ASTP | Health IT Advisory Committee

Health Information Technology Advisory Committee

HTI-2 Proposed Rule Task Force 2024 Virtual Meeting

Transcript | September 5, 2024, 11 AM – 12:30 PM ET

Attendance

Members

Bryant Thomas Karras, Washington State Department of Health, Co-Chair
Rochelle Prosser, Orchid Healthcare Solutions, Co-Chair
Mark Sendak, Duke Institute for Health Innovation, Co-Chair
Derek De Young, Epic
Steven (Ike) Eichner, Texas Department of State Health Services
Lee Fleisher, University of Pennsylvania Perelman School of Medicine
Hannah Galvin, Cambridge Health Alliance
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
Mary Beth Kurilo, American Immunization Registry Association (AIRA)
Katrina Miller Parrish, Patient.com
Kikelomo Oshunkentan, Pegasystems
Randa Perkins, H. Lee Moffitt Cancer Center & Research Institute
Dan Riskin, Verantos
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, CyncHealth
Rachel (Rae) Walker, Elaine Marieb College of Nursing, University of Massachusetts Amherst

Members Not in Attendance

Suresh Balu, Duke Institute for Health Innovation (DIHI)
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Sooner Davenport, Southern Plains Tribal Health Board
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Steven Hester, Norton Healthcare
Jim Jirjis, Centers for Disease Control and Prevention
Hung S. Luu, Children's Health
Dominic Mack, Morehouse School of Medicine
Meg Marshall, Department of Veterans Affairs
Anna McCollister, Individual
Kris Mork, Leidos
Alex Mugge, Centers for Medicare and Medicaid Services
Shantanu Nundy, Accolade
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
Fillipe Southerland, Yardi Systems, Inc.
Sheryl Turney, Elevance Health
Thomas Wilkinson, U.S. Department of Homeland Security

ASTP Staff

Seth Pazinski, Designated Federal Officer
Maggie Zeng, Staff Lead
Molly Prieto, Group 1 Co-Lead
Rachel Abbey, Group 1 Co-Lead
Sara McGhee, Overall Task Force Program Lead & Group 2 Lead
Ben Dixon, Group 3 Lead

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

Seth Pazinski
Good morning everyone, welcome to our final meeting of the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule Task Force. 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 serve as Designated Federal Officer for today. As a reminder, this meeting is open to the public and public feedback is welcome throughout the meeting using the zoom chat feature. Also, there will be a scheduled time at the end of our agenda for verbal public comments. I am going to begin with a roll call. So, when I call your name, if you could please indicate that you are present. And I will start with our co-chairs. Bryant Thomas Karras?

Bryant Thomas Karras
Present.

Seth Pazinski
Rochelle Prosser?

Rochelle Prosser
Good morning, present.

Seth Pazinski
Good morning. Mark Sendak?

Mark Sendak
Present.

Seth Pazinski
Suresh Balu? Shila Blend? I did get a message that Hans Buitendijk will not be able to join us today. Sooner Davenport? Derek De Young? Steve Eichner?

Steven (Ike) Eichner
Good morning.

Seth Pazinski
Good morning. Lee Fleisher? Hannah Galvin?

Hannah Galvin
Good morning.

Seth Pazinski
Good morning. Raj Godavarthi? Gillian Haney? Joel Hartsell?

Gillian Haney
Sorry, I am having trouble coming off mute. Good morning.

Joel Hartsell
Present.

Seth Pazinski
Thank you, Gillian, thank you Joel. Steven Hester? Erin Holt Coyne?

Erin Holt Coyne
Present

Seth Pazinski
Jim Jirjis? Mary Beth Kurilo?

Mary Beth Kurilo
Good morning.

Seth Pazinski
Good morning. Hung Luu? Dominic Mack? Meg Marshall? Anna McCollister? Katrina Miller Parish?

Katrina Miller Parrish
Good morning.

Seth Pazinski
Good morning. Kris Mork? Alex Mugge? Shantanu Nundy? Eliel Oliveira? Kikelomo Oshunkentan?

Kikelomo Oshunkentan
Good morning and present.

Seth Pazinski
Good morning. Randa Perkins?

Randa Perkins
Good morning.

Seth Pazinski
Good morning. Dan Riskin?

Dan Riskin
Good morning.

Seth Pazinski
Good morning. Fillipe Southerland? Zeynep Sumer-King?

Zeynep Sumer-King
Good morning.

Seth Pazinski
Good morning. Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning.

Seth Pazinski
Good morning. Sheryl Turney? Rae Walker?

Rachel (Rae) Walker
Good morning.

Seth Pazinski
Good morning. Thomas Wilkinson? All right, thank you. Are there any members I missed or any members who just joined that would like to indicate they are present? All right, then I am going to turn it over to our co-chairs to get us into our meeting for today.

Opening Remarks (00:03:46)

Bryant Thomas Karras
I am going to have zero opening remarks so we can spend all of our time getting through things.

Rochelle Prosser
Good morning, everyone. We have a lot of work still left over to do. As you see from yesterday, there is a lot of robust conversation. So, I would like us to focus like a hawk today to keep on task and get through the documents. Thank you.

Mark Sendak
Just thank everyone for the time. No other remarks.

Seth Pazinski
Okay. Can we pivot into the Google Doc now? For the agenda, we are going to be focusing on finishing through the Group 1 recommendations. Then we will be pausing at 11:55 to have a call for approval of the recommendations to move forward to the full Health Information Technology Advisory Committee (HITAC). With that, I am going to turn it over to Bryant to get us into the remaining Group 1 recommendations.

Task Force Recommendation Worksheet (Group 1) (00:04:56)

Bryant Thomas Karras
Great. So, if we could scroll down to ... There we go. A little bit lower. All right. Actually, let us come back to Row 11. Scroll down to where we left off, which was row ... I think we were at Row ...

Aaliyah Parker
Nine, correct?

Bryant Thomas Karras
No, 13.

Naresh Sundar Rajan

J, I believe.

Bryant Thomas Karras
13. We are going to come back to the Prescription Drug Monitoring Programs (PDMPs) one at the end. So, this is the next one that we had. So, we are now into the 20s. Mary Beth, are you on?

Mary Beth Kurilo
I am. Good morning, Bryant.

Bryant Thomas Karras
Okay. So, rather than going through every single one, since F21 has a lot of the reciprocal part of F1, I am hoping we can approve it as a block in the three minutes we have remaining for this.

Steven (Ike) Eichner
Let us get a timer up just to keep us all honest.

Bryant Thomas Karras
All right.

Mary Beth Kurilo
I appreciate that some numbering was added. I think that will really help. I think I can very quickly summarize, I think you are right, a lot of this is a mirror to F1. There are areas where we are just asking for clarification. So, No. 1 is really a clarification of how testing will be operationalized. You are going to hear this concern I think voiced through all of the F20s, the need to consider limited funding, competing priorities across public health, recommendations of a long on-ramp, and just conversations with the broader community about the implementation stage of this. But I just want to go on record saying that the Immunization Information Systems (IIS) community really supports the continued strong promotion of adoptions of standards across public health. Hopefully, that is a pretty easy one that folks can support. I see thumbs up from Bryant, thank you.

The second point is really about who would get certified. In the current IIS community, we have about three quarters of the community that is supported by commercial vendor products, and about a quarter of the community that still has home grown or public health central information technology (IT) supported systems. So, we just have a question about how would those be certified or would they be included in a public health certification product process.

Number three is really about clarifying the scope of requirements. So, since there is language in F21 about electronic health record (EHR) data, Fast Healthcare Interoperability Resources (FHIR) access for EHR data for public health purposes, we have a question about if IIS would also be required to be a client for query for EHR data. If so, would that include additional requirements like multifactor authentication, encryption, Clinical Decision Support (CDS)? So, again, that one is just a question for clarification about scope. Unfortunately, in No. 3, there are actually two recommendations joined. So, about two thirds down where we say, “We recommend the bulk FHIR query for IIS be suggested, that is actually a separate recommendation.

Bryant Thomas Karras
I will fix that.

Mary Beth Kurilo
Perfect, thank you. So, that is really, again, supporting the concept of bulk FHIR query, but we feel like more work needs to happen around an IIS specific implementation guide (IG) for bulk FHIR before it is ready for a

recommendation. So, we support – Ready for a requirement I should say. So, we support it being added as an optional strong suggestion for IIS but do not support a requirement for it right now.

Bryant Thomas Karras
Thank you for catching that.

Steven (Ike) Eichner
From the amendment for No. 2, to address IISs that may have different reporting requirements or different business processes such as Texas, which has an opt in model rather than an opt out model, how would that work for passing certification testing? Because we have a different business process.

Bryant Thomas Karras
Steve, we are at time. Gillian has her hand up. Can you put your friendly amendment into the chat? Gillian, your hand is up.

Gillian Haney
Yes, I want to get back to a comment that Mary Beth said at the beginning, which was having an overall statement. I would strongly support having an overarching statement that reflects the multiple tools and components and technologies that public health uses to manage and process different data feeds that are coming into their various systems, particularly for infectious disease surveillance, for example, with Electronic Laboratory Reporting (ELR)/ Electronic Laboratory Reporting (ELR) and other data streams coming in, and the need to have flexibility in terms of certification. Also, I think there really needs to be a more overarching statement about what this certification is actually ... how it is actually going to work, who is going to be certified, to Mary Beth's point, and, of course, the need for funding. I actually put some language in the ELR section that might be able to be used for this.

Bryant Thomas Karras
Great. So, let us table that. Noted, Gillian. Maybe we pull that section out of ELR and create a new header section that is in front of all of the 20s. We are over time on this one. Mary Beth, there is one set of red text there that Hans inserted in. I want to make sure you are okay with that and that there is still consensus.

Mary Beth Kurilo
Yes, you are exactly right. Hans tucked that piece into Recommendation 9. I think our clarification is really that we need to better define parse and filter in each of these specific F20s, because I think it looks different in IIS than it may look in labs. Hans just wants to clarify about being cautious against over filtering and the validation expectations. So, we are supportive of his red text as well.

Bryant Thomas Karras
Okay. That ties in nicely with what Gillian just said. Okay, two minutes over. Let us turn everything green except for maybe that last sentence in nine, which I think you guys can handle that in the editing.

Mary Beth Kurilo
Perfect.

Bryant Thomas Karras
The second to last sentence is still okay with you, Mary Beth? We just do not need this comment should apply to all.

Mary Beth Kurilo
Yes, exactly.

Bryant Thomas Karras
We are going to make a comment to all. Okay. Next section. I am restarting my timer. Gillian?

Gillian Haney
Okay. So, I think one of the challenges here is that there is a recommendation that we use FHIR for syndromic surveillance, which does not yet exist. I think there really needs to be input from the National Syndromic Surveillance Program (NSSP) community of practice to support that. So, I think the one and two can be sent to green and then adding some language about exploring opportunities to reduce payloads, but again to call out inclusion of the NSSP Community of Practice (CoP).

Bryant Thomas Karras
Okay. Interesting. Maybe the edits are below. I thought we had ... It is probably ...

Gillian Haney
So, I think one and two can be turned green. I think if we take the second, my last comment in the last line, and we just take that second clause there and turn that green with supportive, we may need to wordsmith it, but we can do that offline. The intent is stated there. Erin has her ...

Bryant Thomas Karras
Erin, please.

Erin Holt Coyne
Hello. I think there is a lot of confusion with regards to electronic case reporting and syndromic. I worry if specifically referencing case reporting and a recommendation regarding syndromic would not add to that confusion. I think we need to explore the use of FHIR as a recommendation for future looking, future forward. But I do not necessarily think it is appropriate to reference electronic case reporting (eCR) here. I recommend we strike that.

Bryant Thomas Karras
Can we briefly, if we could scroll back up to Row 4 for a second. Hans, Gillian, and I put together a proposed block of text that we did not discuss last time. Future advancement of this standard, I think maybe we need to make sure that it is not put into the certification criteria since it does not exist yet. It is premature to make it part of it, but that we make a recommendation that there be investment in exploration of this for future potential use.

Gillian Haney
I would support that.

Steven (Ike) Eichner
Bryant, there was language in Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule that ONC or ASTP included specifically looking at public health and potentially going too far for other pieces. I would suggest lifting that language for here kind of tailored to syndromic. I can get the page number from the HTI-1 ...

Bryant Thomas Karras
In addition to what is in blue here?

Steven (Ike) Eichner
It may support it. It is language that **[inaudible] [00:16:40]** already used.

Bryant Thomas Karras
So, let us approve turning this blue text to green. That was in No. 3. We did not number this section, that was yesterday. Steve, Ike, if you could put in the chat the reference that you want added there as well as a No. 4.

Erin Holt Coyne
Bryant, can I make a friendly amendment to No. 3?

Bryant Thomas Karras
Yes, please.

Erin Holt Coyne
Where it says the very last, “In observational data that a syndromic HL7, B2ADT, why not just reference the actual implementation guide? I think by listing out the message types in a generic **[inaudible] [00:17:24]**, it opens us up to too much ambiguity. Let us just list the IG itself.

Bryant Thomas Karras
Thank you. I agree. Yes, and there are several sections elsewhere where syndromic is inadvertently referred to as an Admit / Discharge / Transfer (ADT) message, and it is not an ADT message. It is a hybridization of that standard and OUR standard. So, you are absolutely right. It is a separate IG. We will add that as a friendly amendment in parenthesis behind the V2ADTORU. Thank you. At time. Let us scroll back down to the other syndromic section.

Gillian Haney
So, one and two can be turned green. We are going to grab some language in that last point there, the last line.

Bryant Thomas Karras
The GH we can turn into a No. 3.

Gillian Haney
Just the last one, you do not need ...

Bryant Thomas Karras
This was Hans and Bryant. GH should be No. 3.

Rochelle Prosser
Bryant, Seth has his hand up.

Bryant Thomas Karras
Seth, go ahead.

Seth Pazinski
Sorry, I did not want to disrupt the flow of the conversation but wanted to just make a clarifying process point. We do not have the opportunity to substantively edit after the call today.

Bryant Thomas Karras
We are asking Ike to do it real time right now.

Seth Pazinski

I just wanted to make that point. There was a comment about editing later on. But when we go to call for approval, whatever the language is that is in the document at this point is what we will be calling for approval on.

Bryant Thomas Karras
Absolutely. There was a parenthesis at the end of the section that inadvertently got turned green and it should not have. We will try to be more careful. Let us go on to F23. So, I made the comment that this needed more discussion and then Gillian, thank you very much, you added in exactly what we needed. Thank you. So, let us focus on the 1 through 7 first, and then we will come back and see if anything in the prior conversation should be included. Gillian?

Gillian Haney
So, I –

Bryant Thomas Karras
Erin? Go ahead Gillian.

Gillian Haney
I would just say that apropos of my previous comment, Nos. 2 and 3, I would recommend using those as part of an overarching statement to be addressed at the beginning of the F20 criteria.

Bryant Thomas Karras
Seth, if I could ask a process question? Do we have to have comments specific to each criteria? Or can we make an overarching comment and repeat it each time it is relevant?

Seth Pazinski
You can make an overarching comment, just be clear on what it is covering if it is covering multiple provisions.

Bryant Thomas Karras
Okay. Let us leave it in here now. I think for the sake of clarity, we should try to repeat that in each section, perhaps, since we do not have a draft overarching comment yet, and we need it to be done by the time we are done with this call. You comfortable with that, Gillian?

Gillian Haney
Completely.

Bryant Thomas Karras
So, let us turn 1 through 7 green unless there are any objections. Please speak now or forever hold your peace. Hans is not here today, but I think, Gillian, Hans' comment is kind of supportive of yours in that it deals with that nuance that multiple different systems are impacted. Should we leave that red? Do you think it is covered by you ...

Gillian Haney
I am fine if we want to leave the first two sentences and get rid of the "This comment would apply to all criteria." So, I think the first block of red beginning with, "This task force is supportive of," that could be turned green. Then I think we could take Hans' first sentence and turn that green as well.

Bryant Thomas Karras
Okay. All right, timer is up. I guess I was a few minutes ahead. Is everybody comfortable with this, the green sections moving forward into the transmittal?

Gillian Haney
Note from Mary Beth, terms like filter need to be defined for each use case. I think that is true.

Bryant Thomas Karras
We covered that in No. 2, right?

Gillian Haney
Yes. Are you proposing calling that out, Mary Beth? Or do you think it is okay in No. 2?

Mary Beth Kurilo
I just think it is probably okay in No. 2. I think it just depends on if these do get pulled out as general comments, just making sure that those comments apply to each individual use case. But I think 2 covers it.

Bryant Thomas Karras
One of the challenges of making it an overarching is that filter means a different thing in syndromic than filter means in immunization. So, it is hard to make it an overarching.

Gillian Haney
Okay, let us scrap that friendly recommendation. I will table that.

Bryant Thomas Karras
All right, I think we are good. 13 seconds. Let us move on. Reset the timer please. This one is cancer, which has not been getting as much funding through Centers for Disease Control and Prevention (CDC) channels as some of our other more well-funded programs in infectious disease, etc. I think one of the most important things is that NACR, the National Association of Cancer Registrars, be pulled into the conversation. Steve, or Ike, do you have any additional comments here?

Steven (Ike) Eichner
Sorry, I lost my unmute button. I think we are okay.

Bryant Thomas Karras
In the earlier section we talked a lot about differentiating between the FHIR IG for pathology reporting versus the cancer case reporting into the registry. I do not think we need to differentiate that here.

Steven (Ike) Eichner
I think we have addressed where we are dealing with the differences. Do you want to make sure you are looking at right standards, right?

Bryant Thomas Karras
Yes. Why don't we pull No. 2 from above and put it as a No. 2 here as well?

Steven (Ike) Eichner
Probably.

Seth Pazinski
All right. I move we approve and move on. Any objections? All right, let us move on to E-case reporting. Joel, are you on today?

Joel Hartsell

I am. So, some of these, I guess the first one, we are all in agreement on, but others can push back. This was just an expansion of receive, validated, parsed, and filter, but moving to the content of the electronic initial case report (eICR) into the designation system. Again, kind of mimicking what we proposed in F5, including the FHIR and Clinical Document (CD) IG, or persisting the FHIR and CD IG. Any issue with turning that green?

Bryant Thomas Karras
None. Turn No. 1 green unless there are any objections? I think that also kind of mimics the No. 2 that was above that we need clearer definition of what those mean. That is good. I do have a friendly amendment to add Department of Defense (DOD), Homeland, and Veterans Affairs (VA) into your No. 2.

Joel Hartsell
Perfect, thank you. I thought I had already done that. So, that should ...

Bryant Thomas Karras
You did it up above but not here.

Joel Hartsell
Apologies. So, I do not think there would be any changes to this. I think we are good to turn that green. So, this next one is really stressing the point of persisting the FHIR and Clinical Document Architecture (CDA) IG and calling out the challenges of limited resources to prepare for FHIR and maintain and progress existing infrastructure, particularly with a two-year turnaround time **[inaudible – crosstalk] [00:28:47]**. Go ahead.

Bryant Thomas Karras
I like it. Any objections?

Joel Hartsell
Green it is.

Bryant Thomas Karras
Let us do that.

Joel Hartsell
The last one in here is calling out, right now the way it is framed is that public health agencies would generate the relative risk (RR). This is calling out that it is currently generated by digital health literacy (DHL), not the public health agencies. So, further distinction in the language around what is being called out for public health agencies as opposed to public health intermediaries.

Bryant Thomas Karras
So, I think this is a challenge throughout the notice of proposed rule, the bidirectional. In this case, it is not bidirectional. There is an intermediary actor. So, I like that. Let us turn that green unless there are any objections? We could probably, friendly amendment, do we need to include Qualified Health Information Networks (QHIN) as an intermediary steppingstone as well?

Steven (Ike) Eichner
This is Steve. I am not sure we need to list a definitive set of intermediaries. I think you can just say intermediaries at large. If you are looking at a QHIN or a health information exchange (HIE) or APHL Informatics Messaging Services (AIMS) or Institute for Population Health (IPH)/AIMS, there are lots of entities that could potentially serve as intermediaries.

Bryant Thomas Karras
I do think that APHL in particular deserves a call out in that it is acting on behalf of states since it is an association of state laboratories.

Steven (Ike) Eichner
Or at least as an agent. I would call it as an agent rather than on behalf of.

Bryant Thomas Karras
Okay.

Joel Hartsell
The only reason I called out AIMS in particular on this one is because they call out the public health authorities (PHA) or the State, Tribal, Local, and Territorial (STLT) generating the incidence rate ratio (IRR).

Bryant Thomas Karras
Yes, so it is just in contrast to that.

Gillian Haney
This is Gillian. APHL, I do not know that they are an agent of public health authorities. I think they are acting on behalf of, I do not know that there is a legal distinction there, but it may be appropriate to actually keep the language, “On behalf of.”

Bryant Thomas Karras
So, friendly amendment here, instead of the word “not the,” say “on behalf of the.” If everybody is okay with that, I think that gets us through the legalese.

Lee Fleisher
It is Lee. My one question is what if it changes? What I am hearing is it is not a defined in any kind of vague or statue of guidance, correct?

Bryant Thomas Karras
It is effectively a de facto hub. It is the authority operated by APHL with CSTE’s control. It is the single and only place in the country where reportability requirements for every single condition in every single state and territory are uploaded.

Lee Fleisher
Is there a way to say that without using the name? That is my only ...

Bryant Thomas Karras
Why? CSTE is in statute, why not have this hub as ...

Lee Fleisher
I just thought how United Network for Organ Sharing (UNOS) was just thrown out, is no longer the entity or the Organ Procurement and Transplantation Network (OPTN). Things can change. But okay, I can live with that.

Bryant Thomas Karras
This can be our recommendation and ONC can normalize it if they need to. But I think we need to call it out is what we need.

Joel Hartsell
I think in particular, this comment is just explaining why, as well. Why public health agencies. Do we want to change that to STLTs, not public health agencies?

Bryant Thomas Karras
Public health authorities, not agencies. Authorities (STLT)

Steven (Ike) Eichner
Or CDC.

Bryant Thomas Karras
CDC does not ... Does CDC have any specific report abilities in ...

Joel Hartsell
No, not in this space.

Bryant Thomas Karras
So, it is only STLT. There is no federal authority for reportable conditions. All right, next. Thank you very much. We went over on that one, so we are going to have to make up some time. So, I will take the lead on presenting this one. I apologize, I really truly want this to be moved forward, but I think we have to not make birth reporting part of certification yet. We are really not ready. There is no state that is even in Alpha testing of this standard. So, it seems premature to start working on a certification process when it has not even yet been proved to work in one jurisdiction. So, I think if I can propose we approve No. 1, which is that the task force recommends it not be part of the criterium. Everyone in agreement? Silence is yes. Okay, turn No. 1 green. Thank you.

We could approve 2, 3, and 4 as additional work that needs to be done so that this can eventually make it into future proposed rules. One thing in No. 4, in particular I want to call out, and we can spell out these acronyms for people's benefit, but birth and fetal death reporting and vital records death reporting should really go hand-in-hand. I think a lot of us were surprised that death reporting was not the one that was included in the certification proposal because it has gone through testing. At least eight jurisdictions have live vital records, electronic exchanges operational. So, I think Vital Records Death Reporting (VRDR) is much more mature than Birth and Fetal Death Reporting (BFDR). But they are both going into the same vital records systems in states, so it seems like they should eventually mature at the same time for certification. People okay with that, turning 2, 3, and 4 green? Any objections? Erin?

Erin Holt Coyne
No objections. I just think the actors impact that.

Bryant Thomas Karras
We should probably also include the same No. 2 from above that parsing needs to be defined here, from several above, I guess. I also called out the National Association for Public Health Statistics and Information Systems (NAPHSIS) as a key contributor in terms of determining the readiness when we are ready to move these forward. Let us go on to the next. F29. Actually, let us skip past this one and we will go back to do F9 and then come back to this. Sorry. Okay, F9. So, Naresh and myself and some others have been working on trying to come up with something. Prescription drug monitoring program is very complicated and has multiple different actors. Naresh, did you get a chance to read through my proposed blue text?

Naresh Sundar Rajan

Yes, I did, Bryant. I also commented on the proposed language. I did get a chance to talk to National Council for Prescription Drug Programs (NCPDP) folks as well yesterday based on our discussion. I think what we captured there, the three different ways, bidirectional, quarriable, and registry level reporting, those three have to be appropriately assigned within the standards. Some what the other way, FHIR should actually be a point of entry for these exchanges. They are definitely looking for a lever to actually facilitate FHIR based exchanges that make sense.

Seth Pazinski
All right. So, I think with that, are people comfortable with the language in No. 1, hinting at the need for synergy without constraining, because we do not yet know what the final resolve will be? We need to describe this functional criterion while we work on resolving these competing standards. Any objections? Let us turn No. 1 green. I put the URL (Uniform Resource Locator) to the Interoperability Standards Advisory (ISA) for people who are interested in looking at what those competing standards are. Erin, I think I tried to pull your reference into the blue text. So, I think yours can ... Do not turn those green, leave all the rest of the, everything else should stay black. Perfect, you moved it over to the side. Thank you.

All right, now let us go scroll back down to F29. As long as you have all those comments moved over to the side for historical value. So, here, again, I kind of just pointed out that it is going to be really hard for us to certify the systems when there are so many different processes. It is going to end up having to be a functional approach. So, No. 2, further harmonization is going ... There are some typos in there which hopefully can get corrected when this gets into a Word document. But pointing out some of the complexity in several jurisdictions, this operates in a law enforcement arena, several it is in a board of pharmacy, and several it is in departments of health. It is going to be hard for public health certification to really have an across-the-board impact. Erin?

Erin Holt Coyne
I agree with that. Do you think it would be worth mentioning, and I think this was mentioned up above, the problem with some public health jurisdictions not allowing the communication of discrete data or the storing of discrete data at the EHR? That, too, might play a role in ...

Bryant Thomas Karras
Its implementation. Yes, absolutely. The certification of that bidirectional query and response is going to have legal constraints in that in some jurisdictions you can query and look at it on a screen, but it is not allowed to be stored in the EHR, which is super problematic compared to other states request that you incorporate it so that you have documentations that you looked at it. Would also bring that No. 5 forward. Maybe, Erin, make that part of different laws and regulations that apply may impact the storage of those discrete elements. If you could propose some language in the language in the chat, we will insert it.

Erin Holt Coyne
You want me to **[inaudible] [00:44:50]**, write it to add it to 2? Or make it its own?

Bryant Thomas Karras
Either add it to 2 or 3 or make it its own. I think it says two minutes, but I think we are over on this one since we also covered F9. How are we doing on time, Seth?

Sara McGhee
You all had the full 150 for this one.

Bryant Thomas Karras
I am worried we are at 11:45. When did we need ...

Seth Pazinski
We have until 11:55.

Bryant Thomas Karras
Erin **[inaudible – crosstalk] [00:45:47]**. Yes, make those green and then Erin has a friendly amendment to insert into 2, I believe. Watch for it in the chat. I did not have my chat window open. How many more do we have? We can scroll down to see. We have G20 below. Is that the last one? Please be the last one. Okay. Erin, are you ...

Erin Holt Coyne
I am working on it.

Bryant Thomas Karras
Okay. Let us move on and we will come back to insert in the friendly amendment. Who wants to take the lead on this one? Steve, this looks like your writing. Are you on mute, Steve?

Steven (Ike) Eichner
I am unmuted now.

Bryant Thomas Karras
I am going to make the last thing on No. 3, there we go. Talk about the complexity here, Steve.

Steven (Ike) Eichner
Sure. The complexity with looking at application programming interfaces (API) for public health, unlike for regular EHRs, is that public health's infrastructure is not a single system, so that supporting an API query on the front end could actually be looking at data from a wide range of backend systems that may or may not have the relevant data. That adds a great level of complexity and an awful lot of potential customization of a query coming in and puts public health in a position where there may be some issues in terms of inadvertent information blocking because public health does not have the capacity to respond to this potentially wide stream of queries coming in through an API without additional constraints. If we constrain queries through the public health API to those that are associated with implementation guides that have been adopted by that particular public health authority, that helps resolve some of the issues by creating some parameters around which the particular public health agency has experience and capacity to respond. So, it is a disconnect between the infrastructure on the healthcare provider side with a single EHR and public health.

Bryant Thomas Karras
We have four minutes. Do you think that complexity is adequately represented here?

Steven (Ike) Eichner
There could probably be some textual refinement. Again, I think the big piece, and we can just take care of it administratively, is the consensus about recognize this as an issue and can we recommend constraining queries through the public health API to IGs adopted by the public health authority is the big question.

Bryant Thomas Karras
All right, so that is for No. 1. Let us go ahead and turn that green.

Rochelle Prosser
Molly has her hand up.

Bryant Thomas Karras
Molly?

Molly Prieto
Hi, sorry. I just wanted to make sure to clarify some components of the rules before we continue through the recommendations. I do just want to emphasize that G20 was written in a rule for provider facing systems and as an outgrowth from G10. So, this would, as written in a proposed rule, be applicable to provider facing systems.

Bryant Thomas Karras
Okay. So, it would not impact immunization information systems or public health registries?

Molly Prieto
Not as currently written in the proposed rule.

Steven (Ike) Eichner
That might be something we want to clarify because it talks about being applicable to certified technologies, which includes public health if HTI-2 is adopted as written.

Bryant Thomas Karras
It does say that new certification criteria would support ongoing future development of public health FHIR IGs. Oh no, that is in E, not in the rule. Never mind.

Rochelle Prosser
Can we add language as we recommend clarification or guidance from ASTP and ONC on the applicableness to public health? But we adopt the context of the rule.

Bryant Thomas Karras
Yes. Public health does not ... I think, Mark, you have a lot of comments that refer to G10 and G20 from your group. So, these would need to be harmonized with those. You probably have that in your section already. Is that true?

Mark Sendak
You can look those over. Yes, we did have several related to G20.

Bryant Thomas Karras
Mary Beth, I pulled some of your components in 2 and 3 to clarify that the immunization was not subject to these bulk G20 certification processes. Mark, do you think any of these could be harmonized in with your all's comments? Or do we just trust that ASTP did not intend for these to be applicable to public health registries and table these?

Mark Sendak
I know that we did not explicitly say anything about public health registries. So, if there is something you want to include about that, then we should.

Steven (Ike) Eichner
Bryant, I feel like the remaining question is does it apply to EHR like systems that are operated by public health?

Bryant Thomas Karras
If public health is operating in clinic, it probably does.

Steven (Ike) Eichner
Right, so again, that potential **[inaudible – crosstalk] [00:53:34]**.

Bryant Thomas Karras
Let us move forward No. 1, but I think we can leave 2 and 3, which are focusing on Individual Access Services (IAS), those are word for word what was up above, we can leave them there and not try to insert them into G20. Is that okay with you, Mary Beth?

Mary Beth Kurilo
Yes, that works, Bryant. Thank you.

Bryant Thomas Karras
I think we are at time.

Sara McGhee
Bryant, Erin added her text in the chat.

Bryant Thomas Karras
Excellent. Let us approve that.

Erin Holt Coyne
Look at the second one. I caught another typo, just corrected it.

Bryant Thomas Karras
So, between the quotes?

Erin Holt Coyne
Yes.

Bryant Thomas Karras
Is that the entirety of No. 2? Perfect. So, it is a full replacement.

Steven (Ike) Eichner
Bryant, there are a few typos that have been noted by different folks in the chat. Can we say wholistically that the typos will be cleaned up as part of document prep, just to make sure stakeholders are ...

Seth Pazinski
Yes, this is Seth. We can address anything like proofreading in the final. Thanks.

Bryant Thomas Karras
Okay. Cutting and pasting is failing us.

Aaliyah Parker
It will not let me copy for some reason. I will work on that.

Erin Holt Coyne
I have it in Word. I can probably move it over if you want.

Bryant Thomas Karras
Yes, if you have the spreadsheet open, Erin, why don't you drop it in?

Erin Holt Coyne
No problem.

Bryant Thomas Karras
I am going to stay out of that cell. All right, once that is in, just scroll back up through all the beautiful green text. Is there anything that we missed? Keep going. Keep going. All the way to the top. Okay. Seth, thank you very much for your tolerance.

Seth Pazinski
Thank you everyone. I just want to make sure, there was some discussion around comments either being made individually in rows or some overarching comments. Is there anything that needs to be revisited there? Do you feel like we have that accurately captured in the document at this point?

Bryant Thomas Karras
If we had time ... Oh, what is that No. 3 there? Scroll up. There was a ... maybe it was down. The screen is bouncing around quite a bit for me. I do not feel like we have appropriate time to craft an additional overarching comment. We tried to pull our attention to definitions of parse, validate need to be clarified differentially for different registry systems. I think we can make some overarching comments about how complex the public health ecosystem is. For something as simple, conceptually, as notifiable conditions, a state agency might have three different case management systems. One for human immunodeficiency virus (HIV), one for other sexually transmitted diseases or infections, and one for communicable diseases outside of the others. Those three different systems would all have to meet the same certification criteria, so it is a complicated environment. Ike?

Steven (Ike) Eichner
Friendly amendment there and recognizing different state requirements that may or may not be aligned with existing fairly narrow standards in some cases. An example is Texas' immunization registry. In our consent processes, we have to have consents on file before we can retain any vaccination information. That needs to be accommodated as part of our interoperability functions, or we cannot collect any data. So, a technology that was certified might not meet state requirements, then we cannot use certified technology or collect data.

Bryant Thomas Karras
Quick interruption. Scrolling back up to the line that you were just on, what I tried to do here, and if you can move the small text into Column K, I tried to differentiate the green ... I could not handle all of the versioning visually, so I just shrank the text that was in between each of what would not be a number approved green section. If you could clean that up, that will make it easier for you to move it over to the transmittal. Thank you. Sorry to interrupt you, Ike. Gillian, you have your hand up?

Gillian Haney
I totally support those overarching statements. But I think there was still some red language in the syndromic piece that we wanted to include.

Bryant Thomas Karras
To come back to. Let us try to go back to that then. What row was that?

Gillian Haney

Maybe it already did turn. What line is this? Is this at the beginning? I just want to clarify, did we want to put it in this line or was it in the second?

Seth Pazinski
So, I am going to suggest, just because of where we are at with time, if we could move towards looking at Group 3 and Group 2 approvals. Depending on how much time left, we can determine if there is additional time for discussions and edits on Group 1.

Bryant Thomas Karras
So, I found it. F22, the last paragraph there starting with, "Gillian Haney: The challenge," should be moved to No. 3.

Gillian Haney
I do not know if we need my little preamble. It could just be the second, the sentence that we support exploration of opportunities to reduce payloads. I just want to reflect Hans' comment but say that there are very different use cases, but we would support exploration. It is really just that second ...

Bryant Thomas Karras
You can delete the Bryant.

Gillian Haney
Delete the first three lines and keep the second, "We would support exploration of opportunities to reduce payloads and other technical considerations, but this must include the **[inaudible – crosstalk] [01:01:44]**.

Bryant Thomas Karras
You have a different carriage return than what we are seeing on the screen, Gillian.

Gillian Haney
Oh, okay.

Erin Holt Coyne
Last sentence for Gillian's line is what she is wanting to keep. Everything else in red could be deleted.

Bryant Thomas Karras
Up to would, is that correct, Gillian? You just want would kept?

Gillian Haney
Yes.

Bryant Thomas Karras
All right. I believe we can delete my comment and merge the ... I am still not quite sure that there this is consensus that it should be like eCR. I think it may be its own thing rather than an eCR like thing.

Erin Holt Coyne
I think referencing eCR lends to confusion and could potentially limit us when we explore FHIR for the syndromic use case. I think it makes sense we want to speak to a future forward kind of recommendation about looking at FHIR to support syndromic with the involvement of the NSSP makes sense and looking at reducing payload. I would caution about referencing eCR specifically.

Steven (Ike) Eichner
I would agree with that. I do not think it is really necessary because we do not reference eCR for cancer or other kind of things so much, as well as organizational reporting. It is really another parallel activity. I think we can certainly suggest looking at FHIR for future workaround syndromic surveillance, but not refer to eCR.

Gillian Haney
I put my comment in the chat for the language for consideration to turn green.

Bryant Thomas Karras
All right. That is a complete replacement for No. 3?

Gillian Haney
Yes. So, we do not need the challenge –

Bryant Thomas Karras
I support that.

Gillian Haney
So, in summary, No. 3 would just say, "We would support exploration for opportunities to reduce payloads and other technical consideration, but this must include discussion with the NSSB.

Bryant Thomas Karras
Sounds good. Done. Any objections? That that last No. 3 green now.

Aaliyah Parker
I have to manually put it in really quick.

Bryant Thomas Karras
Okay. That is right, you cannot cut and paste out of Zoom. So sorry.

Aaliyah Parker
Does it look good?

Bryant Thomas Karras
Happy that we got through it all.

Seth Pazinski
All right. So, we have about 12 minutes here. So, I want to turn to each co-chair to put forward the recommendations to the full Task Force here to approve them and move forward. So, why don't we start, Mark, if you want to go first, we will start with Group 2, then Group 3, then we will circle back to Group 1.

Mark Sendak
So, one quick question, Seth. Aaliyah, if you can pull up Row 3, there was one change that was proposed I think by Katrina. Sorry, go back to the other sheet, Group 2. I just want to incorporate this change. Is Katrina still on? Yes. Katrina, I just was not sure, did you mean v4 or v5? Or what is Level 0?

Katrina Miller Parrish
Level 0 is a feeder into four, five, and upcoming six. You have to get up to Level 2 for it to be considered for the next United States Core Data for Interoperability (USCDI) version, so Version 6, at least as far as I understand. So,

anyway, I wanted to widen out the review for what should be considered for the future because there is a lot in Level 0 that I think should be pushed up. If we can somehow get that into this recommendation, that would be great. If not, that is fine too.

Mark Sendak
The specific things you want to make sure are reviewed are the laboratory results, your second sentence?

Katrina Miller Parrish
Correct.

Mark Sendak
Would you be okay if I just incorporate those items in the big parenthesis that we have in the recommendations?

Katrina Miller Parrish
Yes.

Mark Sendak
Okay, so I am going to do that right now.

Katrina Miller Parrish
Thank you.

Mark Sendak
So, does that look good? Let me just make sure the formatting is there.

Katrina Miller Parrish
That is fine. It would be great to somehow get that Level 0 in there, but just leave it at what it is and that is fine. We will just leave it there.

Approve Draft Task Force Recommendations (01:08:09)

Mark Sendak
Okay. I am assuming, Seth, I do not need to review individual criteria. I am just asking does the Task Force approve all workgroup recommendations in green in Column J?

Seth Pazinski
Correct.

Mark Sendak
Okay. Can we move forward with all green recommendations in Column J? If there are no concerns, we will move those forward. Back to you, Seth. Anything else you need?

Seth Pazinski
Thank you, Mark. So, let us move to Rochelle and Group 3 recommendations.

Rochelle Prosser
Hi, Seth. If we can go to Row No. 6, please. We removed the language from the HITAC committee that was written here yesterday because it actually was more applicable to Row 9. So, if we can go down to Row 9, please. In Row 9, we actually discuss the QHINs and the aspects of if a QHIN would disappear, the financial instability. We also

discuss certain aspects of the QHIN supporting all exchange processes for HIT, including the one they prefer. So, the language in the black, where the work group recommends ONS provide guidance on the potential of the QHIN lack of adoption of FHIR standardization that occurs for QHIN that do not fully implement FHIR complete interoperability. That is the line we would agree to because the line just below it talks to the FHIR adoption and IG oversight. So, the amendment here is to put the language from Row 6 from the HITAC committee here, which is more applicable to the Trusted Exchange Framework and Common Agreement (TEFCA) common agreement and how QHINs would interact there. So, if there are no disagreements, I would like to turn that black to green on Row 9 in Column J. Yes, please go ahead and turn it green. Thank you. Seth, back to you.

Seth Pazinski
Rochelle, if you could just put forward, just to allow the group to approve the full set of recommendations. Thank you.

Rochelle Prosser:
Sure. Oh, Katrina, you have a question?

Katrina Miller Parrish
I am so sorry, but just what you ... You want that last sentence, need to agree on this line?

Rochelle Prosser:
Yes, we need to remove the need to agree. Thank you.

Katrina Miller Parrish
Sure, no problem.

Rochelle Prosser
Thank you. Great catch, Katrina. So, for the purpose of Group 3, I would like to propose that the entire HTI-2 group adopt all of the recommendations, comments proposed for ASTP and ONC in Column J. By a show of hands. Everyone else. We have a lot of hands not up.

Gillian Haney
Rochelle, are only Group 3 workgroup members –

Rochelle Prosser
No, all of us. The entire group.

Seth Pazinski
The whole task force.

Rochelle Prosser
Yes, the whole task force. Okay, Seth, can you count for me please?

Bryant Thomas Karras
Naresh?

Rochelle Prosser
Naresh does not usually raise his hand on anything on Group 3.

Bryant Thomas Karras

Let us get the consensus.

Rochelle Prosser
Okay.

Seth Pazinski
Rochelle, I am seeing we definitely have a majority consensus here.

Rochelle Prosser
Majority consensus, that is fine.

Seth Pazinski
If there are any concerns, then the committee can move forward.

Rochelle Prosser
All right, if everyone can lower their hands. We have a majority consensus. Thank you.

Seth Pazinski
Thank you, Rochelle. Now we will move back to Bryant for Group 1.

Bryant Thomas Karras
Now that we have our hand raising skills refined, let us see approval of movement of all of the green text, not red or black or blue, forward as part of the transmittal. Mary Beth? There we go. Others? All right.

Rochelle Prosser
Bryant, do not forget to put your hand up.

Bryant Thomas Karras
I had it up. Did it go down? Ike is up. Who are we missing? I think we are at ... are we at a tipping point?

Seth Pazinski
Yes, it looks like we have a majority consensus here, so I think we can move forward.

Bryant Thomas Karras
All right, thank you.

Seth Pazinski
Okay. I appreciate everyone's work on this. I think we are just about at time for public comment. Are there any additional points, Bryant, Rochelle, or Mark that you guys have before we move into public comment?

Rochelle Prosser
Not at this time.

Mark Sendak
No, all good.

Bryant Thomas Karras

I just want to state my appreciation for the staff and team at ASTP ONC for the amazing support and work on this complex task. Thank you guys so much. I look forward to seeing the successful challenge you have ahead of you of coordinating across all of these federal and state and territorial agencies to make this a reality.

Seth Pazinski
Thank you, Bryant. Steve, I see you still have your hand raised. Do you have a comment?

Steven (Ike) Eichner
Leftover, sorry.

Public Comment (01:16:19)

Seth Pazinski
Okay. I will ask that we move to public comment at this point. So, if you are on Zoom and would like to make a comment, please use the Raise Hand function, which is located in your Zoom toolbar at the bottom of your screen. If you are participating by phone only today, you can press *9 to raise your hand. Once called upon you can press *6 to mute and unmute your line. While we give folks a few seconds to raise their hands, on behalf of ASTP, I did want to thank and express gratitude for all the folks who have volunteered your time and expertise through this task force. We greatly appreciate your review and thoughtful deliberations and look forward to the task force co-chairs delivering the results of the task force efforts at the upcoming HITAC meeting on September 12. I also want to remind everyone that the HITAC meeting materials can all be found on HealthIT.gov. I am going to check in to see if we have any hands raised from the public at this point. I am not seeing any and no comments on the line. So, I am going to turn it back to our co-chairs for next steps and to adjourn us. Bryant, Rochelle, and Mark, back to you.

Next Steps (01:17:47)

Rochelle Prosser
I want to thank everyone for their very diligent and hard work that we have gotten done today on the HTI-2 rule, and over the past eight weeks, I believe, that we have been working together, separately in our individual silos, and then today for the past three days for this call. It was a lot of work, a lot of commentary, and a lot of feedback, and most importantly, a lot of teamwork to be heard. So, I appreciate all of your work, all of your time and dedication. Thank you and look forward to making the full presentation to the HITAC committee on September 12.

Mark Sendak
Thank you everybody. Thank you ASTP staff. We could not have done this without you.

Bryant Thomas Karras
I just echo that thanks again. I also want to acknowledge the behind-the-scenes contributions and support that we got from other agencies, the CDC, and all of the subject matter experts that participated and testified to our task force, as well as members of the various associations and communities of practice that all had a hand in helping us to make this the best transmittal it could be. Thank you so much.

Seth Pazinski
Thank you all. Our meeting has adjourned.

Adjourn (01:19:28)

Questions and Comments Received Via Zoom Webinar Chat

Steven Eichner: Friendly amendment for # (and really for all PH systems). The certification criteria need to accommodate state-level requirements and data that may differ from published implementation guides. This is necessary to address issues such as different consent models and authorization to share data requirements.

Rochelle Prosser: Ike, please add your amendment directly to the document where it pertains. Thank you for providing the amendment language.

Steven Eichner: There is language in HTI-1 that ASTP (ONC) used to highlight continued migration to FHIR for public health reporting. The same or very similar language could be used to support adoption of FHIR for syndromic surveillance.

Mary Beth Kurilo: @Gillian, One small clarifier - I think that terms like "filter" need to be defined for each use case - filtering in an immunization information system might look very different than filtering in a case reporting system.

Gillian Haney: @Lee- I seem to recall that you had some excellent comments on the HAI/ AUR sections - could you please check line 8?

Noam Arzt: AIMS/RCKMS sit on the provider side of the transaction, right, via BAA. This prevents non-reportable data sent to RCKMS from being received "by PH".

Noam Arzt: Type in "domain" in #2 there

Noam Arzt: Typo, I meant... still on the screen.

Rochelle Prosser: Thank you Rae for your comments.

Erin Holt: f(29) #2 amendment: "2. PDMP applications often are operated outside the scope of State (STLT) Departments of Health and as such it may be premature to develop a PH Certification Criteria unless it could also apply to Law Enforcement or Boards of Pharmacy implementations. Additionally, there are legal differences between STLTs regarding ability to share and store discrete data by partners. Further harmonization of this domain to emphasize the health impacts need to be done."

Erin Holt: Done.

Gillian Haney: for consideration: We would support exploration for opportunities to reduce payloads and other technical considerations, but this must include the NSSP CoP.

Gillian Haney: Bravo!!!

Noam Arzt: So, the committee did not discuss the Insights Conditions at all? I did not see them under any group's recommendations.

Sara McGhee: Hi @NoamArzt - The committee discussed the Insights Condition at the 8/28 task force meeting. Thanks!

Bryant Thomas Karras: I think MBK did join that group for discussion

Mark Sendak: @Noam, look at row 42 in Group 2 spreadsheet

Noam Arzt: Of course, I can't do that, can I...

Erin Holt: I know we referenced them in the recs for eCR f(5)....

Noam Arzt: But thanks.

Erin Holt: "4. Certification should transition from self-attestation to demonstrated testing to show the capabilities required for electronic case reporting, meeting expected completeness and data quality thresholds. Future work could include future insight measures for other public health-related performance measures...."

Noam Arzt: Thanks, Erin. HTI-2 has the most to say about fixing some stuff in the current immunization insights condition. Not sure I saw any comment about that.

Mary Beth Kurilo: Hi, Noam - We did discuss the Insights Condition, and submitted some comments - and we'll submit additional comments through AIRA - I'm happy to share those with you offline.

Sara McGhee: The HTI-2 Task Force will present the recommendations to the full HITAC at the 9/12 HITAC meeting. Here's the link if you would like to register for the web conference: https://www.healthit.gov/hitac/events/health-it-advisory-committee-72

Gillian Haney: Respectfully request that ONC find a better mechanism that XLS for drafting comments! :-)

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 - September 5, 2024, Meeting Webpage

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