Health Information Technology Advisory Committee

HTI-2 Proposed Rule Task Force 2024 Virtual Meeting

Group 1: Public Health

Transcript | August 20, 2024, 11 AM – 1 PM ET

Attendance

Members

Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Steven (Ike) Eichner, Texas Department of State Health Services, Acting Co-Chair
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Joel Hartsell, Association of Public Health Laboratories (APHL)
Mary Beth Kurilo, American Immunization Registry Association (AIRA)
Kikelomo Oshunkentan, Pegasystems
Naresh Sundar Rajan, CyncHealth
Thomas M. Wilkinson, U.S. Department of Homeland Security

Members Not in Attendance

Bryant Thomas Karras, Washington State Department of Health, Co-Chair
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Gillian Haney, Council of State and Territorial Epidemiologists (CSTE)
Steven Hester, Norton Healthcare
Erin Holt Coyne, Tennessee Department of Health, Office of Informatics and Analytics
Jim Jirjis, Centers for Disease Control and Prevention
Zeynep Sumer-King, NewYork-Presbyterian

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

Pat Knue, Institute for Intergovernmental Research (IIR)
Don Vogt, IIR
Kevin Borcher, IIR
Laura Conn, CDC

Meeting Transcript

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 and Office of the National Coordinator for Health Information Technology (ASTP), and I will be serving as your Designated Federal Officer for today's call. As a reminder, this meeting is open to the public, and we encourage public feedback throughout the meeting. Comments can be made via the Zoom chat feature, and we also have time towards the end of our agenda for verbal public comments as well. So, we are going to get started with our meeting, and I am going to start with a roll call, so when I call your name, please indicate that you are present. I am going to start with our acting co-chair for today. Steve Eichner?

Steven Eichner
Good morning.

Seth Pazinski
Good morning. Bryant Thomas Karras will not be able to make today's call. Shila Blend?

Shila Blend
Good morning.

Seth Pazinski
Good morning. Hans Buitendijk? Lee Fleisher? Raj Godavarthi? I did get the message that Gillian Haney will not be able to join us today as well. Joel Hartsell?

Joel Hartsell
Present.

Seth Pazinski
Thank you. Steven Hester? Erin Holt Coyne? Jim Jirjis? Mary Beth Kurilo?

Mary Beth Kurilo
Good morning.

Seth Pazinski
Good morning. Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning.

Seth Pazinski
Good morning. Zeynep Sumer-King? Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. Thomas Wilkinson?

Thomas Wilkinson
Hello, good morning.

Seth Pazinski
Good morning. I see Hans Buitendijk has joined us. Did I miss anyone, or has anyone else just joined? Okay, well, please join me, then, in welcoming our acting co-chair, Steve Eichner, for opening remarks and to get us into our meeting. Steve, over to you.

Opening Remarks & Continuation of New Public Health Certification Criteria (00:02:29)

Steven Eichner
Good morning, all. Thank you all for your work thus far in Group 1. We have an exciting agenda. Today, we are going to focus on Prescription Drug Monitoring Programs (PDMP) and come back around to electronic case reporting (eCR). Hopefully, we will continue our work and begin to shift from using the worksheet into making our recommendations in a Google document. Let's go to the next slide. We have a quick agenda we can review. As always, we will have public comment towards the end of our meeting. Next slide, please.

So, this is a quick review of our charge. The HTI-2 Proposed Rule Task Force is evaluating and providing comments and recommendations to HITAC on the HTI-2 rule, and HITAC will take our recommendations, review them, and make any necessary modifications and submit them to the Assistant Secretary for Technology Policy. Recommendations are due by the end of the 60-day comment period, which comes placed in early October. Next slide, please.

As discussed earlier, this is our quick update on where we stand in our schedule. Today is, of course, August 20th, and we are meeting and working through a couple of items. We have another couple of meetings left to go, with only one subgroup meeting left, then we will meet as the full task force to compile our recommendations across the different workgroups, compile our materials into a text document, and forward it to HITAC for their review, comment, and forwarding on to ASTP. Next slide.

So, we are now going to get into the meat of our meeting, focusing on PDMP and eCR. Here is a quick review of our timeframes. We are breaking out and using a new tool in our Zoom chat as a timer to help us keep track of time. The meat of our meeting today is focused on PDMP, but we will touch on a few other topics as well, so let's get into the meat of our meeting and talk about computerized physician order entry (CPOE). Can we bring up the worksheet? Let's zoom in a little bit, if we can. Let's zoom up a little further. That is great.

Rachel Abbey
Accel, can we go ahead and start the clock as well? Thank you.

Steven Eichner
Thank you. Hans, do you want to give us a summary of your recommendation?

Hans Buitendijk
Looking at Row 12 on CPOE?

Steven Eichner
Yes.

Hans Buitendijk

Okeydoke. I was just now getting to PDMP. I am right next to that. Let's see. Here are the comments that I was making around CPOE. In A2, related to lab, depending on which lab you are going to be communicating with, there may be different requirements for what data needs to be shared. As an example, if I am ordering and working with my internal lab, let's say a hospital health system that has lab systems, integrated or not, but particularly if they are not integrated, they are a separate system, then the communication need not fully confirm to laboratory implementation guides (LOI) in order to achieve that, and there are many implementations out there. They operate, they run, and if you were to require LOI as an example to be applied there, it would need to support a lot more data to be shared through the order that currently might be shared in other ways already or is accessible otherwise.

If you go to a public health lab on the other side with the work that is happening on Electronic Test Orders and Results (ETOR), then you are much closer to needing to support full LOI or a large chunk of that. If you are communicating with a commercial lab as a reference from a clinic or otherwise that does not have their own lab system, if it is used for public health reporting because it is a potentially reportable result, you would need to include more data than what is necessary for the immediate performance of the lab. They are asking for this in the feedback: Do we need to adopt all of LOI or Laboratory Results Interface (LRI), or some of it? Our reaction would be that it makes sense to tailor it to the environment that you are in so that you do not need to fully support everything always. You support the data that is relevant.

As LOI and LRI have been defined with a very modular approach, you use parts of them to be able to say, "For this scenario, you need to support the public health capabilities of LOI or LRI. For general commercial lab interaction, you need to support this one if there are some capabilities," etc. So, from where this comment comes, we are suggesting that a more modular approach of adoption of LOI/LRI is appropriate. There is already a large install base of Version 2 in place, and having to replace everything, if you will, is not as likely. It is a lot more work, but rather, if the additional data is done in accordance with the newer standards that are in place, we need to add onto it that it can be plugged into existing interfaces as well from a standards perspective. We have demonstrated in many different places where we pre-adopt into Version 2.3.1, and we add things to it that are actually coming from Version 2.9, 2.8.2, or something like that. So, we would promote and suggest that a modular approach working with Health Level 7 (HL7) and others to define what are the appropriate components and when to use them would be very helpful to do to move forward rather than a full-step everything for everything.

Steven Eichner

Accel, let's move to comms so we can show J.

Hans Buitendijk

I have not put in the specific wording yet.

Steven Eichner

Looking at the profiles in LOI/LRI, can we use those to our advantage here?

Hans Buitendijk

Those are the ones that I am indeed pointing to. So, there are component profiles or profile components in LOI/LRI, like public health, like having the ability to hold communications, newborn blood screening, etc., so there are a number of different ones in play that are applicable where you can say, "For this purpose, you need to be able to support that." For example, for communicating a lab order to a lab that, in turn, is going to have a requirement on that kind of a test to report that to public health, you need to support the ability to send additional data according to the lab order's public health profile.

Steven Eichner
Maybe we should think about a recommendation that looks at certification to the particular profile rather than just general certification.

Hans Buitendijk
Correct.

Steven Eichner
Do other folks have opinions or suggestions in that space? Does that help meet our objectives?

Hans Buitendijk
From a public health perspective, the intent is to get the right information as part of the order, so it would help there. There is opportunity to get that without having to use the full LOI for other purposes. If you wanted to, you could support the full LOI, but you would not have to chain the information.

Steven Eichner
So, if we were to develop a recommendation that said rather than looking at general certification against the entirety of LOI/LRI, we should look at, for lack of a better phrase, submodular certification, and you could pick one or more modules or profiles.

Hans Buitendijk
Right.

Steven Eichner
That would enable the Health IT (HIT) vendor to certify their product or seek certification for their product for whatever market their product was targeted at, whether it was focused on entities that have public health reporting or looking at internal uses within a hospital or hospital system where that module is not reporting directly to public health. Is that fair?

Hans Buitendijk
I would say so. I am curious what others think.

Steven Eichner
Do other folks have thoughts? Will this work? Are there any problems with it? Should we go ahead and move this to our recommendation column and work on text to make it green and make it more formal?

Hans Buitendijk
Steve, I will be able to draft more complete statements of the suggestion if you want to put my name next to it.

Steven Eichner
Great, thank you, Hans.

Hans Buitendijk
Looking at the draft before next time would be great.

Steven Eichner
That would be great, yes, because next week, we have limited time. We need to move on and begin to shift things over to the entire task force. Okay, let's go back to our agenda and move on to our next subject.

Mary Beth Kurilo

Steve, just so you do not have silence from the entire group, this is Mary Beth, and I will just weigh in that I think that idea of choosing the subcomponents makes a lot of sense conceptually. I am not close enough to the workflow on the LOI side to weigh in on that piece, but I like the selection of the subcomponent, so I am fully in support, and Hans, thank you for drafting some draft language to look at.

Steven Eichner

Thanks, Mary Beth. I really appreciate that.

Rachel Abbey

Great. Steve, I think we are going to readdress the G20 criteria.

Steven Eichner

Wonderful. So, here, we are looking at standardized API for public health exchange, and on the screen, we have our previous discussion, looking at some of our initial recommendations. Is Raj on the line? I do not think he is here. Joel, do you want to talk a little bit about your recommendation?

Joel Hartsell

Yes. So, it mainly has concerns about subscription for a public health API. We looked at this a little bit for the Fast Healthcare Interoperability Resources (FHIR) app for electronic case reporting and participated in a connectathon earlier this year on this topic, and essentially, some of the major findings were that we can use it to identify the patient, essentially, that initial step in the calls that were needed, but largely, it was not mature enough at this time to do a lot of the business rules that were needed to pull out and identify which case reports and information should be sent, and right now, with the current flow of eCR, the business rules that are running within the electronic health record (EHR) through the app that could potentially use subscription are much less than what public health would likely need to pull specific information for a case. Long story short, I have questions about the intent and the level in which this could be used, and whether it is really mature enough at this point.

Steven Eichner

Or whether it is mature enough with sufficient enough detail.

Joel Hartsell

Yes, yes.

Steven Eichner

I think those two concepts are kind of tied together. It may be mature enough to pull single values out of a subscription, but not sophisticated enough to meet all the needs for public health.

Joel Hartsell

Yes. The way I am envisioning that public health would want to use this would really be to follow up on a case report. Sorry for the eCR use cases, but if you got a case report for chlamydia, you would want to know if a specific treatment you received had azithromycin or ceftriaxone, and not just a particular profile or all the patient information because I have already received that, but you are querying specifically for content and specific content within that profile.

Steven Eichner

Right. So, looking at a more detailed subscription rather than a more generalized subscription request.

Joel Hartsell

Yes. I think that is where the value would be, and at least my exposure has not shown that that value or maturity level is there.

Steven Eichner

At least for some public health use cases.

Joel Hartsell

Yes, yes. But I like Hans's suggestion of looking at specific use cases. There may be other use cases in which this would be useful, and Hans, I do not know if you have thought about that more, and if you had specific thoughts on use cases. Maybe that is where we target this.

Hans Buitendijk

I think that has been one of the questions that we have been talking through across a number of EHRs, about what the use cases would be. Looking at G10 and G20 combined, it currently states that you need to demonstrate support for subscriptions and to what extent we need to do that: All of United States Core Data for Interoperability (USCDI) resources or part thereof? The direction we are heading is that it is hard to indicate for every HIT that is being certified against that what are the top three that everybody should use or that need to be used. That is hard, and saying that we need to support subscriptions for all resources... Well, just pick on one resource, such as encounter.

At that point in time, what subscription on the encounter are you interested in? Is it an emergency room encounter created, a discharge, or something else that happened during the encounter? Even when you say, "subscriptions on a resource," there are potentially multiple ways in which you can look at it. If you look at a subscription on observations and lab tests, are you interested in any final test that was amended? Is it something that was finalized? Which ones are you looking at? Was it very specific ones because you reported it on a case report and something else happened? So, there are many different variations that could be there, so it is unclear what that means.

The direction we were thinking is to say, as a certified software, to pick two or three subscription topics, not counting prior authorization because that is already addressed inside G34 and G35, that are most suitable for your environment. You could pick from G10 or G20, and they could be focused on public health or otherwise, but pick something that is meaningful that demonstrates that we are making progress with subscriptions. We have a good idea that those topics will actually be helpful for that system, for that environment. It is the same approach that was taken for clinical decision support when that started, where the number was somewhere between one and five, to say that you can do any kind of clinical decision support, just pick something that makes sense and demonstrate that you can do it. We are thinking that that might make more sense here, because, like you, Joel, we are trying to think about which use case is not only reasonable in itself, which may vary, but which one is reasonable for everybody, particularly EHRs, because G20 is part of base EHR. So, every EHR that wants to be certified for use in Centers for Medicare & Medicaid Services (CMS) and otherwise must support the three identified. That seems to be too rigid at this point in time.

Steven Eichner

Hans, isn't this focused on public health exchange, so that, looking at subscriptions, any subscription here would need to be focused on a public health use case?

Hans Buitendijk

Well, we were looking at it between G10 and G20, so that does it across those. From public health, specifically G20, do we want to make sure that at least one pulls from G20 resources rather than G10 profiles? That is a

consideration. The question, then, is from a public health perspective, which goes back to what kind of subscriptions are helpful, and we could not really identify any clear ones, and not everybody has to support all the reporting to public health and the variations of that, so what is really all the data that is there? From a public health perspective, what are some use cases that are helpful? We can really identify any one particularly. That is why we were coming up with two to three across G10 and G20.

Steven Eichner
Okay. I think there may be some public health use cases around birth defects that might be of some interest to children with special healthcare needs.

Hans Buitendijk
If you look at those, which are good examples, do specialized EHRs that wish to be certified support that kind of information?

Steven Eichner
I agree, I was just pulling in a couple of examples where subscriptions might be of more use from a public health perspective than looking at support for infectious disease case investigations.

Hans Buitendijk
Right, that is totally fair, but that is a challenge that we then run into. Which examples would be applicable across any EHR, or if you are a specialty EHR for dermatology, geriatric care, pediatrics, or whatever, what is the right one that is used there? Let them pick. So, maybe it is one out of public health, two out of G10, and one out of G20. Pick one. But then, everybody will have to work with public health. Okay, we create a topic. Will public health be interested in that? So, I think there is a bit of back and forth to be figured out.

Steven Eichner
I agree, and I think another concern that I have is that subscriptions in bulk data seem to be a factor not only about the software capability of the EHR or HIT module software, but also the hardware on which the software is running, just from a volume perspective. The ability to support a subscription and the ability to support a subscription where data is supposed to be reported for 1,000 patients or whatever is not necessarily the same question.

Hans Buitendijk
Yes, I would agree with some of these requirements. It is going to be what infrastructure expansion you need to do for the volume of exchange, etc., that is going to happen. That is always going to be a good question.

Steven Eichner
I am not sure if we need to address that concept in our recommendations for consideration because just being certified without some kind of volume requirement or volume measure may limit the utility or capabilities at the end of the day, and I would not want to see a provider in a bad situation with software that was certified as supporting subscriptions, but not capable of meeting the business need in the provider's operating environment. Should we make a comment about something in that space about if the criterion does not address a volume measure? Should that be a consideration?

Hans Buitendijk
What would be the statement of volume measure? Would it be a threshold below which or above which?

Steven Eichner
I would say minimum level off some standard piece of hardware. I do not know. It is not easy. That is part of the challenge.

Hans Buitendijk

Quite a few criteria would potentially impact that. Supporting that functionality would use extra resources, and therefore, extra hardware, whether it is in the cloud or not, is extra.

Steven Eichner

Right, exactly.

Hans Buitendijk

Consider it as part of the criteria to be measured to say that if this would expand your use beyond XYZ, you do not need to do that, you do need to do that, or whatever.

Steven Eichner

Right, and it may be a comment just that the criterion may test just the ability for a subscription, but does not address volume.

Hans Buitendijk

Correct.

Steven Eichner

And it may be sufficient just to call attention to that fact.

Hans Buitendijk

At this point in time, I am reasonably sure that if you have the capability of subscription, you have the capability of bulk data, but use of it is very, very limited, so, being certified does not mean that it is or has to be used. That would depend on other programs to say in order to be eligible, from the CMS side, for example, you must have the capabilities. It does not also say you necessarily have to use it, unless it is a performance measure that might indicate that you have to do this at least X number of times, like prior authorization in CMS has a minimum threshold that you need to use it at least X number of times in a year to do that. So, it is not ONC that would put the requirement on it so far, in that sense. It is just capability.

Steven Eichner

Right, exactly. So, a potential comment in this rule is just acknowledging that limitation, or the limitation of the certification criterion.

Hans Buitendijk

I think the big question is do we want to identify specific public health use cases that would be applicable for all? Not everybody needs to certify to every kind of reporting to public health, but do they have to respond to queries, and/or do they need to be able to subscribe and notify? That is why we were looking at two or three subscriptions across G10 and G20 to have that flexibility and work it out based on a client profile, as well as interest from public health and otherwise, as to what kind of subscriptions they want.

Steven Eichner

Immunizations are not really a primary focus here, but, Mary Beth, do you have any thoughts?

Mary Beth Kurilo

Yes. Similar to Joel and Hans, I think we have some concerns. We can see a potential use case for subscriptions and immunizations, but it seems very early, so, as I was talking to folks across our community, they were really coming back to needing better definition around what that specification was, and also a testing framework to

ensure consistent implementation, so it felt early to put this in rule and regulation. I think there is certainly promise down the road if we look at this and actually do some proof of concept or some pilot testing and add some definition, but I think the overall thoughts from the immunization community were that it seems very early to put something like this in a rule.

Hans Buitendijk

On the comment that Mary Beth made on how to align on the common topics, the additional thought that lines up nicely with that as well that we were discussing was that, as we progress, we can perhaps use FHIR US Core as an example to define emerging subscription topics that everybody needs to do, or, if you are in a certain context, you have to be able to do, so we can use the mechanism over time as we learn to have a repository, if you will, of well-defined subscription topics and have some indication there of whether supporting FHIR US Core is something that everybody needs to do or that they only need to do if they are pediatrics or something else, but that when they do it, they do it consistently.

Steven Eichner

So, looking at the group of experts that we have today, we cannot really identify a single definitive use case for subscription that is in play today, so are we in a good position to say that maybe this should not be a certification criterion yet and/or that development needs to be done before we look at including subscriptions as a supported function or certified function?

Mary Beth Kurilo

I would be comfortable with that.

Joel Hartsell

I agree.

Steven Eichner

That sounds like a path forward, and a recommendation that ONC work with public health and other stakeholders to identify, test, and develop both subscription and bulk models. Is that a good friendly amendment?

Mary Beth Kurilo

Yes, that works for me, Steve.

Steven Eichner

Are there any stakeholders we should specifically call out? Is there any opportunity for this to support pharmacy or other entities that we need to pay particular attention to that have not typically been included? Do we need to include long-term care facilities or other folks that we have not historically had at the table, like schools or other nontraditional trading partners? If you think of any, please add them into our discussion in the worksheet on your own time. Put that down as a homework assignment, please. Are there any more additions to this item, or shall we move to the next? Let's go ahead and move to the next, please, Accel. Rachel, how are we doing on time?

Rachel Abbey

We are good. I think we are going to go on to the PDMP next, and we can start the clock for about 40 minutes.

Steven Eichner

Wonderful.

Rachel Abbey

We do have several subject matter experts (SMEs) on the line, Steve, and we may want to have them introduce themselves.

Steven Eichner
You read my mind.

Rachel Abbey
Okay, great!

Molly Prieto
Pat, would you mind kicking us off with intros? I think you might have some other folks from your team on, but you were at the top of my list.

Pat Knue
Okay. Hello, everyone. Thanks for inviting us to this call. My name is Pat Knue. I am the Director of the PDMP Training and Technical Assistance Center (TTAC). We are funded through a Bureau of Justice assistance grant to provide support, information, and resources to all the 54 PDMPs in the country. Joining me from TTAC is Kevin Borcher. Some of you may be familiar with Kevin. Prior to starting with TTAC, he was the administrator over the Nebraska program with CyncHealth. Prior to my joining TTAC way back in 2012, I was over the Texas program. We have another colleague who was not able to make it today, Don Vogt. He is not feeling well, but he was over the Oklahoma program, so hopefully we will be able to assist you any way we can with this project.

Steven Eichner
Thank you.

Pat Knue
Sure.

Steven Eichner
Hans, do you want to talk a little bit about your recommendations?

Hans Buitendijk
Sure. The question here has a couple of aspects to it. One is that the way that the criteria is defined is not clear as to whether this is intended to focus on the provider and, when you compare with 29, the clarity on what that is. When you just read 9, it seems to be combining something, so that is where some of the questions come in. Generally, medication reconciliation is already supported, so it is unclear how it fits in here in particular, and that is the fundamental question. Looking mostly at 29, is it really providing discrete PDMP data, or is it providing a Portable Document Format (PDF) or view type of data set that is being shared? In that case, reconciliation is a hard thing to do because we would have to pull it out of the document using some other methods that are not always appropriate for that purpose, etc.

So, what we have been talking about and asking whether the intent is getting discrete data that can therefore be ingested in the flow along with other data, such as medications, drugs, etc., but if there is other data as well, we could also do that. So, it starts with the basic question: Are we talking about discrete data? If not, some things may not apply as much and would not be as feasible. If it is, and we can get discrete data, then it changes the discussion on some of the aspects as well.

Steven Eichner

Pat, I would love it if you and your team could share your perspective as well. Any insights you could share would be fantastic.

Pat Knue
Okay. Kevin is definitely more technical than I am, but let me give you a little bit of the lay of the land. There are 54 PDMPs: All the states, DC, Guam, Puerto Rico, and the Mariana Islands. They are state/territory/district-run programs with local jurisdiction laws or state/territory-level laws. So, although most of the PDMPs operate in a very similar fashion, there are differences across the country. When it comes to providing discrete data or providing an image of a PDMP report, that is all over the board around the country. We have been told that some states have statutes in place that do not allow them to share discrete data, so they just provide an image. Kevin, do you have anything to add to that?

Kevin Borcher
I think that is a good summation, Pat, and I see something in the chat about criminal justice agencies. Yes, there are a handful of PDMPs that are operated or housed within a law enforcement bureau or state agency. These are state-run/state-administered systems, and so, those state laws and regulations would have to take into account whether they can provide discrete data or not.

Steven Eichner
Yes, and some of the PDMPs are run by neither public safety nor public health.

Pat Knue
Yes. There are about five PDMPs that are housed in a law enforcement agency. There are 17 with health departments, 17 with boards of pharmacy, and the rest of them are a mix of statewide professional licensing agencies, substance abuse programs, or things like that, but the majority of them are housed in either a health department or a board of pharmacy.

Steven Eichner
Do we know about how many are limited in sharing discrete data?

Pat Knue
Every year, TTAC conducts a survey of all the monitoring programs on different topics, and so, we have asked questions. We do not get 100% response to every question, but we have gotten responses on that question, and I meant to pull it up. Sorry, give me a second. I can run a query to determine it. Kevin, if you have a thought on that, jump in while I am stalling.

Kevin Borcher
Coincidentally, last week, we posted the Harold Rogers PDMP National Meeting in DC, and there was some discussion regarding HTI-2 and discrete data. While Pat is looking up the exact numbers, it seems like it is varied, where some states are allowed to send discrete data, while others either are not allowed or prefer to send an image through their PDMP through integration. Did I stall you out enough, Pat? And then, what percentage supports National Council for Prescription Drug Programs (NCPDP) SCRIPT to support discrete data? I do not have an answer to that.

Hans Buitendijk
Can you ballpark? Small, medium, 50%, most?

Kevin Borcher
I do not know if I could give a fair answer to that.

Hans Buitendijk
That is fair.

Steven Eichner
As a parking lot issue, that might impact using PDMP over Trusted Exchange Framework and Common Agreement (TEFCA).

Pat Knue
Let me interrupt for one second. According to our information on our survey from earlier this year, only 13 states indicated that they were able to share discrete data. I do not know if that is accurate or not, though. We are going to start doing research which hopefully will tell us, going through all the statutes, which ones actually have that and which ones may just do it out of policy. I have not seen the language that prevents it in law. It may be just policy.

Steven Eichner
I guess the other aside is if they are not sharing it as discrete data, what format are they sharing it in? I recognize you may not be able to answer that today, but whether it is a Joint Photographic Experts Group (JPEG), a PDF, or whatever might be of interest.

Pat Knue
I believe it is a PDF. Am I correct, Kevin?

Kevin Borcher
Yes, I believe that is correct. They typically send it via Hypertext Markup Language (HTML), and it is in a PDF format.

Hans Buitendijk
So, of those 13, assuming that it is a reasonable ballpark, how many would support NCPDP SCRIPT?

Kevin Borcher
I do not know.

Hans Buitendijk
Okay. I was not sure whether you mentioned my other question and I missed it. Oh, no. You already got to it. Thank you.

Steven Eichner
What is the distribution of standards that the PDMPs are currently using? Do we know?

Kevin Borcher
Do you mean like American Society for Automation in Pharmacy (ASAP)?

Steven Eichner
Yes. We are also looking at NCPDP 2.17. We know there are a couple of different interfaces that folks are using to connect to the PDMPs. Is there a balance between them, or is it all one flavor?

Pat Knue

I am not sure I understand, and Kevin can bail me out on this one. The data is reported to PDMPs using the American Society for Automation in Pharmacy standard, and there are multiple versions currently in place, but are you talking about the methods to get the data to the user in an integrated environment?

Steven Eichner
I have enough, I think. One of the challenges is looking at having standards that make it easier for providers to interface with the PDMP in a straightforward and consistent manner. Hans, do you want to explain what the interface looks like?

Hans Buitendijk
Sorry, Steven. Are you asking me?

Steven Eichner
Yes. Can you explain what the interface looks like between the EHRs and the PDMP from the provider's perspective?

Hans Buitendijk
Typically, where they are there, it is viewing, you get an image, you get PDF, there might be portals, very limited deployment of anything discrete, so it really varies. It follows the pattern that has been described as to what PDMP is able to do, and where there is discrete data, there is the opportunity, but not everybody has support for that so they can get discrete data in. With most of it, the vast majority would be that they have viewing capabilities, but, as a result, no ingestion capabilities.

Steven Eichner
Do we know if there is a desire from the provider's perspective for discrete data?

Hans Buitendijk
There is, and all other considerations aside for the moment, the interest is that that data can further have context for clinical decision making, and assuming proper authority, rights, etc., having access to discrete data can feed into that capability to provide further clinical decision support beyond the clinician being able to view it. So, that is where there is the interest to help enhance those parts of the flow for which you need to have that data discretely. You could use alerts, **[inaudible] [00:52:13]** otherwise, etc. that you then can start to extend to that scope as well, and again, as appropriate, as authorized, etc. That is where the state variations in policies and law as to what can be shared indicate how far you can go with that, or not.

Steven Eichner
I do not know if the standard supports it, but I am wondering whether the return can include a wrapper of discrete data around the PDMP content so that it could be linked into the EHR or incorporated into the EHR as an image, but a wrapper containing enough identification information to match the patient.

Hans Buitendijk
I would expect that technology can support that, but that is where policies may not allow for that, so it is a view-only. That is a variation of what you can do depending on the jurisdiction you are in on pulling that in further into the simple view.

Steven Eichner
Right, and part of that was kind of a question back to Pat and Kevin, thinking about the idea of a wrapper around the main content of the PDMP data where the wrapper could include patient-identifying information, but not the

medical information, that that would facilitate incorporating the image into the EHR as an image or as non-discrete data.

Kevin Borcher
And I believe that is how it currently works. There are two hubs that are the interoperability between PDMPs, EHRs, and pharmacy data systems as well where it is end-to-end encrypted. The patient-identifying information is even encrypted, so there is an audit ID, but once that is encrypted/decrypted between the two systems, it can contain either discrete data or that image. Last fall, there was the HL7 connectathon in Phoenix where ONC was working to get the FHIR implementation guide for PDMPs going once again, and that should actually be in the voting process with HL7. That has been going on for several months now with PDMP and other stakeholder input, and within that, there was mapping between FHIR, NCPDP, and ASAP, so if it is discrete data, it can be passed through FHIR if, once again, that becomes commonplace, where it currently is not.

Hans Buitendijk
So, part of the challenge there is that it is not yet quite finished or published, and the adoption on the PDMP side may initially be limited based on policies, law, funding, or resources, correct?

Kevin Borcher
Yes, that is correct.

Steven Eichner
Yes, because if it is in ballot now, the ballot will not get reconciled very likely until sometime in early 2025.

Hans Buitendijk
In the meantime, NCPDP SCRIPT would be a consideration as well, but as you indicated, it might be a challenge for TEFCA, depending on how TEFCA wants to accept certain standards or not, and the question also **[inaudible] [00:56:29]** NCPDP SCRIPT, as the adoption for that purpose is very limited as well.

Steven Eichner
Well, the real issue for TEFCA is looking at pushing the non-discrete data, but if there is a wrapper, that would work, so a PDMP could respond to TEFCA as long as the non-discrete data or image was in a wrapper that had the patient information so it could get routed back to the requesting provider.

Hans Buitendijk
Today, if you can put it in the Consolidated Clinical Document Architecture (C-CDA), you have a shot. C-CDA in itself supports it, but it is not necessarily one of the document types that would be widely supported yet, and once we get there, FHIR would support it. NCPDP SCRIPT is the one that currently would not be a standard in the scope of TEFCA.

Steven Eichner
Right, and CDA is not recognized in the CMS regulations for providing interoperability as a transport mechanism for PDMP.

Hans Buitendijk
But it is recognized for many other drug-related interactions, so it is not a big stretch.

Steven Eichner
Is that a recommendation we need to make?

Hans Buitendijk

That is too soon because the standards have not evolved, or, on the flip side, that it is too soon because a substantial number of jurisdictions would be able to share PDMP, but not be ready for it?

Steven Eichner

Or could not operationalize it. It is not that they are not ready, it is that they cannot operationalize it, or that some subset cannot operationalize it without a change in law. But again, that is not necessarily a problem on the certification side, that is on any requirement to use the certified technology.

Hans Buitendijk

Yes, and at this point in time, this would not be… I just want to double check, but maybe ASTP could confirm that there is no date on F9 yet because it is new. That means there is no requirement to implement it, and if, on the other side, F29 is really not in place yet, there is no requirement for certified software to actually start to support it.

Molly Prieto

Hans, there is no date reference in Notice of Proposed Rulemaking (NPRM) for this one.

Hans Buitendijk

Then the question is that, if it is not there, is it helpful to have it in certification or not? Probably by the time that that might happen, we are possibly talking about consideration of a more current version, maybe shifting from one to another, so is this the appropriate time to include it?

Steven Eichner

If there is no date driving certification, it is unlikely that it would get prioritized.

Hans Buitendijk

There is work in progress, but at this point in time, it does not need certification to drive it further, particularly if certification cannot drive it yet or there is no program yet to do that. If policies, and law, and operational start to be available, the interest is certainly there. So, is there a need at this point in time for certification to include it while there are still enough opportunities to move that forward? Certification would not help anyway.

Steven Eichner

And an improved standard about to be released, or in process.

Molly Prieto

I will also note, too, that in this NPRM, these criteria, F9 and F29, are functional criteria, so they do not point to any specific standard today.

Steven Eichner

Right, they are functional criteria.

Hans Buitendijk

I thought that in F29, there were some differences, that you had to support a particular means of transfer, so there was a standard for something. I am just trying to get to the right spot.

Molly Prieto

Let me be specific. So, there was not one for the PDMP-specific standards. You are correct in F29 that the NPRM does reference within the capabilities. Those receive, validate, parse, and filter does point to some existing similarly to the other F20s.

Hans Buitendijk

I think it is a choice between direct protocol and the ONC applicable **[inaudible] [01:02:12]** secure health transport Version 12.

Molly Prieto

Exactly.

Hans Buitendijk

So, there is mention of standards being able to transport a particular way.

Molly Prieto

Yes, correct. So, for further clarification, we do not point to a content-specific standard for F9 and 29.

Hans Buitendijk

But it is permitted to use FHIR R4 for the listing as well, so if they support FHIR R4, that would be fine.

Steven Eichner

Right, but it also allows for the use of proprietary standards by the technology developers that have developed some of the PDMP technologies in use by the states or jurisdictions.

Hans Buitendijk

Yes. F9 has them more optional, and when it talks about filtering and validation, when you only can get view, until you get discrete, there would be a question of what that really means and how you would do that. They might be functional, but they would be hard to attain. So, on the F9 provider side, there would be a number of challenges. At the end of this week, we are going to talk about more to get more insight, but there are questions and challenges as to the functional aspects of that when you only have an image or a PDF available, something like that.

Steven Eichner

So, where do we go?

Hans Buitendijk

We will get more confirmation, but I think we are leaning toward premature at this point in time, based on all the other pieces that need to be put in play, while at the same point in time, that progress can be made because there is interest to get this kind of data more integrated into the workflows.

Steven Eichner

And if we are looking at premature, what are the trigger events when action should take place?

Hans Buitendijk

The PDP side, from our perspective, having the data more widely and consistently available in a structured and discrete format. I am not sure yet whether there is a strong preference that we have to wait for FHIR or whether NCPDP SCRIPT would already be a good starting point, given familiarity with that.

Steven Eichner

Or rule/law change.

Hans Buitendijk

Yes.

Steven Eichner

So, another potential recommendation might be education about the value and utility of discrete data for PDMP administrators.

Pat Knue

In my opinion, that would be wonderful. I think there is some misinformation and confusion about exactly what that entails and how it would be used, although let me say that PDMPs have been around since 1939, and some of the older ones had statutes in place that indicated that the data was available only to the user that requested it, and it could not be further disseminated. Back when they did paper reports, the paper report could not even be put in the doctor's patient files, so there are some old, outdated laws that they did not even attempt to modify for the new technology. That is the situation we are in, that some outdated laws need to catch up with the times.

Steven Eichner

I think Health Insurance Portability and Accountability Act (HIPAA) and privacy are also part of that educational concept.

Lee Fleisher

Hi, it is Lee Fleisher, and I am sorry I am late. That was one of my concerns about the merit-building between the states and how the way this is written can take that into account. So, what I am hearing is that it does appropriately take that into account. I would not say that outdated law is a hindrance, it is just the law, correct?

Pat Knue

Well, many of the states have not revisited their statutes or rules to address changes in technology.

Lee Fleisher

But that is a state's decision, so I would be careful. "Outdated" makes a value judgment.

Pat Knue

Yes, good point.

Steven Eichner

That education might be in collaboration with the Department of Justice and other entities.

Lee Fleisher

And does the variability of what is included in the database matter? Because from my understanding, there is wide variability in how the states are implementing. They all have it, but they may implement it differently.

Pat Knue

At the core, for all the PDMPs, they are collecting almost the same data. They are getting information about the prescriber, the dispenser, the drug, and the patient. Some have some extra fields, but at a minimum, the PDMPs can positively identify who prescribed the medication, they can positively identify who filled the prescription, they know which patient received it, although with some of those fields, it is just a name, date of birth, and address, no set identifier like a driver's license, Social Security number, or anything like that. Most of them just have the basics, and they can identify the medication that was dispensed through the NVC number and quantity. They also have the date that it was issued and the date that it was given to the patient.

Hans Buitendijk

And it is all based on NCPDP transactions that are being shared, correct?

Kevin Borcher

It is actually based on the ASAP format, and not directly on NCPDP. There is some alignment between the two, but there are also some fields that are not in alignment with one another, nor at USCDI.

Hans Buitendijk

Maybe to clarify the source or the initial data sharing that occurs came from NCPDP-based transaction that then is being transformed by some party into ASAP. Is that accurate? I am not as familiar, so that is why I am curious.

Kevin Borcher

Yes. It is typically used as either SCRIPT or telecommunications standards from NCPDP that then get transformed to ASAP.

Steven Eichner

How much variation is there between jurisdictions on implementing the ASAP standards?

Pat Knue

All the states are using some version of ASAP. Some have an older version, Version 4.1, and some have implemented up to 4.2B. There is a new version. Is that one 4.3, Kevin?

Kevin Borcher

5.0 comes in September.

Pat Knue

Okay, so it runs the gamut. There is not even a majority. It is all over the board, from 4.1, to 4.2, 2A/B… They are all over the board.

Steven Eichner

What is in the ASAP?

Pat Knue

That one is yours, Kevin.

Kevin Borcher

There are 102 fields, and in the new version, 5.0, there are 144 fields, and as Pat touched on before, you are primarily looking at the pharmacy information, name, address, store location, prescriber information, name, National Provider Identifier (NPI), and/or Drug Enforcement Administration (DEA) number. The patient information is primarily name, address, date of birth, and potentially gender. If it is for an animal, you may have some species information, and then, you have the prescription information, which does not typically use RxNorm. It uses National Drug Code (NDC), the date issued, date filled, possibly the date sold, depending on the state, quantity, and prescription number. There is also some additional information.

Steven Eichner

Hans, do you know if there has been a crosswalk done between ASAP and FHIR resources? I do not think it has been done against USCDI.

Hans Buitendijk

I suspect there has been, but I am not familiar with what kind of crosswalk may have been done. I think a couple others might know, but if nobody on this call knows, perhaps Scott Robertson or somebody like him might know.

Naresh Sundar Rajan

This is Naresh. Kevin, thanks a lot for doing this. Could you walk us through if you had any initiatives across where you had to map it to USCDI from ASAP?

Kevin Borcher

With the new ASAP 5.0, there is starting to be some alignment in both national organizations and federal agencies, looking at ONC and Project US@, looking at American Health Information Management Association (AHIMA), and looking at Centers for Disease Control and Prevention (CDC) for their race and ethnicity codes. Sex/gender is still an issue coming up with ASAP. So, I believe there has been some mapping between FHIR and earlier versions of ASAP, but I know there has not been mapping with the new 5.0 version. I think there are opportunities coming up for more alignment between ASAP more of the standards, such as USCDI, but they are not there yet.

Steven Eichner

By the way, there is an HL7 project doing a mapping effort between CDA and FHIR resources, Kevin, just so you are aware of that.

Kevin Borcher

That is good to know. Thank you.

Steven Eichner

That may be helpful to you at some point. So, do we have a reasonable recommendation or plan for a recommendation? Right now, we are recommending that there be a delay. Do we have the trigger events where things should go forward? Hans, Naresh, do you have suggestions about what might be trigger events?

Naresh Sundar Rajan

I guess so. One of the things that I believe should be part of the recommendation is that there need formore open discussions around the ASAP standard. Again, it is a similar model, and at the end of the day, you have demographics, you have patient information, you have prescription information, you also have other information that would align with USCDI at the end of the day, but being part of PEMEX at some point in time, the challenge that we run into is resource availability and the availability to actually promote this to the national standard with the USCDI mindset, so that needs to be openly discussed, and when we give a recommendation to ONC to use the standard, there definitely needs to be an amalgamation of all these different approaches to a common approach that would align with the FHIR implementation guide (IG) at the end of the day.

Steven Eichner

Yes, and in alignment with USCDI+ or consideration of USCDI+.

Naresh Sundar Rajan

One challenge that we probably have not discussed here is jurisdictions and difference in governments. If the PDMP data is housed at the Department of Health, like it is in Utah, for example, but in the state of Nebraska, it is housed in two different places, one through a health information exchange and one through the state, there is a difference in the quality of data among these different areas or departments, and when such things happen, your optionality of data varies heavily. In health information, you actually get more complete data through other demographics enrichment and so on, whereas if PDMP prescription access comes through a single source, there is a variation in that, so the governance on that is quite often overlooked. That is also a thing that needs to be discussed in detail.

Steven Eichner

Would you be interested in helping flesh out a draft recommendation?

Naresh Sundar Rajan
I am happy to do that.

Steven Eichner
Fantastic. Do we have any other thoughts right now about PDMP from any task force members?

Naresh Sundar Rajan
I just have one question for Pat and Kevin. Would you be able to walk us through the timeline at a high level on mapping between USCDI and ASAP?

Kevin Borcher
We are willing to assist in any way we can. You may also want to reach out to Bill Lockwood, who is the executive director of ASAP, to get his blessing or permission to do that mapping, and he may be able to assist.

Naresh Sundar Rajan
Perfect. Thanks, Kevin.

Steven Eichner
Pat, Kevin, thank you so much for spending some time with us today. We really do appreciate it. It is most helpful.

Pat Knue
I hope we were some help, and if you have any other questions, do not hesitate to ask. We are here to help you however we can.

Steven Eichner
Wonderful. We have one more agenda item, and then we are going to go to public comment. You are welcome to stay if you would like.

Pat Knue
Okay, thank you.

Kevin Borcher
Thank you very much.

Steven Eichner
What do we have next on our agenda?

Rachel Abbey
Steve, we are going to readdress eCR. That was the question folks wanted to address again and have a little bit more time on. We do have Laura Conn from CDC to provide any programmatic content as needed.

Steven Eichner
Wonderful. Good morning, Laura.

Laura Conn
Hi, Steve.

Rachel Abbey
Also, can we restart the clock for 20 minutes, please?

Steven Eichner
Can we also scroll a little bit to the right? I will give everybody a chance to look and refresh their brains on the workgroup recommendations. Maybe we can scroll up a little bit.

Rachel Abbey
That is the top of the document, but I will zoom in, if that helps.

Steven Eichner
Do we have a typo? "HTI-1 indicates how we send eCR." It should be "receive eCR." It is true for HTI-1, but the language in that item does not quite make sense.

Joel Hartsell
Steve, which line are you looking at?

Steven Eichner
Item No. 2.

Joel Hartsell
Oh, okay. It does not fully make sense if we continue moving forward with FHIR. I think it was just to keep consistency around the language with HTI-1. Erin was recommending including this content in there.

Steven Eichner
Where I was lost is "HTI-1 indicates how we are sending eCR." You get the ER back in the same format. This would be consistent with what was finalized in HTI-1.

Joel Hartsell
With this, I think the intent is to say if we transition to FHIR referencing that…

Steven Eichner
I was thinking the first HTI-1 should say "HTI-2."

Joel Hartsell
Oh, yes, that is fair.

Steven Eichner
That is where I was lost. Otherwise, it would say "HTI-1 indicates that, as reflected in HTI-1."

Joel Hartsell
That is fair. I can rework this language.

Molly Prieto
I would just note, too, that HTI-1 does specify that because HTI-2 proposal is pointing only at FHIR. It is kind of inherent in the language, just for the purpose of the associated recommendation here.

Steven Eichner
It was more of a typo. The first one should have been a 2. Hans?

Hans Buitendijk

I would be jumping to No. 6, so I will be in queue until you get there, unless you want to jump.

Steven Eichner

I am willing to jump.

Joel Hartsell

Do we want to talk about No. 1 first?

Steven Eichner

Oh, sure.

Joel Hartsell

I think we should just make sure of all the profiles in the IG. I do not think they are explicitly calling it out currently, but we should ensure that the electronic initial case report (eICR) and Electronic Reporting and Surveillance Distribution (eRSD) are captured that are referenced within the eCR IG, so explicit verbiage around that would be ideal.

Hans Buitendijk

If I am not mistaken, EARSD would be there for CDA eCR as well, correct? And if you do full FHIR, you have all three. If you do CDA, there is still EAR.

Joel Hartsell

Yes. With CDA, we would also want to include Electronic Reporting and Surveillance Distribution (eRSD), looking at that.

Hans Buitendijk

I think that needs to be clarified. It is either CDA plus eRSD, or it is FHIR, and then, all three.

Steven Eichner

We need to be as specific as we can.

Joel Hartsell

Okay. I will sweep that language offline. We will get that added.

Steven Eichner

Thank you.

Hans Buitendijk

We definitely covered the way that Joel was meaning it to be, but I agree, it can be clearer.

Molly Prieto

Who wrote this language?

Joel Hartsell

This was Erin, myself, Gillian, and several others. We have been going back and forth on the language.

Molly Prieto

Okay. I will just note that you are changing it.

Joel Hartsell
Okay, perfect, thank you. Sorry, I did not put my name in there.

Molly Prieto
No worries. I just cannot see who is talking right now.

Joel Hartsell
Do we want to jump to 3 and talk through that now?

Steven Eichner
Yes.

Joel Hartsell
All right. This one was put forward by the public health agencies in particular, ensuring that certification addresses all functions and data needed for business, so I think one of the nuances in this includes data that is sourced outside the EHRs. Currently, with eCR, if a hospital or healthcare organization uses a lab that has a separate laboratory information system (LIS) or reference laboratory, and as an example, lab information often comes in not using the standard terminologies that are needed to process this efficiently, either by Reportable Conditions Knowledge Management System (RCKMS) or by the public health agencies, so this is a push to ensure that the content is aligned with the certification criteria as well.

Hans Buitendijk
So, Joel, if I hear you correctly, while data may be distributed across multiple HIT within the responsible reporting party, you want to ensure with No. 3 that however that is done, the report includes all the data in whatever system they live on. Whether they are on the EHR or somewhere else, the case report is the collation of that information.

Joel Hartsell
Yes, and in alignment with the standard and defined terminologies.

Hans Buitendijk
Right. I have a question in that regard. There is certification in HIT that deployment may be distributed based on whatever the client provider may have, so the actual implementation of that would be frequently more of a provider having ensured with their multiple HIT suppliers that the data is present in the system that is actually doing the reporting, and that is not measured in certification. So, while we can measure that on certification, a particular HIT has all the data and can send a proper case report, in actuality, whether that system is the single one in place or there are multiple is not in sync.

Steven Eichner
That might be part of the onboarding process with public health, but if the system has at least certified that it can do it, it becomes a matter of whether it is populated correctly in the field, but if the system is not capable of populating a message properly, then it is not capable of populating a message properly. Does that make sense?

Hans Buitendijk
Most certainly. I am wondering whether the focus is that it states to address all functions and data needed to do business, it needs to have all the data, and to be certified, you need to support all the required elements. Typically, the testing done is on all required and must support, or required can be empty, or, in CDA… I always get confused about the language they use there. So, that is clear. You have all the data that needs to be there and can measure

that. When you say "functions," what would need to be done? That would certainly be part of the distribution as well. I am not sure what is intended to be tested.

Joel Hartsell

No, that is fair, and I do not think we have Erin on today, and I do not know what was intended by…

Steven Eichner

With "functions," we are including the EHR internal work or retrieving data from other systems to generate the message. We can certainly refine the language, and I will take ownership of that.

Joel Hartsell

Okay, awesome. Thank you, Steve.

Hans Buitendijk

So, it would be a requirement to not only test that the output includes everything, but you are looking for it to have the ability to receive all the data from elsewhere if it is not otherwise captured in the EHR.

Steven Eichner

Right, to generate it. We are not looking at trying to say it all has to be within the HIT module that is certified to generate it. It has to get the data from somewhere. Whether it is internal or external, we do not really care.

Hans Buitendijk

Okeydoke.

Steven Eichner

Does that make sense?

Hans Buitendijk

That definitely should be clarified. Otherwise, it is unclear what the scope of functions is.

Steven Eichner

That is very much appreciated.

Joel Hartsell

Steve, would you mind taking a crack at that?

Steven Eichner

As I said, I gladly will. Accel, please tag me in that. Please go to No. 4.

Joel Hartsell

In this one, certification should ensure the use and implementation of standards in real-world environments meeting expected thresholds for completeness and data quality. This is more of a callout that future work could include insight measures for other public-health-related performance measures, and that if that work is done, it should align with the current data quality metrics that were developed by the quality assurance workgroup that is comprised of 31 jurisdictions that kind of aligned on what those metrics should be and are used for onboarding validation activities by the CDC onboarding team at APHL and most public health agencies. So, again, there is a focus on data.

Hans Buitendijk

Would the real-world testing certification criteria already cover a good chunk of this? I would see that data insight might not have some of the measures. When you have case reporting, that would be applicable, but will real-world testing cover it?

Joel Hartsell
I think it would cover aspects of this. Laura, what are your thoughts? I am tagging you in on this.

Laura Conn
I think my answer is I do not know. I do not think we have seen much as it relates to real-world testing and eCR that has improved data quality to date, but could it be more stringent and reliable in this space? We would have to talk more about that.

Steven Eichner
Laura, does 3 make sense to you with revisions?

Laura Conn
Yes. Just from a real-world example of 3, I think what is most obvious to me is having external labs provide non-standardized codes either for laboratory tests that have been performed or results of laboratory tests, and not providing standardized codes back to the healthcare system, and therefore not being able to get into an EHR, which then impacts the EHR's ability to trigger and be able to send case reports because they do not get those standardized codes.

Steven Eichner
That is an excellent point. I will be sure to include in my little summary that one of the things it has to emulate is inconsistent lab data coming in. Will that help?

Laura Conn
I think so. I was just providing an example of where we see a pain point, and I think it is a pain point for EHRs, too. If they do not get it, they cannot have it, but in order to maximize the value of the interoperability solutions, we need to be able to get those standardized codes from external organizations, and I think that is part of what this is pointing to.

Steven Eichner
Joel, there is a note to you in the chat.

Joel Hartsell
Yes, I can forward that to you. Give me a second to get it to you.

Steven Eichner
How do we feel about 4? Do we need to make any revisions?

Hans Buitendijk
I am double checking on the real-world overlap, how much of that will be covered, and whether it is therefore helpful to reference.

Joel Hartsell
I can link out to the metrics I am addressing in the comment as well, if that would be helpful.

Laura Conn

I am not sure if Molly or Rachel want to comment on that or the intent of real-world testing, and if that could be strengthened to address this.

Molly Prieto
I might defer to my colleague Jeff, who I think is still on the line, in regard to real-world testing content.

Laura Conn
Thanks, Molly.

Jeffrey Smith
So, those requirements are spelled out in the 405 section of Part B. The elements of a real-world testing plan are spelled out, but the measures are self-developed by developers and submitted in plans. Does that answer your question?

Hans Buitendijk
I think part of it is as the elements as new standards drop into certification, would the elements therefore include case reporting by virtue of what is already there? I am trying to find in the rule whether real-world testing would then effectively expand to include that or whether it would be something that would have to be named separately in the rule.

Jeffrey Smith
Got it. Give me one quick second.

Steven Eichner
We have just about three minutes left on this item.

Hans Buitendijk
I agree, that is a core difference. That would be more of an Insights question. You can take this from my perspective line, Jeff. I am checking as well.

Steven Eichner
We may need to table that and come back.

Jeffrey Smith
It would expand. As to whether the category would be included in real-world testing, we do not call out specific F criteria, so any F criterion would be subject to real-world testing.

Hans Buitendijk
That is what I thought. Okay.

Steven Eichner
Do we have any issues with 4, or is it locked down?

Hans Buitendijk
It may help to also reference that recognizing it is picked up in real-world testing as well. The combination of these measures and real-world testing is where we are looking to advance the quality.

Steven Eichner

Okay. Accel, can you note that as real-world testing and give it to me, please? Do we have any questions about No. 5?

Joel Hartsell

This one just references the importance of coordination and **[inaudible] [01:37:52]**.

Steven Eichner

And No. 6?

Joel Hartsell

Hans, I know you have some thoughts on this, but we are essentially suggesting that two years after the introduction of 3.1, all EHRs are working towards 3.1 rather than FHIR, or all that we are actively working with, such as the APHL and CDC, that are in general availability or actually sending data. So, this shift to FHIR is likely going to require EHRs to prioritize the adoption of this new standard, and through discussions with EHRs, it is a larger lift, and we will likely limit their ability to maintain and enhance the data quality of existing interfaces, so there will also be additional burden on EHRs associated with this to go through that onboarding process as well, and data quality checks with the Public Health Assessments (PHA), APHL, and CDC.

Hans Buitendijk

The suggestion I was going to make on 6 was that given that, the recommendation would be that that remains flexible on the **[inaudible] [01:39:13]**, but particularly on the F25 side, which currently states that it would switch over into FHIR, we suggest that PHAs are either going to extend support for CDA because it just got put in, and there is a lot of work and adoption that is going on, and they may have started with FHIR or not, to have a longer line of support, and in the meantime, if it is not the PHA, that the intermediary also has the opportunity map from one to the other. I think we talked about that a little bit, but it would be helpful to recognize in here that we need to have a longer period where the two can run in parallel so that provider EHRs, PHAs, and their suppliers can more dynamically shift from one to the other, and at a later point in time, we might say it is time for everybody to go to FHIR.

Steven Eichner

So, do we push for certification of January 1st, 2029?

Hans Buitendijk

I would not say that. I would just say that in January 2028 to make everybody's **[inaudible] [01:40:30]** FHIR is too soon, and that that needs to be determined later, but in the meantime, you can continue on CDA, or you can start to transition to FHIR. We need to be flexible about that.

Joel Hartsell

Hans, are you suggesting stronger language for the EHRs that we continue CDA and FHIR, not just the public health agencies?

Steven Eichner

We have about another 30 seconds.

Hans Buitendijk

I think it is for both to be able to run longer in parallel between the two methods rather than forcing to go too quickly to FHIR.

Joel Hartsell

Okay. I can rework some of this language on that as well.

Steven Eichner
Joel, if you want help on that, I would be happy to give it.

Joel Hartsell
That would be great. I will coordinate with you offline.

Steven Eichner
Sounds good.

Joel Hartsell
Do we have 20 seconds to run through F25?

Steven Eichner
Rachel, do we have time?

Rachel Abbey
I think we have five minutes, and then we have to go to public comment, but we can reset the clock for five minutes. Thanks.

Steven Eichner
Joel, it is yours.

Joel Hartsell
All right. So, we updated the language in F25 a little bit. It says receive, validate, parse, and filter electronic initial case reports. I think historically, it did not include reportability response, but essentially, not just the eICR, but also the reportability response, and added this language around "into the destination system," so, where it is relatively vague, I think the goal of "receive, validate, and parse" is not just populating a database, but getting the data in a useful state and into the destination systems for use by the public health agencies, and so, if we are going to include this, I think those additions would be helpful. Any thoughts or hesitancies around that, Laura or others?

Laura Conn
Nothing from me.

Joel Hartsell
Okay. No. 2 is kind of the same as F5, and then, No. 3 is a similar flavor to No. 6 and F5, and I can work on some stronger language with you, Steve, but essentially, the transition to FHIR, the simultaneous timeline, is going to require divided effort with the same amount of funding to prepare for FHIR adoption while maintaining existing eCR infrastructure and is likely going to slow the utility of the eCR data for support, new technology, and new solutions. Any thoughts on this? Hans and Steve, based on your comments earlier, I think I agree with stronger language that we would recommend dual support for longer and that certification should be pushed out a little bit for FHIR.

Hans Buitendijk
Yes, it should be pushed out from a required perspective. You can start "now," but… And for those that are using the FHIR-based app, there is more flexibility. If the APHL has mapping capabilities in both directions to PHAs, we can throttle that up as we go, depending on where people are at.

Joel Hartsell

With APHL with the transforms, a lot of that is to enable jurisdictions to start seeing FHIR eICRs. Without that real-world data, it will be challenging for jurisdictions to augment their systems in effective ways. Okay, we did not need the full five minutes. We can make this language a little more specific.

Steven Eichner
I am happy to help, both with the timing and working on the text. Seth, let me turn the floor back to you for public comment.

Public Comment (01:45:45)

Seth Pazinski
Thank you, Steve. We are going to transition to the public comment portion of our agenda. If you are participating by Zoom today and would like to make a comment, please use the raise hand feature, which is located on the Zoom toolbar at the bottom of your screen. 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 raise their hand, I just want to give a couple reminders. First, the next Group 1 meeting will be next week on August 27th from 11:00 a.m. to 1:00 p.m. Eastern time, and as a reminder, this will be the final meeting of Group 1, and then, the following week, the week of Labor Day, we will be moving to the full task force meetings where we will be looking at the individual group draft recommendations and working to come to consensus as a full task force on the final set of recommendations during that week of Labor Day. Also, this is just a reminder that all HITAC meeting materials can be found on HealthIT.gov and are available to the public. I am going to just check on the Zoom here. I do not see any hands raised. Accel, do we have anyone on the line? I see that we do not, so I am going to turn it back to you, Steve, for next steps and to close out our meeting.

Next Steps (01:47:26)

Steven Eichner
Thank you. Do we have any additional comments or any outstanding items we need to touch on today? The floor is open for task force members to raise any questions or issues.

Hans Buitendijk
If we have any suggestions, we put them in the column next to it, Column K, correct?

Steven Eichner
Yes, please. As Seth said, we have one more task force meeting of Group 1 next week, and then, the full task force will be meeting rapidly over three days during the week of Labor Day to compile the work of the different workgroups into a master document and submit that to HITAC for its review. I would like to thank all of our subject matter experts that were guests today, Laura, Pat, Kevin, and others, and I would like to thank the task force members for their valuable contribution. We could not do this without you. Everybody's input was very, very important. I would also like to thank the Accel staff and our ONC friends for making this happen and giving us a wonderful opportunity to provide feedback to ASTP. Thank you so much for your time and effort, and we will see you next week.

Joel Hartsell
Thank you.

Adjourn (01:49:04)

Questions and Comments Received Via Zoom Webinar Chat

Noam Arzt: Aren't some PDMP's controlled by other parts of STLT government in some cases, like a criminal justice agency? How would that seeming lack of control by PH be managed/factored in?

Hans Buitendijk: What percentage of PDMPs would be able to provide discrete data vs. view/image/.pdf?

Noam Arzt: Oy. Even worse.

Hans Buitendijk: What percentage supports NCPDP Script to support discrete data?

Susan Clark: Having been a state contractor I would like to also offer that those PDMPs housed within a smaller agency that is not public health have a higher likelihood to be under-resourced and particularly under-resourced with technical expertise.

Naresh Sundar Rajan: There is always optionality of the data available in ASAP standards defined, which Pat and Kevin can talk more about. There is variance across the states definitely, that needs to be taken into account.

Naresh Sundar Rajan: @Joel can you point us to the data quality metrics if it is published in a place anyone can access?

Naresh Sundar Rajan: Thanks!

Jeffery Smith: Real world testing plan elements here: https://www.ecfr.gov/current/title-45/part-170/section-170.405#p-170.405(b)(1)(iii)

Noam Arzt: I missed a few meetings: has the committee discussed relevant changes to PH Insights Conditions?

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 20, 2024, Meeting Webpage

Transcript approved by Seth Pazinski, HITAC DFO, on 9/19/24.