely helpful because Admit / Discharge / Transfer (ADT) measures in V2 are just not well-suited to continue to expand it with clinical data. FHIR is much better suited for it than whatever the trigger events are, specific to syndromic surveillance. The content is an analogy to. It is not reflected by it.

Bryant Thomas Karras
To clarify, you are not saying that syndromic surveillance messages are ADT messages, but the format is similar to ADT messages. Syndromic surveillance is its own HL7 IG.

Hans Buitendijk
It is. It is using ADT messages from HL7 V2.

Bryant Thomas Karras
But not explicitly because ADT messages has identifiable information.

Hans Buitendijk
From an HL7 perspective, it is an ADT message without viable information. And an ADT message structurally, whether you have identifiable data in it or not is not as conducive to the increased amount of clinical data. That is why we are suggesting that an approach akin to, analogous to, but not shifting to a case reporting FHIR-based collection of data that is triggered based on appropriate events for syndromic surveillance.

Bryant Thomas Karras
We have had this discussion before. We will have to take this offline. There is no trigger event in syndromic. The event is everything.

Hans Buitendijk
That is why I am okay to remove it here and discuss it later. We have some terminology there from a technical implementation perspective. We have some terminology alignment to do.

Bryant Thomas Karras
Gillian, your hand came up.

Gillian Haney
You just said what I was going to say. Everything about triggers.

Bryant Thomas Karras
With Hans' withdrawal of his comment, it is the last paragraph, the fourth one, I presume, Hans. Are we okay with turning the second and third paragraph there green?

Steven Eichner
We are concerned about the timeframe for implementation. What January 1, 2027, really means you would have to have it released into usage something like September 1, 2026, if we are going to do any testing, unless you have it deployed.

Bryant Thomas Karras
That seems like a reasonable comment to make. It is a quarter ahead minimum. Still, for a large state, that is a lot of transition to make, so hopefully, some providers will be ready much sooner than that.

Steven Eichner
You also have to modify the state system to receive the data. From a procurement standpoint, unless modifying the system was already part of a purchase order or something today, you might be hard-pressed to get the technology modified by September 1, let alone January 1, if you had to do a new procurement.

Bryant Thomas Karras
Right. Do we want to recommend 2028 like we have done with others? This is still V2, so it does not seem like it is as much of a transition that is necessary. Stick with 2027 or December 31, 2026?

Erin Holt Coyne
I was just going to comment that from what I gathered from our syndromic folks in Tennessee is that the implementation guide that is referenced really is not adding much new. It is just attempting to clarify existing guidance. This likely will not be considered an entirely new interface or switching standards. It might be helping with clarity around conformance and that sort of thing.

Steven Eichner
Okay.

Bryant Thomas Karras
Now, I am having trouble finding my notes. Did the program area at CDC not tell us that there was a Release 1.1 instead of a Release 1? Or am I mixing up syndromic and something?

Erin Holt Coyne
I will look it up real quick.

Gillian Haney
Let us both look it up. We will find it faster.

Bryant Thomas Karras

Steve and Gillian, tell us what we can turn green so we can move on. Your audio broke up for me.

Steven Eichner
Yes, turn green. First paragraph goes green.

Bryant Thomas Karras
Are people comfortable with Steve's suggestion on the availability in September so that the cutover can be at New Year's?

Gillian Haney
I am fine with that.

Bryant Thomas Karras
Let us turn that one green as well. Any opposed? Hans, thanks for your clarification. I am sure you and I will be having discussions about that in the next rulemaking. Let us move on to F3. We are going to have to make up some time because we are sliding. We should be about two or three more along the way. Hans, you are the lead.

Hans Buitendijk
I started and then Erin provided comment. I put a couple of additions in that as well. I think we have covered it. Erin, jump in if I missed something.

Bryant Thomas Karras
I put some new comments in Column G, but hopefully, they are covered.

Hans Buitendijk
After yesterday morning –

Bryant Thomas Karras
There are some concerns on the timing, but let us jump over to your text first.

Hans Buitendijk
Do you want me to paraphrase them?

Bryant Thomas Karras
Are these iterations?

Hans Buitendijk
They are separated into the different aspects, and so there was clear recommendation on each fact.

Bryant Thomas Karras
Let us start at the top and turn them green.

Hans Buitendijk
The first one is when we discussed that this particular criterion F3 should focus on the reporting aspects and any references to ordering relevant to lab tests for public health would better be done in A2. That is the essence of it. It is not a removal from HTI-2 of lab orders but it is **[inaudible] [00:36:01]** in the context of A2.

Bryant Thomas Karras
Okay.

Erin Holt Coyne
The way this reads now is a bit confusing because it is referencing orders and results. And it suggests that public health would be receiving orders. We need the orders to convey the necessary information to the labs so that they can support the communications to public health. We do not need to receive orders as a reporting mechanism. We would get a case report that might have order information or we would receive the lab results itself.

Hans Buitendijk
If we were to look at A2 that is where more clarity is provided. You have lab orders. Depending on which lab it goes to, commercial lab, public health lab, performing lab and on behalf of another lab, there are variations in how much of the proposed laboratory implementation guides (LOI) would be necessary to make that work so that the reporting lab at that point in time has adequate information to do the reporting to public health.

Bryant Thomas Karras
We will re-reference that when we get to A2. Let us turn that first paragraph green. Second paragraph.

Hans Buitendijk
Since there are a couple of aspects that there are dates for the provider side but not for public health, the intent here is to identify one such data set because there is adequate time for both parties to then achieve those dates and be ready. Some of them are already in the provider side because of the nature of renewal of certification. What we hope to achieve is that everybody is aligned and things are developed in a timely fashion after they are done being used.

Bryant Thomas Karras
That lines up with my comments that given 100 different laboratories in an average sized state, 2028 seems ambitious. Sufficient time is going to be necessary on both sides. Do we want to put a line in the sand of what a realistic time is like 2029, 2030, or leave that up to ASTP?

Hans Buitendijk
I have no idea what the time would be.

Erin Holt Coyne
My public health colleagues might shoot me for this, but I think I would prefer to keep it at 2028. This is going to be our opportunity to clean some things up and to unstandardized. If we keep kicking that can down the road, by the time 2029 and 2030 comes around, we will have missed out on the opportunity to clean up what we are already getting and probably faced with a new standard entirely.

Bryant Thomas Karras
Whatever replaces FHIR will be available by then. We will not shoot you. We are nonviolent so we will just hug you really aggressively. A realistic timeframe could still include 2028.

Hans Buitendijk
From our perspective, it could just make sure they are reasonably aligned. Otherwise, you have a risk of developing something that is not going to be used yet, or we have something else that happens first and then, we are not ready because it is out there late. We want to have everyone synced.

Bryant Thomas Karras
Let us turn that green.

Hans Buitendijk
The next one is just to point to the **[inaudible] [00:41:14]** updated. I have not put the actual full name in there.

Bryant Thomas Karras
Perfect. I think Erin, we need to have this comment circulated amongst as many jurisdictions as we can, as well as HL7 and JFIT and whoever else is going to be commenting because it is going to be a challenge for ONC to justify, including an IG that was not in the notice of proposed rulemaking, unless they get an overwhelmingly large number of commenters all triangulating in on the same standard. We will need to make sure people know the importance of referencing this exact IG.

Gillian Haney
I can take that to JFIT and we can highlight it on our calls to.

Steven Eichner
I was thinking to also get it in Connect.

Bryant Thomas Karras
Edition 5 is not specifically mentioned in this Notice of Proposed Rulemaking (NPRM). It is pointing at edition. Let us try and get that corrected, otherwise, we will be stuck with a dead letter, as they say.

Erin Holt Coyne
The next paragraph goes hand-in-hand. The first red paragraph is about the IG itself; the second paragraph is about the specific public health profile component that should be used. Those can go hand-in-hand.

Bryant Thomas Karras
Why do we not eliminate the space between those two so that they stay together and turn them both green?

Hans Buitendijk
So just put and between them and split it?

Bryant Thomas Karras
A semicolon or something.

Steven Eichner
And a little wordsmithing on the second paragraph and we are not going to do that now. But a little wordsmithing because right now, it looks like a double negative so we should reword that.

Bryant Thomas Karras
That is a weird, almost double negative.

Steven Eichner
Exactly. Again, we do not need to wordsmith it now if you want to just tag it. I would just tag it.

Bryant Thomas Karras
The staff can just make sure that it is not interpreted as an "or" but it is a clarification. All right, next. Hans or Gillian.

Hans Buitendijk

The next one, the discussion was around having all development data and some discussion around that data might be in different systems, but indicating here is that the party that pulls the report needs to have it or needs to have the ability to have that information so that it can be a complete report by December.

Bryant Thomas Karras
And Erin, you are comfortable that you have the right additions in there? You can delete out that Erin added in the final text. I assume it will be in the final rule, Erin.

Steven Eichner
Bryant, tag that paragraph. I can take a quick look at it on afterwards because there are a couple of other places where we have similar language about criterion needing to pull data from other places.

Bryant Thomas Karras
Yes.

Steven Eichner
I am not trying to wordsmith here but if you tag me on it, I will try to synchronize that data between the different places that it occurs in the writeup.

Bryant Thomas Karras
We have to be careful we do not get to micromanage. The functional endpoint. I guess what you are saying, Steve, is that EHR systems cannot use as an excuse that the data is someplace else. We want them to actually jump through the hoops of pulling through another system.

Steven Eichner
It is more along the lines of the test certification needs to demonstrate that is generating the full message. If it is coming out the EHR, fine. But if it needs to pull from somewhere else, that has got to be a part of the certification criterion, too.

Gillian Haney
Regardless of whether or not the other system is certified.

Bryant Thomas Karras
We are going to run up against the dilemma of modular certification. Unless we do after implementation testing, real-world testing, that is not possible. You have your hand up?

Erin Holt Coyne
If the expectation is that whoever the actor is to conform to the specific implementation guide that is referenced, this might be naïve, but their responsibility that the information is known to make it available to the interface.

Steven Eichner
Exactly.

Gillian Haney
Agreed.

Bryant Thomas Karras
Yes. It is just that the F3 is targeting the EHR provider, not the actual actor.

Steven Eichner
From a certification criterion, if it is coming out of the EHR, fine, past certification criterion. If it is not the EHR, the EHR needs the capability to get it from somewhere else. Either one works and that it gets you to that certification criterion. Right?

Hans Buitendijk
Then, we need to recognize that it is capable of doing it and it can have all the data in there. The fact that it was actually configured in combination with other systems goes beyond certification. You need to recognize that. And as long as it is there, that is it.

Steven Eichner
It is the capability, not the actual doing it all the way through from the start.

Hans Buitendijk
That is why we have less control of what is on there.

Steven Eichner
Right. It would be bad to have something certified as capable of sending it if it does not have the data to send. And then, the provider then says, "I cannot get the data in my system."

Bryant Thomas Karras
Guys, we are halfway through and we have done less than one quarter of the topics. Are there anymore we can turn green right here and move on?

Hans Buitendijk
Is the one we just talked about ready for green? It sounded like we are on the same page.

Steven Eichner
Yes. I think it is green, but it is just synchronizing the text because we do the same thing in three other places in other criteria. I was going to get all that text aligned.

Bryant Thomas Karras
The next paragraph, again, has some Erin suggestions. Go ahead.

Erin Holt Coyne
I was suggesting a rewrite of the laboratory required to report the public health sentence. The way that it ended, it says, “While the ordering provider only needs to report to public but should not be required to receive laboratory orders." In an attempt to clarify that a bit, I said, “The laboratory required to report to public health must have the ability to receive laboratory orders and include data relevance, public health and report to public health while the ordering provider only needs to report to public health for case reporting and should not be responsible for also reporting lab orders separate from the case report.”

Bryant Thomas Karras
That makes sense. I am thinking in our jurisdiction, the laws may not fully align. I think we still have just lab reporting, not case reporting as legal requirements.

Gillian Haney
You do not have provider reporting?

Bryant Thomas Karras
It is provider reporting of positive lab results.

Erin Holt Coyne
Right. But you would expect the provider to pick up the phone, not the laboratory.

Bryant Thomas Karras
We should say both. We say the provider has to call us, the lab has to call us, everybody has to call us, but the provider never does.

Erin Holt Coyne
Considering the argument against public health reporting and the burden it causes, I think if we were to now require the providers also report and labs also report laboratory orders, we are going to shoot ourselves in the foot.

Bryant Thomas Karras
I totally agree with you. I am trying to think about all the rule changes that we have to do locally. I will shut up now but let us delete out the Erin suggested edit from the middle of that paragraph. And is that last sentence a replacement, Erin, or an additional clarification?

Erin Holt Coyne
It was a replacement of the laboratory. The very second sentence, the laboratory required report, it was a replacement of that sentence.

Bryant Thomas Karras
Which goes all the way to providers?

Erin Holt Coyne
Yes.

Hans Buitendijk
I have no problems with that adjustment of that sentence, but I realize reading that that the responsibility of going back to a rule-based focus of criteria, that the responsibility of the lab required to report has the ability to receive that. We want to indicate that as best done in a separate criteria F whatever, that is for lab reporting laboratory that they have the ability to receive that information. The ordering provider can put it on the order, the lab needs to have the ability to receive it. Part of this needs to be addressed in F3 and part of it is to further be addressed in some new criteria that is focused on the lab.

Gillian Haney
I concur with Hans.

Hans Buitendijk
However that is phrased but I really we do not totally catch that in the phrasing.

Bryant Thomas Karras
We need a Laboratory Information Management System (LIMS) F criteria or maybe it is an L criteria or something.

Hans Buitendijk
We still have F30 through 40.

Bryant Thomas Karras
We can also have it end in a three, I get you. Let us turn that green. Thank you for the cutting and pasting surgical execution there. And then, Erin, is this last one also clarification?

Erin Holt Coyne
No. You just leave it red. I would just stick with the green that you have.

Bryant Thomas Karras
Let us move onto F4, cancer.

Hans Buitendijk
I added so we get to both. The key there is to not require the use of FHIR-based implementation guide for cancer registries, but rather focus on the efforts to adopt Clinical Document Architecture (CDA)-based reporting. And I think that is where the comment would then go into we support the CDA version. And we are not in disagreement with the FHIR. The focus should be on enabling the CDA in that regard. We do not want to have a required shift to FHIR at this point in time. That is the essence of that comment. There is optionality but enable adoption, otherwise focus on our midstream shifting over require to find. That seems to soon.

Steven Eichner
And how do we feel about the record of Association Cancer Registries for that or guidance, which still seems to be a bit left out of the certification criterion? Their guidance is as of January 2024. It is old. It is Version 5.1.

Hans Buitendijk
No concern with the versions that are being listed. More of a concern is that one would have to be done while the other one sounds like it is already being removed.

Bryant Thomas Karras
Clarify that again. STU 1.0.0 is not the most current, right? Erin, you have your hand up. Is that an HL7- specific version correction?

Erin Holt Coyne
I believe there is a cancer pathology IG in FHIR. I will confirm that. My comment here was going to be distinguishing between in the recommendations, we should probably specifically address the cancer case report as one and a recommendation for the cancer pathology report as two.

Bryant Thomas Karras
Okay.

Steven Eichner
I agree. Do we want to move forward on the cancer pathology report using FHIR? How do we feel about naysayers working because that is still focused on V2 and CDA?

Hans Buitendijk
Taking the pathology report on the side because I do not believe there is current CDA in play. It is focusing on FHIR right now. Just the cancer registry one is that there is a CDA version and a FHIR version. And the intent of the comment and discussion that we had was along the lines of let us not require the switch over to FHIR through this rule at this point in time so we have the ability to progress and advance the pace of adopting the CDA-based as well as opposed to stopping that effectively as we are just getting steam there but still, allow somebody that wants to start with FHIR, let them do that. But let us not disable CDA.

Steven Eichner
There is a V2 pathology report that was revised to March 2024.

Hans Buitendijk
I was talking about the cancer registry, not the pathology.

Bryant Thomas Karras
Let us separate out the cancer pathology lab components versus the case reporting components. This is a question for ONC or Accel staff. Did the cancer program area folks who do not have access to the spreadsheet, did they send in any final recommendations about what the current release that should be referenced is?

Jeffery Smith
This is Jeff. What we can reference and what we can adopt is really only what we have proposed. I do not have any other information on whether there are newer versions or when those might be balloted.

Bryant Thomas Karras
I think they were already balloted and released. Jim, do you have any updates from your CDC colleagues or can you get back to us?

Jim Jirjis
I am glad you brought it up with Jeff on the phone here because the question is on the one hand, we cannot include anything that goes beyond the NPRM that is stated in it. Bryant had mentioned something earlier in the call about if there is a preponderance of feedback, are we still bound to not get anything new, even if there is an overwhelming push for something that is not in the NPRM?

Bryant Thomas Karras
Jeff, I totally concur that if it has not even been balloted yet, that makes sense. But ones that have already gone to ballot just in March or May after the proposed rule was drafted, it seems like there is a potential wiggle room there.

Hans Buitendijk
We made the comment already in LOI/ Laboratory Results Interface (LRI) on the Electronic Laboratory Reporting (ELR) to suggest using Version 5, which was published after the rule went through its process. But that is not the most current one published. I think it is a fair comment. Whether ONC can honor it or not, I think that would be up to ONC. If we feel that is the better recommendation, we have done it in the past. I think it is a fair comment.

Jeffery Smith
That is exactly right, Hans. That is what I was going to say. You should put into your recommendations exactly what you think, and we will do what we can on the backend. That will be a discussion that will happen internally.

Steven Eichner
The other end is, and I do not know if it is worth putting in recommendation language, if it cannot be included here that it should be considered for Standards Version Advancement Process (SVAP).

Bryant Thomas Karras
Jim, back to you. Not asking for you to make any recommendations, but just factually report from the program area what is the current IG that the program area is building towards and that their cancer registry plus software is supporting?

Jim Jirjis
Perfect.

Bryant Thomas Karras
Just the facts, ma'am.

Jim Jirjis
Absolutely. For those who do not know because I am with the federal government, the HHS, I also am bound not to opine. That is why I am staying quiet, but I will get back to you on that.

Bryant Thomas Karras
Hans and Ike, I like your suggestion that we make it really clear the distinction between the case report and the pathology report so they are not inadvertently considered an or, but they should be a yes/and.

Steven Eichner
And two different IGs apply or at least two IGs apply. It depends if you are doing CDA and FHIR or just FHIR or just CDA.

Hans Buitendijk
To be clear, in the rule language at the end of the document, it is very clear that it is optional between the two cancer registries, CDA and FHIR, with some timelines in there. But the cancer pathology is required. In the actual rule language, there is no doubt that you have to have a cancer registry and you have to have pathology. But there is no need to introduce here something to the contrary that would make it an ‘or’. We want to make sure that we do not do that.

Bryant Thomas Karras
Good. Can we turn any of this green or do we need to come back to it?

Erin Holt Coyne
Probably clean up and come back.

Bryant Thomas Karras
Let us scroll to the next one, F5, eCR.

Joel Hartsell
We went through and we updated based on the feedback from the last call to make the language more targeted and directed. The red is the changes. Steve, Erin, and I worked on this and Gillian. With the first one, I think the one that needs a little bit more revision is four. Any thoughts on that. Essentially, our recommendations are to kind of persist the choice of CDA or FHIR for a little longer, for No. 1.

Bryant Thomas Karras
That sounds good. Let us turn No. 1 green. This is just a wordsmithing thing we can clean up later, but do we need to repeat the HL7 FHIR in front of the RRIG?

Joel Hartsell
Probably, yes. I can take that as an item to add in.

Bryant Thomas Karras

We talk about CDA in between the two. Is it that there is a CDA RR and a FHIR RR? We are not getting them co-mingled.

Steven Eichner
There is a response from FHIR but it is not really a RR, it is incorporated into the transaction.

Bryant Thomas Karras
I think it is good to go but I want to make sure we do not confuse people.

Steven Eichner
That is why that part is confusing is that the content is the same, but it is not an RR separate message. It is just part of the FHIR transaction.

Hans Buitendijk
Another way is that in the CDA, there was an option to have them in different documents described and in FHIR, everything is defined in one IG.

Bryant Thomas Karras
No. 2. Thanks for numbering these, Joel. It makes it a lot easier.

Joel Hartsell
Sorry. I realize I did not put my name on it. It was a group effort. No. 2, I guess I word smithed it a little bit, but just suggesting that HTI-2 should indicate that wherever the electronic initial case report (eICR) is sent, the same format would be returned FHIR or CDA. That is just being consistent with Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, since we are recommending persisting FHIR and CDA.

Bryant Thomas Karras
It should not affect the change, but an intermediary like APHL, if a state agency can only do one and not the other, you can still handle both. You would be able to be compliant with HTI-1 and send back.

Joel Hartsell
Yes. We are actively implementing the transforms for the PHAs, but regardless of the healthcare organization EHR sending FHIR or CDA, we can return whichever now.

Bryant Thomas Karras
Turn No. 2 green. And you did some **[inaudible - crosstalk] [01:09:06]**.

Joel Hartsell
Just an example to make it more clear. I think those heavily involved with eCR would understand that example, but the laboratory information, if it is received from a system outside the EHR should persist standardized codes when returning the data.

Bryant Thomas Karras
Especially as we are onboarding case reports from providers far afield of our local jurisdictions, this is going to be incredibly important that people are consistently using Systematized Nomenclature of Medicine–Clinical Terminology (SNOMED CT) and Logical Observation Identifiers Names and Codes (LOINC®) and not local codes because there will be no way for Washington to resolve a local code from a hospital in Florida that we have never seen before.

Steven Eichner
This is one of those paragraphs that needs to sync up with the same kind of language about wherever the data is coming from.

Bryant Thomas Karras
I appreciate that. After onboarding a Trusted Exchange Framework and Common Agreement (TEFCA) mediated Continuity of Care Record (CCR), we know very well that sometimes hospitals that are more aligned with another state do not always see eye-to-eye with our requirements.

Steven Eichner
And we also included **[inaudible] [01:10:43]** or entry as a specific call out as needing to be supported.

Bryant Thomas Karras
And race and ethnicity requirements. I will not wordsmith those in here. Let us turn that green.

Joel Hartsell
No. 4 I think needs a little bit of refining still just to make it more clear what we are looking at and I can try to get to that as soon as possible (ASAP). Bryant, when do you need this by?

Bryant Thomas Karras
A solid team winner, when did we commit to sharing the documents with the full –

Seth Pazinski
We were planning to share them Friday morning of this week. By close of business Thursday.

Bryant Thomas Karras
Wednesday would be better so that you get some time.

Steven Eichner
Joel, I made a little bit of editing for earlier today.

Joel Hartsell
You did? Okay. Maybe we can circulate offline and I can try to make sure that Erin, Gillian, Steve, are all kind of looped in and we all agree. I do not think it looks bad, but there might be some other considerations we might want in here.

Bryant Thomas Karras
I know you have other groups to support on Thursday. But is there a possibility we can reconvene Thursday to finalize?

Joel Hartsell
I have an in person and I am in DC traveling.

Bryant Thomas Karras
We will try to do it offline.

Steven Eichner

Just a general comment, when we are saying public health agencies, let us try to standardize on State, Tribal, Local, and Territorial (STLT) throughout if we are looking at stakeholders and participation. That is kind of a note for the editors just for consistency so that we are hitting everybody and it is not exclusive to CDC but we are really full participation in there.

Bryant Thomas Karras
And in some cases, it is federal for the survey reporting. The recipient is not the STLT, it is the federal agency. All right. We will not turn No. 4 green until you have had a chance to double check. Let us know when that is resolved. If you can reply all to the members of the Task Force.

Joel Hartsell
This one I just added in the United States Department of Defense (DOD) and the United States Department of Veterans Affairs (VA).

Bryant Thomas Karras
Perfect. Are there any other federal agencies?

Erin Holt Coyne
It says and others.

Gillian Haney
Should that comment be reflected elsewhere as well as a summary statement?

Joel Hartsell
I think Erin said this is included in several others. You were saying the updates to include DOD?

Erin Holt Coyne
It should be consistent, I think.

Bryant Thomas Karras
And it is one that is just problematic in that HHS, one good thing is that with ASTP's elevation to being an Assistant Secretary, they now have a lot more purview over other HHS branches. But they still do not have any authority over DOJ, DOD, and VA. We are asking them to coordinate but they cannot force.

Steven Eichner
Do we need to mention resources for states and locals here, too? And do we need to classify necessary technology and policy improvements?

Gillian Haney
I think that is covered. It says all parties. We can say all parties including STLT.

Steven Eichner
Right now, it says federal agencies, not anything at the state or local level.

Bryant Thomas Karras
Let us add STLT after all parties, including STLTs. To ensure all parties affected, right in front of I, the first line of No. 5 after the word affected.

Joel Hartsell

I think we also need to include intermediaries.

Bryant Thomas Karras
That is good. Intermediaries and STLTs.

Steven Eichner
Designated intermediaries.

Gillian Haney
We are wordsmithing.

Steven Eichner
I know. As a note, we need to lose the word federal.

Joel Hartsell
Gillian is keeping us on track. Thanks, Gillian.

Bryant Thomas Karras
Turn that green and let us go to No. 6.

Steven Eichner
Lose federal.

Bryant Thomas Karras
I do not think we should lose federal.

Steven Eichner
From a wordsmithing standpoint, just to clarify that other intermediaries are not federal or STLTs are not federal.

Erin Holt Coyne
Ensuring that all parties affected including those.

Bryant Thomas Karras
But the resources are going to need to come from the federal agencies. And I would add one more federal agency instead of just assuming it is under the others, United States Department of Homeland Security (DHS).

Steven Eichner
I read it differently earlier looking at the federal agencies needed resources to implement, not the federal agencies were giving resources to others to implement. That is an important clarification. Thank you.

Gillian Haney
Can I just make note of a comment in the chat, Indian Health Services?

Bryant Thomas Karras
Thank you, thank you.

Gillian Haney
Although they are not a federal agency.

Bryant Thomas Karras
They are.

Gillian Haney
Okay.

Bryant Thomas Karras
It is the Tribal Health Boards that are not federal, but they would be included under STLT.

Shila Blend
Yes. They still use the federal system with connections.

Bryant Thomas Karras
Some do.

Shila Blend
Yes.

Gillian Haney
Is the language correct so far that nonfederal designated intermediaries in STLTs?

Bryant Thomas Karras
I am going to disagree with removing the word federal that Ike suggested and I think this reads well as it is.

Steven Eichner
I agree with the way that it is written right now. I misread it.

Bryant Thomas Karras
Just put dollar signs behind instead of the lowercase S at the end of STLT, we will use the dollar sign. Just kidding. No. 6, I am afraid to open it up.

Joel Hartsell
I think with this one, the main additions from over there is kind of persisting the choice of FHIR or CDA and then, really driving the point home at the end that this retesting towards the transition like post transition to FHIR will slow the ability to turn off manual reporting and persists that burden of manual reporting.

Bryant Thomas Karras
I am going to ask I feel like a repetitious question and in addition to Joel perking up your ears, if Jim Jirjis can tune in. Is Jim still on?

Jim Jirjis
Yes.

Bryant Thomas Karras
Is the Release 3.1 and Release 2.1.1 the correct version. Are those what are referenced in the Notice of Proposed Rulemaking or is this another instance where we need to get the user community to all chime in with the same release?

Joel Hartsell

So I believe 3.1 and 2.1.1 are referencing HTI-1. And those are correct. Right now, everything is 1.1, CDA is 1.1.

Bryant Thomas Karras
And there have not been any corrections or modifications since those?

Joel Hartsell
I guess there is the errata last week, too, 3.1 and 1.1. But maybe we do not include that.

Bryant Thomas Karras
It is too new? One thing that I think we can make as a blanket statement across all of our transmittal is that to the best of certification programs capability, people who voluntarily go beyond the current standard do not get penalized for being compliant with corrections.

Joel Hartsell
That is fair.

Hans Buitendijk
There is a note there is that from certified software perspectives, it has to be for us recognized in either the rule or in SVAP otherwise, it can get problematic. You could ask, but I am not sure whether it is going to help because it really needs to get SVAP then. And there is still time between now and then just from past experience. We have had, for example, FHIR US Core 3.1.1 was in the rules and then, very quickly they were asked to, based on feedback and content, that there was a FHIR US Core 4.1.1 or whatever. But there was a next version that got into SVAP very quickly to allow for being able to utilize any kind of error correction, as well as other things that needed to happen. But we look at SVAP to be there if it is not there. We cannot veer from it unless the standard is recommended or optional.

Bryant Thomas Karras
And I think there is a nuanced difference with minute corrections that make some improvements versus like there was a notice of proposed rulemaking that referenced the wrong one entirely and it would have been catastrophic if it did not get corrected in the final. Hopefully, this is not one of those cases where the errata or the dot version is almost slightly better.

Hans Buitendijk
A comment that in this one, in No. 6, frequently I am suggesting not to reference EHR vendors because a lot of are Hormone Replacement Therapy (HRT). But in this particular case, I just want to make sure because as far as I know, there are no EHRs that would submit these cases.

Bryant Thomas Karras
Something strange just happened on my screen. The things we previously turned green have gone back to black and red. Is everybody seeing that?

Shila Blend
I am having the same issue. I am also having some network issues so I will refresh the page real quick and see if that fixes it.

Gillian Haney
I am seeing it, too.

Steven Eichner

That will happen if someone else has document open and rewrote.

Bryant Thomas Karras
Oh, no!

Hans Buitendijk
You can only have one person doing editing and everyone else views in a cell, otherwise I am not sure.

Bryant Thomas Karras
Hopefully, the wonderful wordsmithing we did is cached in somebody's brain so we can redo it.

Hans Buitendijk
While we are refreshing screens, I noticed that Row 2 that we skipped that, so we went row by row,

Bryant Thomas Karras
There was an overall. Got it. We will come back to that. We have about half an hour to get through 14 of these. We are going to have to go faster. And there is no Control Z on the Google sheet, is there?

Steven Eichner
Only Control C, copy.

Bryant Thomas Karras
Is somebody else in the spreadsheet?

Hans Buitendijk
I am in the spreadsheet but I am only viewing.

Gillian Haney
Me, too.

Bryant Thomas Karras
No one is actively editing? I do not see any other –

Steven Eichner
I am not in the spreadsheet at all because I made a mistake once on that and went inside of it. I do think inadvertently hitting a button and redoing work is no fun.

Bryant Thomas Karras
After we have finished, why do we not go in the hot wash and we can try to reconstruct the additions we made to No. 5. And did we make any other substantial changes?

Gillian Haney
This is recorded so we can at least hear.

Aaliyah Parker
Sounds good. Thank you.

Steven Eichner

It is video recorded so you can see it, too. What might be helpful is once in a while, just take a quick screenshot and that way you can have that as a quick reference.

Bryant Thomas Karras
I am having flashbacks. We lost some of our edits when we did the public health Task Force. Gillian, hopefully, you are not having post-traumatic stress disorder (PTSD). Next is No. 6. This is the National Healthcare Safety Network (NHSN) antimicrobial resistant. I think this is another one where at the eleventh hour, the CDC program area mentioned that they either had just balloted or a revision was in the process of going through in R4. They want to start using R4 in 2025. But what is in the Notice of Proposed Rulemaking is Release 3. One of the things that we will have to determine is if improvements are substantial and if the EHR community wants to do one versus the other. Has Electronic Health Record Association (EHRA) weighed in on this, Hans?

Hans Buitendijk
Yes. It is a topic that we are looking at and the text that you see will be reflective of that. From there, we can, obviously, modify and correct whatever. But that is the perspective that we have within EHRA. At Centers for Medicare & Medicaid Services (CMS), we started again with Quality Reporting Document Architecture (QRDA) reporting on the cadence on what is in regulations and what is going in SVAP and trying to keep them aligned because CMS has annual updates. It is always interesting how that goes. You were suggesting that we get ONC, and in this case CDC, in line in that way as well and arrive on the cadence so it becomes more predictable in that regard. The question is what is the right first step to get there?

Bryant Thomas Karras
And I am not even sure. Can we use SVAP?

Hans Buitendijk
As soon as there is the guide that is at hand or the standard at hand is in the regulation, SVAP can be applied. SVAP you can see for FHIR US Core because FHIR US Core is named in a regulation. If the standard is not yet named in any way in a rule published then, SVAP cannot be introduce it. But over time, it evolves to the next version until the next regulation sets the next lowest bar.

Bryant Thomas Karras
In the Interoperable Standards Advisory, the ISA, similarly or even more flexibly, there could be references to things in there that are not at all in regulation.

Hans Buitendijk
Correct. ISA is, “a library” of everything that is out there that could be considered for some purpose, which is not the same as it is in a regulation. It does not have that restriction.

Steven Eichner
The misappropriate tax Boro is a guideline.

Hans Buitendijk
Sometimes we consider it a library.

Bryant Thomas Karras
Sometimes with competing standards.

Lee Fleisher

This is a clinically important issue. There is a United Nations event in September making this a worldwide issue, so anything we can align with the latest version would be important from a public health perspective.

Bryant Thomas Karras
Jim, can you factually report back on what the program area's sense of urgency is for Release 4? Is that in response to international pressures or regulations? And if I remember right from their presentation, they said they had done a one or two hospital test implementation of the new release that went well.

Jim Jirjis
I can get more info on urgency of R4 and what is driving it.

Hans Buitendijk
Part of the context is the target date on the provider side is January 2027, January 1 or December 1 of 2026. I am not sure which one of the two it is. But that is the target line to have it implemented, so would everybody be ready by that time? Notwithstanding the comments that were just made, just to clarify the context that three were suggested to do that and then use SVAP to get to four is that, currently, it is partly R3 and partly R1 being used. Step one is getting everything on R3 and not split between R3 and R1, and then go up to R4. That was the thought behind it. That is for context only as to why EHRA was thinking in that direction. If there are other arguments that would push it stronger in R4, that should be then considered.

Bryant Thomas Karras
Can we turn any of that green? Any opposed? Let us turn from recommend on green and maybe turn Ike plus one black so that Steve Eicher does not become part of the final rule. Thanks so much. But Jim, if you can get back to us. And if any factual information about what is happening internationally with antimicrobial resistance efforts, Lee, if there is something about that. Is that World Health Organization (WHO) activity, I presume?

Lee Fleisher
It is WHO. I think, Jim, you are going to be in New York for the United Nations (UN) General Assembly call. At least that is what I have been told.

Jim Jirjis
You guys want me to find out the context for what was driving R4 and if the timing of HTI-2 compromises anything. I can get back to you.

Bryant Thomas Karras
And if there is any international regulation requirement that has different target dates. That does explain why CDC's National Healthcare Safety Network (NHSN) was being much more aggressive on their timing.

Lee Fleisher
Believe it or not, 2028 is the 100th anniversary of Fleming's discovery. That is what is going on.

Bryant Thomas Karras
Wow. Next is another NHSN activity, the healthcare surveys. This one does not impact states or STLTs as much, it is much more of a federal survey. I am a little bit neutral on my proposed language here. Starting with we recommend, what I suggested is that we do recommend supporting both for this time period of the CDA-based survey report and the new FHIR IG. And again, Jim, clarification, I searched my email and I do not have anything in mine recommending with the exact reference. But if we could expand that that middle Column I a little bit. I think there are some notes there that were taken during the presentation from NHSN. Yes. It was 1.0.1 that has gotten through ballot but was not mentioned in the notice of proposed rulemaking. Is that right? Oh, no. It is in the

rulemaking. And 3.1 for the CDA and 1.0.1 for the FHIR. I think this one, if we can just confirm with certainty from the program area, Jim, that we have the right standard referenced, I think we are fully supportive. Shall we go ahead and turn this green?

Hans Buitendijk
Question, there is an and in the red text and there is an or in the motion notes in I.

Bryant Thomas Karras
It should be or. Certification does need to support both. It is one or the other.

Hans Buitendijk
So, the HIT can select with one and it is that CDC will be able to continue to receive CDA. There are no cutoffs here for some period of time but not in the rule.

Bryant Thomas Karras
If it turns out that there is not a newer IG in the works, you can turn that sentence black. But, Jim, if you can confirm. I may be confounding antimicrobial resistance and survey work. We covered in the same session.

Aaliyah Parker
I think it is my network. I am going to connect to my hotspot real quick so I might drop off.

Bryant Thomas Karras
It just turned red again. We have 15 minutes left. I am wondering can people continue on for an extra period of time or do people have to drop off at the hour?

Hans Buitendijk
I have some flexibility.

Seth Pazinski
We will need to close the meeting at the scheduled time.

Bryant Thomas Karras
Do we need to do public comment in 10 minutes?

Seth Pazinski
Yes, but we can turn back with any remaining time until 1:00.

Bryant Thomas Karras
All right. I hoped to at least get through into the tens.

Aaliyah Parker
Are you able to see my screen?

Bryant Thomas Karras
I am seeing red text, and it still says and. That needs to be changed to or. Jim, if you can confirm and get back to us. Thank you. It is great to have the liaison from the CDC on. Shall we move on to try to get through No. 8 in three minutes and then, open it up to public comment, come back? Ike, were you drafting these?

Steven Eichner

Yes, I was. The issue is that G10 and G20 are scoped to United States Core Data for Interoperability (USCDI) and USCDI Public Health, ultimately. But if all data points that are required in the HL7 guide go beyond that, there is a problem in implementation,

Bryant Thomas Karras
Are you saying that what is referenced here in vital records, birth, and fetal death reporting may conflict with G10?

Steven Eichner
It may go beyond what is included in the USCDI and public health USCDI plus. It is misaligned.

Bryant Thomas Karras
STU 1.1 needs to be modified to come into alignment?

Steven Eichner
Or USCDI needs to be modified.

Bryant Thomas Karras
I think the program area of vital records mentioned that although they are referencing this STU, what they intend to certify is only the traditional birth reporting, not fetal death. Is it the fetal death that is the conflict?

Steven Eichner
I do not think so.

Bryant Thomas Karras
All right. That is problematic.

Hans Buitendijk
It depends a little bit about in which direction we are looking. Generally, the USCDI, USCDI plus, G10, do not reflect all the data that we communicate in case reporting, lab reporting, whatever, all kinds of things. The specific implementation guides cover all the data that is relevant for that. So, in itself, I am not convinced it is a problem that birth and fetal death reporting data in the guide is not present in G10, G20, or USCDI because the implementation of it would focus on the data that is relevant for that report. In that direction, I am not convinced there is a problem per se. The other direction there is not a problem is that the question is should we include any data from fetal birth and death reporting into G10 and/or G20, the concern there is if we do that, G10 and G20 are already pretty large. And now, they get larger with data to determine HIT cannot certify against because they carry that data. We have to be very careful much more in the other direction to suggest that everything that is not in G10 or G20 that is in the birth and death reporting in this guide ends up there.

Actually, we have a bigger problem because that would be that less HIT will be able to certify against it, unless they create capabilities that they do not need. I think that is the bigger issue. We have seen implementation guides and standards being used for specific use cases that are not fully representative in G10 and G20. Generally, that is okay. The other direction is a problem.

Bryant Thomas Karras
Yes. I think that this is something that we are going to be challenged with again and again is that having specific IGs for public health use cases as opposed to a generic FHIR application programming interface (API) capability using the USCDI is going to always be a little bit at odds with each other. But perhaps we need to get into a realm where we are creating public health profiles that specify how those G20 APIs are specifically constrained to be in compliance with public health needs.

Hans Buitendijk
And the question that still remains, depending on context, the system, etc., G10, G20 as they are currently evolving are getting increasingly too big for all certified HIT to be able to manage data. It is just not appropriate

Steven Eichner
More specifically, so just to elaborate on your point, the IGs are supporting multiple use cases where if you are looking at a specialty EHR, specialty HIT, you are not going to be supporting all of the use cases by nature of the user of the system. But in order to be certified, you have to get the entire truck. You cannot just get the **[inaudible] [01:49:19]**.

Bryant Thomas Karras
I am going to pause us for a second and, Seth, if you can open things up to public comment.

Public Comment (01:49:31)

Seth Pazinski
We are going to move to public comment at this point. If you are participating via Zoom today, you can raise your hand through the Zoom feature at the bottom of your screen. And if you are participating by phone only today, you can press *9 to raise your hand and once called upon, you can press *6 to mute and unmute your line. While we give folks a few seconds to queue up, if we have any public comments, just a reminder that going forward we will be pivoting to the full HTI-2 proposed Task Force meeting starting on Tuesday, September 3 next week. And then, we will be continuing with the full Task Force through September 5. The meetings are from 11:00 a.m. to 12:30 p.m. Eastern Time for Tuesday, Wednesday, Thursday next week. And as a reminder, all HITAC meeting materials can be found on healthit.gov. Let me check. Do we have any public comments on the line? We do not have any on the Zoom. Bryant, I will turn it back to you.

Next Steps (01:50:52)

Bryant Thomas Karras
Let us try to wrap up this one at least. Can we go back to the spreadsheet?

Steven Eichner
We need to go down a bit.

Bryant Thomas Karras
You are zoomed in probably. We are on Row 10 birth reporting. You jumped in the discussion here, Ike, of alignment with G10 and G20. If we turn back to just the recommendations around the implementation guide STU 1.1, can we say that?

Steven Eichner
It gets better.

Bryant Thomas Karras
It is better than nothing? Is this one where we need to say that there may not be enough progress or proving out of this? I think Michigan has done some testing around it and some other states but a lot of the EHR or the public health vendors or the F28 component are not going to be ready.

Steven Eichner

The other difficulty is that there is still a gap between some jurisdictions and what is actually included in the IG that there may be states that are collecting more data than what is included or what is supported. You have got a problem about yes; you can use certified technology but certified technology may not be enough in some jurisdictions. And that puts an additional burden on the provider for custom modifications if they are going to use the FHIR standard. And then, the impact, of course, in the CMS reg is that CMS requires providers to use certified technology to do it but public health cannot support that particular technology. You get around that with declaring readiness for that standard, but it gets messy.

Bryant Thomas Karras
Scroll over to the left and let us see what is in the create provider birth reporting in accordance with FHIR IG 1.1.0 STU 1.1. There is no date deadline on this one as opposed to some of the other ones that had the 2028. Is this really a voluntary signaling and we can be supportive of it? And maybe it will start to move the needle, Hans, or is this one where we need to say we are not ready yet?

Steven Eichner
Without an action date, I do not think anyone is going to move forward on it.

Hans Buitendijk
Right. And I think the challenges are a couple fold. One is that insufficient maturity and operational use or readiness, the first version, where that, typically, is a little bit more of a challenge. Then, Version 5, I was suggesting to go to Version 6, which is a different scenario that we were in. In this case, this is very early on. It seems to be too early. There are no dates. And the question that is raised is could this all be obtained through G10 and G20. Our prior concern is that that might lead to including things and G10 and G20 that are specific to this specialized reporting.

Bryant Thomas Karras
I have always thought that USCDI plus should be aware of these kinds of modular things getting included, not in the Core.

Hans Buitendijk
I agree with that. And then, we need to figure out how we are going to manage G20 because currently, G20 is proposed base EHR requirement, which means that any EHR, if it were to be in G20, every EHR would have to support it, which still goes back to the same issue that we raised before is that in the other direction than what is currently written down in the cell. Having to guide more than G10, G20 is, from an implementation perspective, not a problem. Having G10 or G20 include data that is unique to birth and fetal reporting, that is a problem because that imposes on every EHR, if not every HIT that wants to be certified.

Bryant Thomas Karras
How do people feel? I want to hear from some folks other than Ike and Hans on this.

Hans Buitendijk
I am happy to work with Ike to come up with a draft. We can go back and forth over the next one or two days and see we can find that middle ground. Ike, would that work?

Steven Eichner
Absolutely. I am free any time after 1:00 Central Time.

Bryant Thomas Karras

All right. And then, Naresh, are you able to stay on or meet with me separately? I am not seeing Naresh on anymore. Shoot.

Seth Pazinski
We are at time. We will need to adjourn but we can follow up as needed.

Bryant Thomas Karras
All right. We barely got through half and did not get quite through half of the ones we need to get through, Seth.

Seth Pazinski
We can chat in the debrief and come up with a game plan for next week.

Bryant Thomas Karras
All right. Sounds good. Well, thank you all. I lost my hat and am rubbing my four head in ponderance of how we are going to get this accomplished. But I really appreciate everybody sticking through this.

Adjourn (01:58:21)

Questions and Comments Received Via Zoom Webinar Chat

Jim Jirjis: JJ just joined

Noam Arzt: Immunization Registry or IIS? Feels like a step back in terminology.

Erin Holt Coyne: Do we need to address MB's comment addressing the reference to IIS vs Registry?

Erin Holt Coyne: There is an HL7 V 2 IG specific for Syndromic where ADT is the primary message type

Erin Holt Coyne: What is included in the HL7 product grid as published is "HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 - US Realm"

Hans Buitendijk: Two clarifications on the discussions:

- we should not look at bulk data as a replacement of existing capabilities, rather an additional format to use larger data sets.

- we should consider in future syndromic surveillance discussions that HL7 v2 format for the intended data content is not optimal, while a FHIR based approach should start to be explored. There the "trigger event" is a manual decision or a system event is a separate consideration. HL7 v2 ADT message format was selected early days given the then current scope of content. In FHIR it will be easier to include the variety of data, whether de-identified or not. Those would likely not be considered ADT messages.

Hans Buitendijk: Note also that the provider has certain controls to enable data to be shared within their configuration, so certified software can do it, but it then must be configured as well.

Erin Holt Coyne: But I don't think the Cancer Pathology V2 IG is an actual published IG from HL7. I believe its published from NAACCR.

Erin Holt Coyne: for what its worth.

Erin Holt Coyne: eICR- CDA

RR- CDA

eICR, RR, and eRSD- FHIR

Erin Holt Coyne: i don't think it looks bad

Noam Arzt: Isn't "real world testing" handled elsewhere in regulation?

Hans Buitendijk: Yes.

Hans Buitendijk: It picks up on updated/new criteria.

Noam Arzt: So should a comment on an "(f)" criterion make reference to real-world testing or is it inappropriate?

Noam Arzt: And IHS?

Noam Arzt: Yep

Hans Buitendijk: I am not convinced it is needed, but it would not hurt to clarify a point and confirm to avoid any ambiguity.

Noam Arzt: This is not a Google sheet. It's Excel.

Erin Holt Coyne: IT was something like..... ASTP needs to work with respective federal agencies (CMS, CDC, DOJ, DoD, VHA, IHS, and others) to ensure that all parties, including STLT PHAs and intermediaries, affected by these enhanced standards are resourced to make the necessary improvements.

Gillian Haney: ^ agree with Erin...

Jim Jirjis: BRB

Jim Jirjis: yes

Gillian Haney: I can stay until 12:30

Jim Jirjis: thanks

Jim Jirjis: back

Noam Arzt: Gotta drop. Good luck with this...

Jim Jirjis: have to drop also

Erin Holt Coyne: Thank you!

Questions and Comments Received Via Email

No comments were received via email.

Resources

HTI-2 Proposed Rule Task Force 2024
HTI-2 Proposed Rule Task Force 2024 Group 1: Public Health - August 27, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 9/30/24.