HTI-2 PROPOSED RULE TASK FORCE 2024 MEETING

GROUP 1: PUBLIC HEALTH

August 13, 2024, 11 AM – 1 PM ET

VIRTUAL

MEMBERS IN ATTENDANCE

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
Zeynep Sumer-King, New York-Presbyterian
Naresh Sundar Rajan, CyncHealth
Thomas M. Wilkinson, U.S. Department of Homeland Security

MEMBERS NOT IN ATTENDANCE

Steven Hester, Norton Healthcare

ASTP STAFF

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

PRESENTERS/ DISCUSSANTS

Joyce. A Martin, CDC/IOD/OPHDST/NCHS
Karl Soetebier, CDC/IOD/OPHDST
Daniel Kurowski, CDC/IOD/OPHDST
Jeffery Smith, 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 United States Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy (ASTP), and I will be serving as your Designated Federal Officer today. This meeting, as a reminder, is open to the public, and public feedback is welcome throughout the meeting. You can make comments in the Zoom chat feature. Time is scheduled at the end of our agenda for verbal public comments for anyone interested in taking advantage of that opportunity. We are going to go ahead and get started with our meeting and we will start with a roll call. I will start with our Chair, Bryant Thomas Karras.

Bryant Thomas Karras
Present.

Seth Pazinski
Shila Blend.

Shila Blend
Good morning

Seth Pazinski
Good morning. Hans Buitendijk

Hans Buitendijk
Good morning.

Seth Pazinski
Good morning. I did get a message that Steven Eichner will be joining us late. Lee Fleisher.

Lee Fleisher
Good morning.

Seth Pazinski
Good morning. Rajesh Godavarthi.

Rajesh Godavarthi
Present.

Seth Pazinski
Gillian Haney.

Gillian Haney
Present.

3

Seth Pazinski
Joel Hartsell.

Joel Hartsell
Present.

Seth Pazinski
Steven Hester. Erin Holt Coyne.

Erin Holt Coyne
Good morning.

Seth Pazinski
Good morning. Jim Jirjis. Mary Beth Kurilo.

Mary Beth Kurilo
Good morning.

Seth Pazinski
Good morning. Kikelomo Oshunkentan.

Kikelomo Oshunkentan
Good morning, I am present.

Seth Pazinski
Zeynep Sumer-King.

Zeynep Sumer-King
Good morning.

Seth Pazinski
Naresh Sundar Rajan.

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. And Thomas Wilkinson.

Thomas Wilkinson
Hello. Good morning.

Seth Pazinski
Good morning. Thank you. Is there anyone I missed, or anyone who just joined?

Joyce Martin
Hi. This is Joyce Martin.

Seth Pazinski
Hello.

Joyce Martin
Good morning.

Seth Pazinski
Thank you. Now I am going to turn it over to Bryant to get us started. Go ahead, Bryant.

Jim Jirjis
Jim Jirjis just joined. Sorry.

Bryant Thomas Karras
Better late than ever. Thank you, everybody. Can you hear me okay? My audio just glitched out for a second.

Seth Pazinski
Yes, you are back.

Opening Remarks (00:02:40)

Bryant Thomas Karras
So, again, as always, we have a whirlwind of topics to discuss. We have a slight change to the agenda you will see in just a minute, to try to more logically follow the discussion. We will try to stay focused, and we have a timer established so we can see how the minutes are clocking down and try not to get behind, so we have plenty of time for public comment at the end for the last ten minutes. Next slide, please. Did you want me to run through the schedule or will somebody on the ONC?

Rachel Abbey
Bryant, there is a more detailed schedule moving forward.

Bryant Thomas Karras
Great. I was like, I do not see where the changes are going to be. On the subsequent slide, you will see where the topical shift will obviously occur. Then again, we will leave the last ten minutes, from ten minutes until 1:00 for public comment. So, those of you who are not our subject matter experts who are on deck to assist in the discussion or a member of the subcommittee, stand by for the queue-up questions in the chat. And a reminder to panelists to use the chat to everyone, so our guests can see the discussion as part of the public record. Anything else, Seth?

Seth Pazinski
No, we can keep going.

Bryant Thomas Karras

All right, let us move on. Reminder of our charge and the clock ticking down to the 60 days, but we have an accelerated timeline. And then we have to have our committee's recommendations put together in advance of the vote of the full HITAC committee. Just an update reminder, we do have HITAC committee in two days on Thursday, and I will be providing, along with the other co-chairs, an update in the progress we have been making. So, if there is anything the committee members want me to convey for that, please let us know.

All right, so here is today's and the upcoming meeting. I will be out of town for the 20th, and I believe Steven Eichner, who has not yet been able to join us as he will be a few minutes late, has agreed to take over the co-chair role to run through the topics for that day. Next slide. All right, and we are coming down to the wire, just a couple of meetings left. Next slide. All right.

Rachel Abbey

Bryant, the next slide has the detailed agenda.

Bryant Thomas Karras

Ah, perfect. Next slide. All right, let us get into it. We have 15 minutes queued up for continued discussion from last week, and then we are getting into one of the new criteria, birth reporting, which is F8. And then slightly transitioned here, we are going to do birth reporting measurement or certification immediately after. So, F28 will be switched with F22. Then we will dig into the application programming interface (API). I anticipate that will take more than one meeting, but we will get that discussed as much as we can. We have allotted a full 30 minutes. All right, next slide. We are going to switch over to the spreadsheets.

Rachel Abbey

I think we are moving on to the Google Sheet, yes. I was going to do that.

Bryant Thomas Karras

It just came up.

Rachel Abbey

Yes, we can see it.

Bryant Thomas Karras

Will we be able to see the timer when the Google sheet is displayed, or will that be off camera?

Rachel Abbey

I think we will be able to see it. This is trial and error here.

Molly Prieto

You should have just gotten a pop-up on the right-hand side of Zoom to add the timer, to be in the right task back, and then that way we can all see it. So, You do need to be signed into Zoom to be able to see it. So, if folks are not signed in that might be a reason.

Bryant Thomas Karras

I may need to have a Zoom update. So, I am not able to see the Zoom pop-up on my old computer here. I may need you to prompt me with countdowns. Has the clock started ticking?

Molly Prieto
Once the timer begins, it should display for all. I think we can get it started.

Bryant Thomas Karras
All right, let us get into it.

Rachel Abbey
I can help let you know, Bryant, if you do not see it.

New Public Health Data Exchange Criteria and New Standardized API for Public Health Data Exchange (00:09:40)

Bryant Thomas Karras
Thanks. We read through the Electronic Laboratory Reporting (ELR) last time, so we do not need to dive into that, but shall we kick off? Oh, there is the time, but now I lost everything else.

Aaliyah Parker
Okay, let me take it off.

Bryant Thomas Karras
Let me try a different screen.

Erin Holt Coyne
I see a timer in the top right corner counseling down.

Bryant Thomas Karras
There it is. Perfect, 14 minutes and counting. So, Erin, you had some homework assignments. Do you want to lead the discussion on your thoughts, or read your new proposed language? Proceed how you think is best.

Erin Holt Coyne
Okay, I am going to pull up my version, so I can see it. It looks like the stuff I added this morning is not there anymore.

Gillian Haney
I suspect you need to make the square bigger

Erin Holt Coyne
No, it is gone.

Gillian Haney
Or the row.

Erin Holt Coyne
It looks like it is gone. I have it in a separate document. And I will read it.

Bryant Thomas Karras
Okay, good. I am glad you said that. A good warning to folks, as we are dealing with multiple editors at once, be sure and keep a copy of any comments you make in case they need to be repasted into the spreadsheet.

Erin Holt Coyne
It is certainly possible I pasted on in the wrong line. I will double-check and make sure that is not the case.

Bryant Thomas Karras
Scroll over to the side. Maybe it is in one of the other cells.

Erin Holt Coyne
Let me just read it.

Bryant Thomas Karras
Okay, go ahead, Erin.

Erin Holt Coyne
The first one was clarification of the intent behind the reference to LOI, lab orders, in F3, and how it relates to A2 is requested, so that was number one. Number two, if laboratory implementation guides (LOI) remains in F3, language should be added to clarify its relationship to lab reporting, public health, and the computerized physician order entry in A2, and recommend removing the reference to LOI in F3. If LOI is kept in A2, if the reference to LOI is kept in F3, then the following language is proposed. For laboratory tests that could produce the result of a reportable condition, all data elements identified in the LOI public health component should be included in the order, so the performing lab has all of the data to produce a conformant result message using the Laboratory Results Interface (LRI) public health component profile.

Many jurisdictions require reporting of suspected cases of reportable conditions. In these instances where there is a suspicion of a case of reportable condition and where a provider or a reporting entity may submit a lab order to aid in making a diagnosis, public health would expect to receive an initial electronic case report for the reportable event from to provider or reporting entity, as opposed to a receipt of an electronic laboratory order reported to public health by the performing laboratory or filler. The electronic case reporting (eCR) report could contain the lab order communicated in the appropriate Clinical Document Architecture (CDA) entry in accordance with the electronic initial case report (eICR) or eCR implementation guides (IGs), respectively. We felt the transmission requirements should be updated. So, update transmission requirements via update standards Health Level 7 (HL7) Version 2.5.1, Implementation Guide, Laboratory Results Interface, LRI, Edition 5, as opposed to release 4, U.S. realm with the date of May 2024, which is the most recent version, and to specifically call out the LOI public health component Version 3. So, I am going to copy and paste all of this and drop it, so folks can see.

Bryant Thomas Karras

Perfect. Do you want to drop it into the discussion section, which is a lot less **[inaudible – crosstalk]**?

Erin Holt Coyne
Oh, yes, I can.

Bryant Thomas Karras
So, we will not have to scroll off of the screen. We can see both at once. Thanks, Erin. That was amazingly succinct and complete. One friendly amendment, I wonder if we should try to be future-proof and describe its inclusion in both the CDA e-case report, as well as future FHIR-based e-case report.

Erin Holt Coyne
That is what I am trying to get here, by the eICR, which is CDA, and eCR IG, which is, the eCR is the Fast Healthcare Interoperability Resources (FHIR).

Bryant Thomas Karras
The eCR IG does mention the FHIR, good. It forwardly ...

Erin Holt Coyne
We can certainly clarify.

Bryant Thomas Karras
For certain, for the next few years, CDA is going to be the most commonly implemented at state health departments. Beautiful.

Erin Holt Coyne
There was another comment. It is not necessarily specific to lab but certainly came up, I think, in our discussion last week regarding whether or not the laboratories have all of the necessary information within the system that is sending the result message. So, there is another statement, certification, and this is about certification. Certification should include addressing all functions and data needed to do business, e.g., report laboratory results, including necessary demographic and additional information, including data sourced from systems outside of an electronic health record (EHR) that contain data required for inclusion to conform to the production of a complete exchange consistent with all of the certification criteria. Probably in need of some wordsmithing, but I think you can get the gist.

Bryant Thomas Karras
I love the intent there. Is Jeff Smith with us today?

Molly Prieto
He sure is.

Jeffrey Smith
I am indeed. I was on mute.

Bryant Thomas Karras

Perk up your ears. Our intent there with that recommendation is that public health feels the certification criteria on the EHR systems needs to go a little bit further into making sure that child information that may be in the billing system or may be in the Laboratory Information Management System (LIMS) needs to be included in the real-world testing so that when these certified systems go into place at our clinical partners, they are able to fully transmit all of the required components, even ones that originate outside of the EHR system. It has been problematic over time as we try to implement these messages that people say things like race and ethnicity are collected elsewhere, not in our system, so it is an empty field. It makes it hard to have a complete picture of what is happening for situational awareness and the national picture.

Gillian Haney
Or inhibits the ability for public health to follow up in a timely manner

Bryant Thomas Karras
Yes, that is true. The excuse we have heard often is the current phone number and address are collected by the billing system, not by the EHR system, so we do not have that in the lab. We need to call them for public health investigation. Please provide it.

Rachel Abbey
Bryant, Hans has had his hand up for a few minutes. I did not know if you wanted to get to him.

Bryant Thomas Karras
Yes, go ahead, Hans. While you are doing that, I am going to switch to a different screen so I can see people's faces at the same time or hands at least.

Hans Buitendijk
I will put my face up as well. So, a couple of quick questions, and I appreciate the direction that the recommendation is going. Just a couple of thoughts on refining it from an EHR perspective. I think the first one, clarification of the intent, I would suggest that we can go with the statement made in the second part, recommend removing reference to LOI in F3. F3 is about reporting, so the order is already done, that should be dealt with in another criterion. I would just keep it simpler and say instead, recommend that LOI is addressed elsewhere, and it is. Then in A2, we can talk about the variety of different ways in which LOI can be used. I would suggest that we be more firm and combine 1 and 2 into it. Address it in A2, and then we will come back to. Generally, though, the thought that is described in there to focus on, effectively, a form of modular capabilities, focus on the LOI PH component that needs to be supported when you suspect there is a need to report downstream.

There are a couple of other ones outside of public reporting where LOI should be considered to be used as in a modular capability rather than a replacement in full. We can address that as part of A2 feedback. That is the main comment on the first part, to combine and just have the singular recommendation, I move it here. On the other part that may be addressed in here as well, there is a comment that I put in a column over, earlier today. It is in Column G, that a variety of the (f) Public Health focused criteria, as well as this one, include the filtering and validation requirement. I think we have to be careful about that. From an interoperability perspective, it needs to adhere to the standards, so assume that includes all the data that is relevant and potentially some of the optional data as well, but it includes that. The function of validation

and filtering on the data may very well depend on what you are trying to do with the data, whether you do or do not.

Where validation succeeds, and what the standard provides, we have to be cautious about that because now we get out of sync between an easily scalable, adaptable approach. We want to put a word of caution in this, but if we put out the LOI we do not need to. But in this one and any other one we are filtering, and validation is provided, to be cautious about what that means. It is not getting into the analytics and the capabilities that the other system needs to provide. That may or may not need to do any certain kinds of validation, as well as the reality is that we have to be careful filtering things out, and being required to filter things out or reject messages on certain validations because that means that you are dropping out other data that still might be relevant. Real-world data is not perfect, and it means the transactions will not be perfect. We need to make them better, but imposing that rather than having flexibility seems to be a strong requirement by the criteria.

Bryant Thomas Karras
I think **[inaudible] [00:23:10]** it is going to be a challenge **[inaudible] [00:23:15]**.

Gillian Haney
I think we lost Bryant.

Rachel Abbey
Bryant, you are cutting out.

Hans Buitendijk
I was afraid I was cutting out.

Bryant Thomas Karras
... the **[inaudible] [00:23:36]** area, like APHL. So, it is going to be an interpretive dance.

Seth Pazinski
Hey, Bryant, we have you back now, but you cut out for the beginning part of your comment.

Bryant Thomas Karras
Give me a minute. Erin, if you could lead the discussion with Hans for a bit? I am going to switch to a different device. This is getting ridiculous.

Molly Prieto
We are almost through on this timer, but Erin, you do have your hand up, so I think if we can have a few more comments then we can wrap it up.

Erin Holt Coyne
Hans, I appreciate your comment, and I completely support being a lot more firm with regard to the specificity in combining one and two. My question is, it is always likely, a possibility. that there was something intended behind the inclusion of LOI here that maybe I am not seeing, and I do not know if that was the case, or if it was referenced because they go hand-in-hand. I do not know. If there was a legitimate

11

reason for its inclusion here that we have not seen or discussed yet or whatever, we should at least be aware of that, right? Molly, sorry.

Molly Prieto
Just to answer that question, Erin, this particular topic, the lab interoperability, we took a slightly different approach in the criteria that included the transmission and then the receipt validation filter components. I know we have gone through a lot through the F1, F21. It was the mirroring of that because of the inclusion of A2. A2 includes the creation and transmission of the order adhering to LOI, whereas F3 includes the receipt validation parts and filter of the order, according to LOI, so they were in that Notice of Proposed Rulemaking (NPRM). Those different actions were covered between A2 versus F3, just for that clarification point. Still very much appreciate your comments and needed clarification.

Hans Buitendijk
I think that is part of the concern from a provider perspective. There is a need to send them the lab order, so A2 deals with that. The Public Health Assessments (PHA) has the receipt of a either lab order if it is a public health lab or by way of the LRI or ELR it will get the data that came about to the lab to then forward to it. We have to be very careful that if you are trying to describe in F3, and that is why we are very much looking at recommending just do not include LOI and F3 because it is a provider focus. If there needs to be a lab focus on what the lab does, then let us not mix the two together because that is a different role than a provider.

So, that would become a recommendation that creates separate criteria for a lab that is in receipt of a lab order that in turn the results might be used for public health, and we go from there. Otherwise, the way it is phrased, it is going to require to provider's HIT to also receive an LOI and demonstrate that where there is no need to do that. I think that is the crux, Erin, that we are more interested in providing a firmer recommendation, let that play out, but have that hand in hand with role-specific criteria. Some of these things are being mixed with PHA and non-PHARMA, as opposed to recognizing it is a provider, a lab, and a PHA, three different roles that need to be played to make it successful.

Erin Holt Coyne
Yes, I agree with that. I think clarification on the actors and the roles, particularly with this one, and the need for the synchronization across all three is important and critical. It will only help make this more implementable in the long run.

Bryant Thomas Karras
We are at time for the discussion for this. I do think maybe a diagram is in order, although I have never seen a diagram in the federal rule, describing actors in this trifecta situation, as opposed to the simplified concept that we heard of a pitcher and catcher. Things can get complicated when there is a third-party laboratory, and things also get complicated when public health agencies are acting as the laboratory itself. That is another situation where the lab order itself may be being targeted or sent towards a public health agency, in which case, we are in more control over the mandating of certain ask and order-of-entry questions. But again, or the LIM system in a given state agency may not be capable of receiving some of that information that we so desperately want and need and need for our investigations.

Hans Buitendijk

I will be happy to work with Erin to do wordsmithing on the recommendation to get some of those things in, adjust the other one, and focus on labs as well.

Bryant Thomas Karras
Understood. Be aware, Hans, we want to look at this as an opportunity to try to get those secondary actors up to speed. We know the LIM systems did not get the kind of infusion of meaningful-use dollars that the EHR systems did, so this could be an opportunity to bring it up to the same playing field.

Hans Buitendijk
I would certainly support that. After all, interoperability is a team sport, but it would helpful that it criteria have clarity, so you do not over-impose on certain HIT to do things that are not relevant for the context they operate. I would rather see more criteria, as we started to do right now, obviously in this proposed rule of having a provider perspective, a payor perspective, public health perspective. Let us not hesitate to have a lab perspective in there as well as a participant in that ecosystem. Those are the capabilities that we expect from a lab system or from a reporting system to make that more clear. So, I think we are after the same goal

Bryant Thomas Karras
That is a good suggestion.

Hans Buitendijk
The question is how.

Bryant Thomas Karras
Yes. All right, so we have eaten into our time. Erin, are you okay with moving on? Is there any final wrap-up, or do other committee members have any concerns with what is being proposed, barring a little bit of wordsmithing that still needs to be done?

Hans Buitendijk
Quick process question, how do you want to collaborate, by marking up in the current highlighted cell or otherwise?

Bryant Thomas Karras
Track changes is difficult in a spreadsheet, but ...

Hans Buitendijk
What we have done typically in the past, is just put in the text and red line it manually. You can visually see as if it is a markup. It is a little bit more work, but it works.

Bryant Thomas Karras
We could use this last cell for proposed finalized language.

Seth Pazinski
As we start to transition the individual comments for having initial drafts of the recommendations to leverage this Column J, and put the proposed language there. Then we added instructions at the top, that if the text

is in black that means it is draft. As the group comes to a consensus, we can mark it green. At that point, we are stopping the editing.

Bryant Thomas Karras
Good. Green is good. All right, thanks.

Rachel Abbey
Bryant, should we move on to **[inaudible – crosstalk]** reporting?

Bryant Thomas Karras
Yes. We have a two-part, 8 and 28, I believe.

Rachel Abbey
Yes.

Bryant Thomas Karras
Do we need to scroll up first? Where are we?

Rachel Abbey
We need to go to F8 first. So, you would scroll down. Yes. Here we are.

Aaliyah Parker
Can you see? I am at Row 10. Are you able to see F8 right now?

Rachel Abbey
Yes, we see it.

Bryant Thomas Karras
Yes, thank you. All right, do we have any subject matter experts on from vital records, from Centers for Disease Control and Prevention (CDC) folks?

Joyce Martin
Yes, this is Joyce Martin. Paul, are you on?

Bryant Thomas Karras
Would you be willing, as a federal voice, to read the language? If we can scroll over just a hair so the whole thing is on the screen. Perfect. That is Hans' comment. Can you scroll over to the language as written first?

Joyce Martin
The middle column for Hans.

Bryant Thomas Karras
No, it should be all the way over to my ...

Molly Prieto

This one is a little bit shorter, so it might be in F, in that row. There is not much. I do not think we have a ton of language.

Aaliyah Parker
Sorry, I hid it.

Molly Prieto
Yes. F is hidden, but I think E should cover that.

Bryant Thomas Karras
Okay. Oh, shoot. My screen is not the whole thing. So, if you can read Column E, starting with No. 1, new?

Joyce Martin
Okay, stop me if I am reading the wrong thing. New birth reporting, transmission to public health agencies, create provider live birth report for electronic transmission in accordance with the HL7 FHIR vital birth and fetal death reporting. Move to the middle column.

Bryant Thomas Karras
Right. So, Hans, you have a comment there.

Hans Buitendijk
Correct. The comment I make there is relative to the questions around inclusion of some of the other data into G20 that are relative for birth reporting. It raises a general question that is not unique to this one. When you look at G10, and now with the new one, G20, with the public health data, they are both proposed as a part of a base EHR, which means that you must, if you want to certify and be certified EHRs, you need to support all of that. Depending on the kind of EHR specialties, and setting the focus on some of that in, in particular when you look at birth reporting, it is not as relevant in the hospital. Yes, if you are an EHR for geriatric, not as likely. So, the general concern we have raised, and then this is another example of, that on the other hand, it is fine that G10, G20, those kind of **[inaudible] [00:37:22]** you have A9 in that same category with CDA, Consolidated Clinical Document Architecture (C-CDA), that there is an ability to convey and have access to everything, but only if the EHR or the system that you are looking at manages that.

If they do not, we could create many different small criteria, and that is not very helpful. But rather have a construct that can say if the system only manages in a discrete structure, but must be a discrete fashion such data, then it should be able to make that available if it is part of G10, G20. But if it only has that data as most in a document that it is included in there, it never needs to extract it and manage it separately, but it can view it, that is a different story. But if it does not manage it in that way, as individual data, then why does it need to now create support and capabilities to do so for a setting that is not applicable? I think it is just generally in and of itself, it would be nice to add these kinds of things over time to G10 and G20. Birth reporting is another example of not every system needs to support that. So, why are we bringing everybody to do that? Find a more elegant fashion to do that.

Bryant Thomas Karras
There is definitely a track record of modular certification, kind of a framework where only systems that need to perform particular tasks certify into that capability. I am imagining birth reporting could be one of those

that certification to ... I totally agree with you, Hans. If it is a geriatric-only EHR, pretty unlikely they will be doing any birth reporting. But if it is a full-fledged system like Epic or Cerner that gets used in a magnitude of different systems or settings, absolutely, it needs to have that as a built-in capability that does not require additional costs to implement. We have to strike a balance and figure out how we signal and ensure those capabilities are built in, while also working towards that G10, G20 capability for an all-inclusive FHIR-based approach. We will get to that discussion in one of the last sections.

I am going to go a little bit contrary, Hans, in thinking I am not totally sure that the F8 criteria went far enough. I would have loved to have seen it be a complete vital records certification process where it was moving towards birth, death, fetal death, and more all-inclusive capability signaling the importance of that role in public health, monitoring who is alive in our jurisdictions, and who has died and died from what in our jurisdictions, that becomes really critical. If we can start to signal how important it is that we have the standards accelerated ... we have seen signals from CDC in recent years that they are moving towards a FHIR API component for the national vital records system. I think feeding that all the way down to our state and local capabilities is a good thing.

Hans Buitendijk
If one were to do that, you then have to consider the same thing is that within the one criterion, modular, today, from a certification perspective is that you have to do everything in the criterion unless the criterion happens to specify a choice. In the case of G10, G20, it does not. You have to support all of them, but then you have to be careful that you have those choices and what you actually manage. For example, for birth reporting right here, there is guidance around birth and fetal death, not other vital statistics. There might be another guide for other aspects.

I was not arguing it should be less or otherwise, but when you do these kinds of things we have to make sure that the criterion and content are applicable to a particular system, and some that do not manage that, do not encumber with that requirement because they need to do too much. It might be easier to do and consider around vital statistics. Perhaps there are different sections to is, so maybe there are multiple criteria, one or more, or whatever. When we get to G10 and G20, for public health they become general buckets. That is where the concern is the most.

Bryant Thomas Karras
I can only speculate why death standards were not included in this. Perhaps it is 95% to 99% of birth records come from a birthing center or a hospital-based environment, whereas death reports come from a multitude of different, oftentimes nonclinical partners, like funeral homes, etc. So, it may not be as mature of a landscape yet to include here. Others from the committee?

Hans Buitendijk
There is one other comment on the standards specifically. I will have more details to come, but there is a concern that this particular guide is not necessarily scalable. I need to get more information about it, but I wanted to provide that input today. There is a little bit of a concern **[inaudible] [00:44:34]** going on around the applicability. There might be a question here for this group, or there might be better insight. Are the proposed standards reasonable and appropriate to scale across all PHAs across the country, or is it still relatively specific to certain aspects, regions, or otherwise?

Bryant Thomas Karras

Erin, as a co-chair of HL7, have you heard the concern coming forward that there is a scalability issue with 1.1.0?

Erin Holt Coyn

I have not.

Bryant Thomas Karras

Maybe that is an EHR hat you are wearing, Hans?

Hans Buitendijk

Yes, I am looking at it from an EHR community perspective on these topics. That is why that question is starting to come up, so that is why I want to create awareness. We are digging. If anybody has concerns about that, that would be good to know. If not, that would be good to know, too.

Bryant Thomas Karras

STU 1.1 has been out for a while. I would hope that concerns would have been fed back to proposed improvements.

Hans Buitendijk

Anything STU 1, whether it is **[inaudible] [00:46:23]** or not, is typically still fairly early on in the deployment. This being FHIR, it will be very early on in the deployment. If this would have been V2-based it would be a different story. FHIR is always a question with the first version, how widely has it been adopted, and what is the scope. That is where we are hearing that, so we are doing a little digging.

Bryant Thomas Karras

Okay. Hopefully, there is somebody from Oregon or Minnesota on, listening public, where I think some of those pilot testing of that standard have taken place.

Unknown Speaker

Michigan is on.

Bryant Thomas Karras

Michigan is, okay. Hopefully, folks from those jurisdictions are on. Go ahead, Erin.

Erin Holt Coyne

Is the question whether or not we should be including birth here as opposed to focusing on death, and whether or not it needs to be restricted to specific facilities, or what is the desired outcome here? I know of all of the groups, putting my HL7 public health worker hat on, of all of the groups, probably besides immunization, who have done their homework, I feel like vital records and statistics have been churning through standards development. For as long as I can remember, they had a whole suite in 2, in 2.5, and 2.6. I think they had CDA versions. Now, they are moving to FHIR and expanding that out to include the communications with medical examiners to electronic death registration systems to back it upstream. It sounds like the question is whether or not birth is appropriate to include here, but maybe I am misunderstanding.

Joyce Martin
I do not see that there is any ...

Bryant Thomas Karras
When say ... go ahead, Joyce.

Joyce Martin
Sorry. I just do not see there is any question about birth being included. The question was why death is not, and I am afraid I cannot answer that because I am not involved in the death side.

Bryant Thomas Karra
Hans is concerned that even birth has a scalability issue, that it may not be mature enough to be included in systems nationwide. Hans, can you speak for yourself?

Hans Buitendijk
No, that is the question. We are hearing some concerns around that, so we are trying to figure out how to formulate our feedback around that. Unless, I say otherwise, I am talking from an Electronic Health Record Association (EHRA) perspective, not Oracle specifically unless I indicate that. So, here the question is that is starting to come up in discussion that had started, has not finished, is this guide ready for adoption at that scale, given its limited use? That is the concern. It is a question at that point.

Bryant Thomas Karras
Echoing back to our CDC colleagues, and I would love for you to share what you can, F8, and then more importantly, perhaps, F28, which we will start talking about in just a minute, where the public health systems need to be ready to receive these FHIR birth reports, that is when I think the scale really will start to be possible, Hans. You are absolutely right. In this exact moment in time, not trying to think of three years from now, but in this exact moment in time, there are very few public health agencies that can receive the new and improved automated birth reports, as opposed to the manually entered portal-based birth systems that most states are operating today. It is a cart and a horse thing. We need the EHRAs to be moving in the right direction and we need funding from the feds to modernize our infrastructure to be able to receive those.

Hans Buitendijk
As extra color based on some of the notes, and again we are following up, but it appears this guide has been used with a couple of organizations, one EHR vendor, data that is not fully representative of what the guide enables, but what is in United States Core Data for Interoperability (USCDI). So, from that perspective, it is that question of whether it has been sufficiently exercised.

Bryant Thomas Karras
Field tested.

Hans Buitendijk
And field tested to say it is ready. In this kind of public health, FHIR always creates the extra question if we build it, will they come? Should we spend more time priority-wise on other things that we know we build it,

and people will be there on the other side to receive it? It is a purely prioritization and maturity question. It is not a question of whether should we not get there at some point in time, but are we ready this round?

Bryant Thomas Karras
Can we get folks from the CDC program area? Can you speak to how many public health agencies have been involved in pilot testing this implementation guide?

Joyce Martin
A handful. I think it is absolutely the case that we are not ready, but we are close. I am concerned if we do not do this now then it will be a potluck of folks implementing, and it not being standardized if that makes sense.

Bryant Thomas Karra
Yes. So, Joyce, is in the one where there is a clear signal that this is the direction to go, but unlike the other systems where there is a deadline that the old standard is going to go away in 2028, here is one where you know the flight path will be much longer, but ...

Joyce Martin
That it is going.

Bryant Thomas Karras
It feels like you are recognizing that the writing is on the wall.

Joyce Martin
I think there is no question about that.

Bryant Thomas Karras
Hans, knowing that it is a field of dreams that we do not expect all of the players to show up for, but at least, those that are ready, willing, and able. Then we are going to need federal funding to enable that modernization to come, maybe not in a nationwide scalable time period, but in a bit-by-bit time period.

Hans Buitendijk
I think it is one of the questions that we generally have with these kinds of new criteria. They are based on what the external drivers are of public health. They are not part of base EHRs. And so, it adds up to, what do I need to do for the setting I am in. So, the criteria itself, if you do not do this, you do not need to do it. If it is not asked for you do not need to do it. For us, it is not as critical from that perspective. It is more the questions we are being asked related to G10 and G20 where the data from this comes up.

Bryant Thomas Karras
Yes, make sure they are ...

Hans Buitendijk
That is more the problem.

Bryant Thomas Karras

Yes, I hear you. We will need to make sure there is not any customization done to F8 that makes it incompatible with G10. Acknowledged. Can we scroll down to F28?

Molly Prieto
I want to do a time check here. We are a bit over already on this topic.

Bryant Thomas Karras
On both?

Molly Prieto
Great question.

Bryant Thomas Karras
Did we use up both F8 and F28? I thought we still had time for F28.

Molly Prieto
We have not yet, but we can restart the timer. We were about two minutes over on F8, So, we can restart that timer now.

Bryant Thomas Karras
Great, restart the timer, but you can subtract the two minutes we went overtime on the other.

Molly Prieto
Perfect. Thanks, all. Great conversation.

Bryant Thomas Karras
This is the other side of the coin on the exact same topic. This is where I was starting to drift into it. I will be honest. Some states' vital records systems are strained because they are a legal document having to do very particular things. I think the challenge we are going to have here is that we can make these recommendations for certification on the PHA side, but some of these improvements may need rules or laws to change, to get away from a paper-based approach. Someone from the CDC program area, would you be our voice of the feds?

Joyce Martin
I think I am it. Establish new certificate criterion, at 170, 315, F28, birth reporting, receive, validate, parse, and filter in accordance HL7, FHIR vital records, birth, and fetal death reporting.

Bryant Thomas Karras
Thank you very much. I do not see any recommendations from you here, Hans.

Hans Buitendijk
No, this was on the **[inaudible – crosstalk]**.

Bryant Thomas Karras
Thank you for not micromanaging the public health side.

Hans Buitendijk
I could make a general comment on filtering and validation across the board, which applies to this one too, but other than that, no.

Bryant Thomas Karras
I will be honest. Filtering is an odd term to be used here. I suspect it was used to be consistent across all of the measures or rule changes. If someone is born in a jurisdiction, you do not exactly filter them out, but perhaps there is something I am missing. Steve or Ike, have you been able to join us yet? It is 9:00. Were you able to join from Texas?

Seth Pazinski
Looks like he just came on audio.

Bryant Thomas Karras
Okay. We will see if Texas has some thoughts. Any other jurisdictions?

Joyce Martin
Just a quick comment on your earlier comment about states struggling with the legal aspects of this. My understanding, experience is that the legal impediments are typically with the items collected, not with how it is collected, and with resources.

Bryant Thomas Karras
Correct. Yes, the challenge is going to be that moving to a FHIR-based approach if the particular data element that is required in a given state does not have a FHIR data element or bundle to accompany it, then how can they move to the collection via that mechanism? Fortunately, FHIR allows for local customization, but it is going to raise havoc on our EHR colleagues.

Joyce Martin
Okay, if I understand you, it is almost exclusively for public health items, the states report according to the U.S. standard. There are some variations on that theme but for the most part, it is pretty universal, and we have ways to enforce that even more strictly if we so desire.

Bryant Thomas Karras
Good. That is great to hear, that the variation is not as broad as we see infectious disease reporting criteria, for example.

Joyce Martin
It was in earlier years. It is much, much less so now. We've worked hard to get it standardized.

Bryant Thomas Karras
Nice. Are there any reports on that subject in terms of what the gaps are, or what outliers are still not totally in alignment?

Joyce Martin

Yes, I am sure we can come up with something for you. Most public health tumbles that we would be interested in here are reported consistently across states. There are only one or two to my memory that are not, but the crucial ones are.

Bryant Thomas Karras
Are all of those crucial data elements included in the FHIR IG already?

Joyce Martin
Yes, yes.

Bryant Thomas Karras
Excellent. If you could share those with us or with our ONC colleagues so, we can reference them in our comments, that would be phenomenal. Hans, I hope that reassures our EHRA community that there is some consistency across the country, so this is a much more doable expectation of what is to be included.

Hans Buitendijk
I certainly appreciate that part of it. The more they are aligned, the easier it is from a scaling perspective and addressing all of the needs.

Joyce Martin
So, to be clear, what you would be interested in is a list of items on the FHIR IG that are not reported nationally at this stage.

Bryant Thomas Karras
Correct, or similar to when the immunization program presented to us they talked about how 98% of the states have tested against a particular I guess. Obviously, we are not in that situation here, but you could kind of describe how the data elements that are in this IG are what is requested in X percent of states, and there are not going to be a lot of variations. Some kind of documentation of that could help reassure our colleagues on the vendor side that it is not going to be the Wild West.

Joyce Martin
Got it. We can do that.

Bryant Thomas Karras
Thanks. It is not speculating if you are just reporting to us what exists in the world right now, so thanks so much. How are we doing on time?

Molly Prieto
We have about nine minutes.

Bryant Thomas Karras
Minus two.

Molly Prieto

Yes, minus two from birth, and we went over five minutes on lab, and I was pre-planning on borrowing some of that from syndromic since we had the first half of that conversation last week.

Bryant Thomas Karras
Hans and I have been doing a lot of talking. Joyce, before we move off of birth, so appreciate you joining us today. Anything else that you would like to say or any other committee members?

Joyce Martin
I am good, thank you.

Bryant Thomas Karras
At the risk of eliminating our ability to catch up some time, is there any concern from folks that the fetal death reporting in any way creates controversy or legal problems for mothers and reproductive health issues across the country?

Molly Prieto
From an NPRM perspective, we only did propose the live birth component. The implementation guide has both components in the name, but from an NPRM perspective, we only did include live birthing and not include fetal death reporting within the criteria.

Bryant Thomas Karras
So, it is in the reference standard but that is not what you are proposing to measure or require.

Molly Prieto
Correct.

Bryant Thomas Karras
Excellent, that gets us away from controversy. Okay, good, thank you for that clarification.

Joyce Martin
All states report fetal death at 20 weeks. There is no variation at all, so it is feasible to do so. It is not a controversy as it might sound like it would be, but it is absolutely not for fetal death of 20 weeks and greater, at least for now.

Bryant Thomas Karras
Are those transmitted on to federal vital records for national reports?

Joyce Martin
That is a different ... yes ...

Bryant Thomas Karras
In a de-identified way?

Joyce Martin
Yes, but the fetal death systems are not always electronic at the state level, so that is a big challenge.

Bryant Thomas Karras
Long live the Excel spreadsheet. Go ahead, Ike.

Steven Eichner
That would impact public health's ability to receive it. Fetal death data, if they are not maintaining an electronic system, that creates a challenge. I mean, theoretically, it could be received electronically and then migrated to manual, but that creates additional work and a change in reporting processes, probably.

Bryant Thomas Karras
I am going to arbitrarily set the clock to one minute left on this subject and we are going move on. Speak now. Are we ready to move on?

Rachel Abbey
Bryant, do you have someone assigned to pull this recommendation together? Maybe we could ask a volunteer.

Bryant Thomas Karras
Great suggestion. Steve, since you are late, do you have any ability, bandwidth, or interest in crafting some language on the vital records?

Steven Eichner
I would be happy to.

Bryant Thomas Karras
Hans had suggestions earlier in the F8, but we do not have anything here proposed for F28.

Steven Eichner
I would be happy to.

Bryant Thomas Karras
I think you missed the decision. Hans was hoping for modular on the F8 because not all situations, you know, geriatric, EHR systems are going to be doing birth reporting.

Hans Buitendijk
To clarify that, if you currently are on EHR and F8 itself, and you have no reason to do birthing reporting because you are in a geriatric setting, etc., you do not need to do F8. But the question that is raised in F8 about G10 and G20 to include data in those criteria then that additional birth data in G10, G20 would become a requirement on EHR. So, the question on modular or manage the data and be certified to what you manage is really applicable to G10, G20. Birth reporting is just added to the mix. **[Inaudible – crosstalk]** G20, that we put the comment there.

Bryant Thomas Karras
Okay.

Hans Buitendijk

Rather than on F8 itself, although the question is based in F8.

Bryant Thomas Karras

Perfect. Let us move on to a continuation of syndromic now, I believe. Do we have program area folks on?

Karl Soetebier

I can read.

Bryant Thomas Karras

Thanks, Karl.

Karl Soetebier

Sure. So, establish new certification criteria at 170.315 F22, syndromic surveillance, receive, parse, and filter. That will support and enable users to receive, validate, parse, and filter electronic syndrome-based public health, in accordance with existing or newly identified HL7 251 syndromic implementation guide.

Bryant Thomas Karras

So, we are getting old school for a minute. We are not talking about FHIR for a change. I do not see any recommendations from our committee in the discussion here. Is that because we are just good with this? Let us open it up for discussion. Hans, go ahead.

Hans Buitendijk

The reason I did not put anything in there yet, it is more a fear-oriented topic, and Bryant, we have been talking about this off and on in other areas. The question is that syndromic surveillance is adding additional clinical data, more and more, understandably. I have no argument with that. The format that is being used is a version two Admit / Discharge / Transfer (ADT) message. In addition, increasingly different states, jurisdictions, are asking for identified data rather than de-identified data of syndromic surveillance. I want to make sure I state it correctly because we have had these discussions before.

It is not that I am arguing that syndromic surveillance needs to be merged with, but rather that the format and the method by which case reporting is done, that there might be an opportunity to start to think about it. This is not current HTI-2, but when you start to think about it, can we start to align it with eCR-style reporting because that is more suited to have that mix of demographic, clinical, and other data, the triggering events, etc., the content is different. It has a different purpose, but there are so many priorities. Why are we continuing to use an ADT message for what is effectively a short, clinical record of sorts that is relative and triggered based on syndromic surveillance triggers? I just want to comment and say, yes, okay, the latest version of the standard seems reasonable, but we need to start to think about the future.

Bryant Thomas Karras

So, folks on the committee are getting some insight into heated discussions Hans and I have at connect-a-thons, and I think we even debated this or included some indications in our task force recommendations from '21 and '22, that exploration needs to be made in modernized interfaces and standards to have read the syndromic surveillance as a methodology for an eventual phasing out of 2.x standards. Gillian, we have

you on from CSTE, who operates the syndromic surveillance community of practice, and program area folks, Karl, your team is on and listening from the CDC perspective.

We do need to think about the future, and one of my feedbacks that I will try to draft something up here, so people can comment on it offline between now and the next session, is that even within this accepted standard, we are still stuck in the transport mechanisms of old. Secure File Transfer Protocol (FTP) as the required transport from the CDC program does not seem to be as modern and as resilient as it could be, given that we now have newer methodologies and infrastructure with Quality Improvement & Health Equity (QIHE) and Integrating the Healthcare Enterprise (IHE) standards being utilized by the majority if not all of our clinical partners who are submitting the syndromic surveillance standards.

Gillian Haney
Bryant?

Bryant Thomas Karras
Gillian, go ahead.

Gillian Haney
I agree with everything that you and Hans are putting forth. I do think we need to look forward, and there needs to be careful deliberations because syndromic surveillance is different from other data health transmissions. We need to bring in some of the members of the community practice to weigh in on this. Syndromic surveillance goes to the National Syndromic Surveillance Program (NSSP). Sometimes it goes directly to the states before it goes up to the NSSP, so an introduction of an implementation guide that would be aligned with eCR, for example, would have to have some very careful considerations in terms of filtering, in terms of what is being sent up to NSSP, due to privacy issues. I think there needs to be a broader conversation, so we can move forward with looking at a new standard very deliberately and cautiously because it is different.

Bryant Thomas Karras
Yes.

Karl Soetebier
If I can add too ...

Hans Buitendijk
[Inaudible – crosstalk] to be as identified or de-identified as well. That should be addressable.

Bryant Thomas Karras
Say that again, Hans. You broke up at the start. All right, well, go ahead, Karl.

Karl Soetebier
Just to add the context for this criteria is the certification of public health systems. While I fully agree we need to find an alternative to ADT, and that FHIR holds some promise, the current mechanisms of both FHIR and subscriptions are not proven as a replacement for an all-hazards approach to the surveillance, and one of the advantages that ADT brought is that it is am in-place, readily available, secondary use of

health care data that it has not been proven that FHIR can do that same thing as it stands right now. I think that is also true when you think about transport from the QIHEs and HIEs in this country too, the coverage and percentage of the penetration is not ubiquitous. It is a direction to move towards, but when you are thinking about trying to certify a public health system, I do not think public health can be the edge of the technological progress, right, but I do not know. I am curious to hear what other people think.

Bryant Thomas Karras

So, I would love to hear, and maybe this is an EHRA assignment, Hans, what the state-of-the-art in patient registration in urgent care and emergency rooms is. Is there an FHIR replacement for ADT messages that are well adopted or has a horizon coming? I hear you loud and clear, Karl. This is not like case reporting where there are specific criteria that trigger an event, and then the FHIR or CDA can be transmitted. This is something we want to hear about every single case that is coming in, and that free text of pre-diagnosis gets captured. I do not know that there is a good FHIR-based replacement I have seen out there yet. I stand ready to be corrected.

Hans Buitendijk

If you want me to react, I do not think there is anything particularly that we can say that is the syndromic surveillance equivalent of it. It is rather stating there are some emerging and increasingly adopted methods, like eCR, that can generate CDA or FHIR whether the trigger events are manual or otherwise. It can contain a variety of data that seems to be increasing. The variety of data seems to increasingly be more suitable than the ADT transactions that I use. I think it is much more of a future discussion that we can figure out, but to highlight this we need to think about it because we are encumbering a flow and a transaction format and approach that is increasingly getting less suitable for what we are trying to achieve.

Bryant Thomas Karras

Yes.

Karl Soetebier

Steven has his hand up.

Bryant Thomas Karras

Oh, thank you. Ike.

Steven Eichner

I am thinking of the transport mechanism. It seems to me this is an outlier from all of the other standards where public health has had the flexibility to select whatever transport mechanism it feels best suited to the environment. I wonder if we want to continue to support the use of secure FTP as the only mechanism, or whether we can look at **[inaudible] [01:22:44]** set of choices, or whether we want to look at recommending any transport mechanism, to your point, of supporting different channels of getting data in public health.

Bryant Thomas Karras

Speaking of what is technically possible now, is secure FTP really the only transport mechanism that your current NSSP infrastructure will support?

Karl Soetebier

It has been the lowest common denominator between health care and public health. Health care runs primarily on National Library of Medicine (NLM), Virtual Private Network (VPN)-based interconnections, but that has been a barrier for public health from the standpoint of firewall connections and permissibility in the state government to establish private VPN tunnels in many cases. So, in many cases, secure FTP became the lowest common denominator. CDC deployed FINMS, and there is still a lot of FINMS that is in use.

Bryant Thomas Karras
I was happy to see FINMS was not in the rule. That would have hurt me.

Karl Soetebier
It was a solution for the problem in its day. So, I do not know if there is at present, to my awareness, a more viable alternative, unless the changing landscape of cloud-based hosted systems makes a VPN more permissible. That would be the only other thing from my knowledge that health care would be amendable to in terms of a way to move that data. FINMS solution was the guaranteed-delivery HTTPS solution. That is sort of the state. Again, going back to the spirit of this was to allow public health to be certified to receive, and so it does move the needle on that.

Bryant Thomas Karras
I am not criticizing here, but it does feel a little bit like a step backward compared to everything else in the rule. It is an older-school approach. I hear you that it is a common denominator. This is where I am wondering if we as a committee have an opportunity to say, yes, the systems need to be required to send secure FTP because we know every health department can support it, and definitely, CDC can support. The other optional mechanisms, maybe we can make them better than optional, and we want to start to explore more sustainable and scalable approaches.

Steven Eichner
If we do not evolve beyond Secure File Transfer Protocol (SFTP) that is where we are going to be. It may be a very good, consistent floor but do we want to raise the bar and create a menu set?

Bryant Thomas Karras
I think we do.

Karl Soetebier
Do we want to do that on the back of the public health certification, or do we look to other parts of reg to do that in terms of more on the health care side? This is about requiring public health to support alternate transport mechanisms, right?

Steven Eichner
Actually, this is about the technology support, not whether public health has to do it, just to clarify. To me, it is an ABC or an AB kind of choice that public health as a program might have flexibility to request or require reporting in multiple different mechanisms than SFTP. But if the certified technology is only certified to SFTP that creates a potential gap, where if it was certified to SFTP and something else, then public health would be in a better position to select or make available either A or B to the health care providers looking to report data. It would be convenient if there were certification criteria to a different transport standard in addition to SFTP.

Bryant Thomas Karras
Gillian, I know you are not the lead of the syndromic community of practice, but I am wondering if someone on the CSTE staff, who are closer to the ground than this and maybe through you could be charged with gathering information, like how many states across the country receive the data directly to the state rather than relying on the NSSP as being the only recipient of the syndromic feeds.

Karl Soetebier
Forty-three public health jurisdictions maintain or operate a local syndromic system.

Bryant Thomas Karras
Excellent.

Gillian Haney
Outside of NSSP, Karl?

Karl Soetebier
Correct, yes.

Gillian Haney
Is that states, or does that also include ...

Karl Soetebier
There are sites. It includes, for instance, in Texas in the regions, or individual counties in some cases in California.

Bryant Thomas Karras
Okay, so it is not 43 states.

Karl Soetebier
It is 43 sites of public health authorities and the balance, the remaining 30, leverage NSSP as their primary operation system.

Bryant Thomas Karras
Do we know what mechanism those utilize? Some are probably still FINMS?

Karl Soetebier
Yes, many of them are. Even in jurisdictions where they are leveraging NSSPs, their primary system, they may use local infrastructure to manage the inbound receipt of data from their healthcare facilities. So, it is not a one-to-one there. It is a good question. The landscape is FINMS or SFTP. I know some jurisdictions do have some VPN connections that they have established, and there are a smattering of health information exchanges that are leveraged as well, which is a different game. But some [**inaudible – crosstalk**] Iowa, for the whole state, for example, is a single health information exchange.

Bryant Thomas Karras

Same thing here in Washington. It is a crazy quilt of standards, which drives our healthcare partners a bit crazy. I worry the unintended consequence of this rule that only SFTP is required is it could have a negative impact. When people go from a 2015 certification to a 2025 certification they will only support secure FTP, and we will actually lose some of the modernization that has occurred in jurisdictions that have leveraged infrastructures that was funded by meaningful use and ONC.

Karl Soetebier
I think including language around API-based transport will probably be a logical thing to do. It is not clear to me that is something that is widely in use today, but that does not mean we cannot make sure the door is left over for it. I totally agree with that.

Bryant Thomas Karras
Any kind of survey reports from the community of practice, Gillian, or the program that describes not just the common denominator but what is possible across jurisdictions would be fabulous.

Gillian Haney
What is your time frame and if feasible, Karl you will need to help me with the framing.

Karl Soetebier
Sure.

Bryant Thomas Karras
We only have two more meetings before we need to have things wrapped up pretty well.

Molly Prieto
We are about two minutes over, and I do want to make sure that Jeff has the time to do a G20 introduction, and we can continue that into the next meeting, but do really appreciate this conversation, and Karl, you being on. API capability is an optional component within the regulatory text here, just as a note.

Bryant Thomas Karras:
We may want to make a comment that, like we have seen in other federal regs, that optional components could be made required in a given jurisdiction that was ready to exercise those options. In previous rules, there was language that said the public health agency could specify the transport mechanism, for example. So, we may want to pull those forward from prior rules and make those comments here.

Gillian Haney
Can I ask a quick question?

Bryant Thomas Karras
Gillian, do you have much on your plate? Could you Can you help to craft that and get feedback from your community? Go ahead, Gillian.

Gillian Haney
I am not sure if I have the bandwidth, to be perfectly honest. I can try, but I do feel like we need to bring in the community to be part of this discussion. Can we utilize more generic language about a need to look to
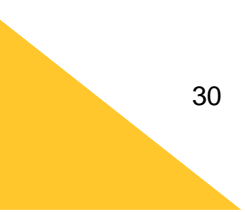
the future and maybe punt it a little bit, just because I do think this requires broader conversations than the two weeks that we have left?

Bryant Thomas Karras
Yes. All right, we will come up with an assignee, and try to figure out how to bring in those conversations. Maybe there is an NSSP meeting or a community practice meeting where you guys can, outside of this, propose some groundswell. All right, let us move on to the next section.

Hans Buitendijk
Quick question on that, did we skip A2 for today, or was that totally done last week, since we skipped rows?

Molly Prieto
I think we did talk about it last week, but you are right that today we did not do a follow-up. If we feel we do need to follow up on that topic, we can add it to the ongoing list in our catch-all meeting that will be on the 27th.

Hans Buitendijk
Okay.

Molly Prieto
Thanks, Hans. Appreciate it.

Bryant Thomas Karras
Yes, Erin brought it up a little bit, but yes, any one of these topics could have taken the entire session.

Hans Buitendijk
Just to highlight it, I put a comment in there for whenever we get to it. Does not need to be today.

Bryant Thomas Karras
Okay, all right. So, I think up next is the API G10, G20, and Jeff, I think we have you on deck to read or orient us to this language, please.

Jeffrey Smith
Sure. I will read this and then we can go from there. So, we propose a standardized HL7 FHIR-based application programming interface for public data exchange at 45 CFR 170.315 G20. This would extend the capabilities included in the standardized API for patient population-level services at G10. The new certification criteria would support the ongoing and future development of public health FHIR IGs, leveraging a core set of existing modular and extensible capabilities and standards.

We think there are a number of benefits this certification criterion would bring, including helping usher in and further facilitate a FHIR-based ecosystem that would support a wider array of public health data exchange use cases, streamline and reduce burden for health care organizations and developers, while expanding public health authority's access to critical data for action, extend the capabilities included in the standard API at G10 as I mentioned, as well as require support for FHIR resources that are profiled in the U.S. public health profiles library implementation guide.

We think this criterion would ensure that public health authorities have consistent access to discrete functionalities, defined capabilities, and standardized data from providers using certified health IT systems for a range of public health use cases, as well as support ongoing future development of public health FHIR implementation guides, leveraging a core set of existing modular and extensible capabilities and standards. I do not know if there is a subsequent row there, or is this pretty much all we have?

Bryant Thomas Karras
Scroll down a little bit more. I think that is it for what we had queued up for today.

Jeffrey Smith
I can provide real quick, additional lines of color here. So, when we say the criterion extends the capabilities and requirements of G10, this is part and parcel with a host of additional proposals that we got to create modular certification criteria at 170.351J, which group two is working through. I would say, big picture, what we are trying to do is create a way to have consistency and modularity across all of our G criteria. Essentially, the buckets that we are proposing are that G criteria would have similarities if not the same requirements for registration, authentication, and authorization, and then have G criterion-specific requirements for information access, and what we are calling API workflow capabilities.

In the context of G 20, what that means is registration, authentication, and authorization would be the same for G10 and G20, and then on the information access, we articulate the use of US public health profiles library profiled resources, as opposed to the US core implementation guide. And then in terms of the workflow capabilities, we propose that G20 would support subscriptions, as well as data access. In combination with the G10 certification criteria, a system that was hypothetically certified to G10 and G20 would have, essentially, the full suite of API capabilities, including subscriptions, workflow triggers, event notifications, etc. I will stop there. I think that is as much color as I can provide.

Bryant Thomas Karras
Let me ask you some factual questions, Jeff. Is the public health profile library that is referenced in this rule similar to USCDI? That is a moving and evolving resource in that if syndromic surveillance were to create a profile library and implementation for subscription to all cases that present in the emergency room, there could be an FHIR-based, API-based mechanism that could be a successor to the classic ADT-based syndromic surveillance. I that hypothetically allowable under this framework?

Jeffrey Smith
Conceptually, the US public health profile library's implementation guide is meant to be a cousin to the US core implementation guide. So, our intention with proposing the US public health profile library's IG was to propose a public health-specific dataset of common data elements that would support various public health exchange use cases. There are reusable content profiles that are represented in the US public health profiles library that complement the US core implementation guide.

There is a process, or there has been a process up to this point, and we anticipate a process of some kind would be moving forward to ensure normalization or harmonization between the US core and the US profiles library, and again, some kind of process to identify when the US core version is insufficient for the public health use case, at which point, the US public health profiles library implementation guide may be in
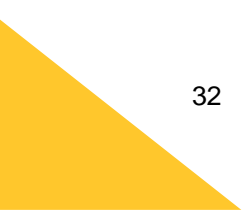
place where that public health-specific data element would be included. It is not dissimilar to, but I would not want to give the impression that it is the same, as the USCDI plus public health. These two are separate but certainly, they are, and I think we do talk about this in the proposal, that we are very cognizant that they are of similar concepts, and so it is not infeasible to think at some point in the future if we were to adopt our proposals that there would be a very close future development of the two.

Bryant Thomas Karras
I cannot believe we are down to three minutes. Are there any hands up?

Hans Buitendijk
I cannot get my hand up.

Bryant Thomas Karras
Go ahead, Hans. I see you are busy in the chat.

Hans Buitendijk
Yes, a little bit, and in the comments. I did copy the birth reporting discussion around the impact on the G10, G20 down here so that it is in this context that we can further pick it up. And the question or comment beyond that, I want to repeat the other one, is that with the introduction of subscriptions in G10 and G20, which is currently defined as very open-ended, you need to support subscriptions for all of the resources in G10 and G20. That is raising questions around, well, to what purpose? Would it not be more appropriate, and that is the direction we are heading there, to say can we define a small set of use cases, subscription topics that are commonly of interest, because depending on the context, etc., there might be a wide variety of subscriptions out there that are of interest, but can we define a couple of specific ones, and ideas range from let us define five, and certify software to that implement at least three of your choice or something like that.

Keep that focus because subscriptions is fairly new. Can we have a variety of ranges? That may be context-sensitive uses that are very relevant. So, start narrow and build up. It is not much different from the original clinical decision support requirements that certified software had to implement some as long as it was against a certain dataset, but you did not have to implement everything against everything. That will be more of the gist of the kind of feedback. Be careful to create a large scope that you have to implement, and we do not know yet where they are best used. So, that is the suggestion. Narrow it, focus it, and build it from there. There is one already in prior authorization that needs to use subscription. Is there anything in public health that we could say that is a reasonable, general, one, two, or three that make sense, that we have consistent subscription capabilities for? Let people make a choice.

Joel Hartsell
Regarding electronic case reporting, I have some concerns about the maturity of subscription for some of these purposes. It is a road we went down a while ago when we were developing the eCR Now app for triggering even, and for public health use, is from the public health agency side leveraging subscription to pull a lot of the critical information. Those business rules are going to play a heavy hand in it. I think the value is not just give me everything on this, but this individual-but-specific criteria based on the condition that takes it to a level that, at least I have not seen subscription be an effective tool for. Of those use cases,

I have some hesitancy on the value for electronic case reporting to push the value forward beyond where it is currently at until subscription progresses. That is it, but I would welcome other thoughts.

Hans Buitendijk
I think that commend aligns and resonates very well with where we are coming from. It is unclear, so focus on some. And I think what I am hearing Joel say is, even if I translate it to how we look at G10 and G20 combined, let the implementer identify some key use cases, the subscription topics, where there is a sense that it is very applicable, implementable, and then start to roll the ball forward and learn. Doing everything across everything is the question. What are the rules, including what Joel provided?

Bryant Thomas Karras
Joel, where is the nexus of activity for the public health library and profiles? Is that something APHL is taking on? Is that something ONC is funding a continuation of? How do we get more of public health aware and involved in that capability or that direction?

Joel Hartsell
That is a great question, Bryant, and I will have to circle back to you on this. I know APHL is involved as far as how to pull others in. I will need to circle back on that.

Kathleen Tully
Historically, this was funded through CDC, and Lantana helped to develop I guess. There has been engagement through the public health workgroup on this, and Laura just put that in the chat. Moving forward, it is something that ONC and CDC are looking to work on just specifically to have more concrete alignment between that and USCDI+.

Bryant Thomas Karras
All right, I was three minutes negligent. Sorry, I was struggling to get my screen restarted and missed the countdown timer zeroing out. Let us open up for public comment.

Public Comment (01:50:58)

Seth Pazinski
Thank you, Bryant. Accel, can you please open up our line for public comment? So, just as a reminder, if you are interested in making a public comment, if you are on the Zoom you can make a comment. Use the raise hand feature, which is located on your Zoom toolbar at the bottom of your screen. If you are participating by phone only today, you can press star nine to raise your hand. Once called upon, you can press *6 to mute and unmute your line. We will give folks a few minutes to raise their hands. Just a reminder, that next Group 1 meeting of the HTI-2 proposed rule task force will be on August 20 from 11:00 a.m. to 1:00 p.m. Eastern Time. Also, a reminder, all of the slides, agendas, and materials for HITAC meetings are available on healthit.gov. Let me check with the Accel team. Do we have any raised hands at this time?

Accel
No hands raised.

Seth Pazinski
All right, seeing none, I will turn it back to you, Bryant, for next steps and closing us out.
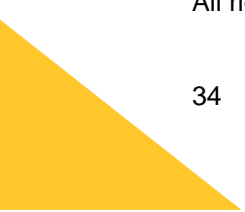
Next Steps (01:52:17)

Bryant Thomas Karras
Okay, so we are at five minutes to conclusion. We have got a ton to wrap up in the next few weeks. We have two more sessions just for our group, and then we enter into the sprint to the finish. the 3rd, 4th, and 5th of September is when we have to already have our language and comments for each of the components, F, G, and A criteria logged into the spreadsheet and into consensus green text, so they can be brought forward for discussion with our sister groups, Groups 2 and Group 3, who have been meeting concurrently. There is also potential crossover. Some of you are participating in the other groups, and there are public health-focused people who have been pulled into those groups as well. We will want to do our own homework and review what has come down the pike for those groups so that the 3rd, 4th, and 5th is not the first time we raise the public health concerns that might need to be addressed in those sessions. So, we have got a lot to do in the next few weeks.

So, next week, the prescription drug monitoring program is up, and Steve, I am counting on you to lead that discussion in my absence. We will have some federal colleagues on from CDC program area to help describe factually what the environment is like. But any last thoughts or volunteers for crafting up some of the syndromic language that is needed? Dead silence. Is my microphone working, Seth?

Seth Pazinski
I hear you loud and clear.

Steven Eichner
Silence is golden, I guess.

Bryant Thomas Karras
All right. I assume we cannot have a federal employee craft up draft language.

Molly Prieto
We cannot.

Bryant Thomas Karras
Otherwise, I would assign it to you, Karl.

Karl Soetebier
Fair enough.

Bryant Thomas Karras
Gillian, let us see if we can get some input from the community of practice folks, and you or I can pull that language forward.

Hans Buitendijk
I will be happy to.

Steven Eichner

I will help as well,

<u>Bryant Thomas Karras</u>
Thanks, Steve.

<u>Hans Buitendijk</u>
You got me, too, Bryant, to help.

<u>Bryant Thomas Karras</u>
Great, Hans, especially for the vendor component of that transmission, that is huge. I would love to get some sense from your perspective. Is it jarring to have so many of the new transmission mechanisms modernized? And then this callback to secure FTP, does that cause issues for implementation, would be a great offline conversation for us to have.

<u>Hans Buitendijk</u>
I am not hearing that concern because these are "isolated" capabilities, and we have the full mix of capabilities typically available. It would be nice if everything is the same, but it is not.

<u>Bryant Thomas Karras</u>
All right, so there is already a laundry list requirement. Okay, we are at time. I am going to try to end and respect everybody's contribution. Thank you so much. We are officially adjourned.

Adjourn (01:57:01)

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT
No comments were received during public comment.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT
Gillian Haney: Providers also need to report certain conditions to PHAs on suspicion...

Erin Holt Coyne: But providers would be reporting via a case report not a lab order, correct.

Gillian Haney: I would think so, yes.

Gillian Haney: good point Hans.

Noam Arzt: And only a BIRTHING hospital at that I would suspect...

Noam Arzt: We lost the spreadsheet view...

Noam Arzt: Thx

Jim Jirjis: good point, Bryant, but are the IG's developed for that?

Noam Arzt: Seems to me that birth is really restricted to a limited number of birthing facilities, and death reporting may be broader assuming death reporting really does come from "the field." I would think these are all hospital functions, right? Is there anything here that restricts it away from ambulatory sites?

Dan Chaput: It is unlikely that death can be included in the final rule because it wasn't proposed. The community would not have an opportunity to comment.

Hans Buitendijk: +1 Dan

Hans Buitendijk: Sorry for break-up. Just was noting that sensitivity of data, including identified and deidentified, can be addressed in FHIR.

Hans Buitendijk: eCR reporting is being widely adopted though, and the question is modeling it after that.

Gillian Haney: A concern is that data are sent to a platform owned and hosted by CDC so my comment is only that we need to have deliberate conversations to ensure privacy protections remain in place.

Nick harrar: I mean even if it turns into a http(s) post for files instead. that at least moves the needle and still stays secure. then even cert public and private key exchange even further enhanced it.

Hans Buitendijk: Can you clarify why jurisdictional variation needs to be highlighted? Isn't that already true for all public health reporting? While there is an ONC certified version, we have to adhere to the jurisdiction specific requirements.

Noam Arzt: Why would a system certify to both (g)(10) and (g)(20)? I though the (1n) criteria were for EHRs and the (2n) criteria were for the PH side. Am I confused about that?

Gillian Haney: agree Joel.

Laura Conn: CDC funded the development of the USPHL effort through ecr standards work.

Steven Eichner: PDMP is on deck for next week!

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 13, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 9/11/24.