

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) PUBLIC HEALTH DATA SYSTEMS TASKFORCE 2022 MEETING

October 19, 2022, 10:30 AM – 12 PM ET

VIRTUAL



Speakers

Name	Organization	Role
Gillian Haney	Council of State and Territorial Epidemiologists (CSTE)	Co-Chair
Arien Malec	Change Healthcare	Co-Chair
Rachelle Boulton	Utah Department of Health and Human Services	Member
Hans Buitendijk	Oracle Cerner	Member
Heather Cooks-Sinclair	Austin Public Health	Member
Charles Cross	Indian Health Service	Member
Steven Eichner	Texas Department of State Health Services	Member
Joe Gibson	CDC Foundation	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Erin Holt Coyne	Tennessee Department of Health, Office of Informatics and Analytics	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Bryant Thomas Karras	Washington State Department of Health	Member
Steven Lane	Health Gorilla	Member
Jennifer Layden	Centers for Disease Control and Prevention (CDC)	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
Mark Marostica	Conduent Government Health Solutions	Member
Arien Miri	Baptist Health	Member
Alex Mugge	Centers for Medicare & Medicaid Service	Member
Stephen Murphy	Network for Public Health Law	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Jamie Pina	Association of State and Territorial Health Officials (ASTHO)	Member
Abby Sears	OCHIN	Member
Vivian Singletary	Taskforce for Global Health	Member

Name	Organization	Role
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Carelon Digital Platforms (an Elevance Health company)	Member
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director of the Office of Technology
Dan Jernigan	Centers for Disease Control and Prevention	Deputy Director for Public Health Science and Surveillance
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Craig Newman	Altarum	Presenter

Call to Order/Roll Call (00:00:09)

Seth Pazinski

Okay. Hello everyone, Seth Pazinski, with the Office of the National Coordinator for Health IT. I want to thank you for joining the Public Health Data Systems taskforce meeting today. We have a number of presenters with us today, and I want to thank everyone for participating, including the members of our taskforce. As a reminder, all taskforce meetings are open to the public, and your public feedback is welcomed throughout the meeting during the Zoom chat feature and then during the public comment period that will be taking place toward the end of our call at 11:50 Eastern Time this morning. We will start off with roll call of the taskforce members. So when I say your name, if you could please indicate your presence. I will start off with our taskforce Co-Chairs, Gillian Haney.

Gillian Haney

Present and good morning.

Seth Pazinski

Morning. Arien Malec?

Arien Malec

Good morning.

Seth Pazinski

Rachelle Boulton?

Rachelle Boulton

Here.

Seth Pazinski

Thank you. Hans Buitendijk?

Hans Buitendijk

Good morning.

Seth Pazinski

Good morning. Heather Cooks-Sinclair? Erin Holt Coyne?

Erin Holt Coyne

Good morning.

Seth Pazinski

Okay. Charles Cross?

Charles Cross

Here.

Seth Pazinski

ONC HITAC

Okay. Steven Eichner?

Steve Eichner

Good morning. Present.

Seth Pazinski

Good morning. Joe Gibson?

Joe Gibson

Good morning.

Seth Pazinski

Good morning. Rajesh Godavarthi.

Rajesh Godavarthi

Good morning.

Seth Pazinski

Okay. Jim Jirjis?

Jim Jirjis

Good morning.

Seth Pazinski

Okay. John Kansky?

John Kansky

Good morning.

Seth Pazinski

Good morning. Bryant Thomas Karras?

Bryant Thomas Karras

I am here. Good morning, everyone.

Seth Pazinski

Good morning. Steven Lane? Jennifer Layden? Leslie Lenert? Hung Luu?

Hung S. Luu

Good morning.

Seth Pazinski

Good morning. Mark Marostica?

Mark Marostica

October 19, 2022

Present. Good morning.

Seth Pazinski

Good morning. Arien Miri? Alex Mugge? Stephen Murphy?

Stephen Murphy

Good morning.

Seth Pazinski

Good morning. Eliel Oliveira?

Eliel Oliveira

I am here, and good morning.

Seth Pazinski

Good morning. Jamie Pina?

Jamie Pina

Present, and good morning.

Seth Pazinski

Good morning. Abby Sears?

Abby Sears

Good morning.

Seth Pazinski

Good morning. Vivian Singletary.

Vivian Singletary

Good morning.

Seth Pazinski

Fillipe Southerland?

Fillipe Southerland

I am here. Good morning.

Seth Pazinski

Morning. And Sheryl Turney. All right. Anyone I missed needs to announce themselves, or anyone who has come on since we started. All right. Thank you, everybody. I will turn it over to our Co-Chairs, Arien and Gillian to get the meeting started.

Arien Malec

All right. So today we are going to get an overview of HL7 Public Health Work Group as well as an important view into public health law. I think we have had some good conversations about minimum necessary and how we better balance the need for privacy and security, and also the need of covered entities to meet their standard under minimum necessary and meet the public health mission. So we are going to have a good conversation there. And then, as usual, we are going to try to spend the majority of our time digging through our recommendations to date both on the spreadsheet and also introducing the draft transmittal and try to conclude as usual with our public comment. But we do not have that much more time to go before our final report out. So it is time to dig into the details and make sure that we flesh through everything that exists in the worksheet and get that over into the transmittals, so we have a good transmittal draft. But with that, I will turn over to Gillian to lead us through our panel discussions.

Gillian Haney

Great. Thanks, Arien. I think the only thing that I would add is if we could also before we get to the worksheet is talk a little bit about the parameters around the transmittal document and how it will be going to be used and access to it. So we will put that in the parking lot until we get there. So thank you very much to Stephen Murphy and Craig Newman to coming and giving us a presentation this morning. Arien has already mentioned what will be covered, so I think we can just get right to it. Craig, you are up first. So just as an FYI, the HL7 Public Health Work Group is the entity that facilitates publishing of the HL7 standards for public health. Welcome, Craig.

HL7 Public Health Work Group Projects (00:05:45)

Craig Newman

All right. Thank you. And I will apologize in advance. I am also sitting in a hotel, so unfamiliar wireless and sounds. And downtown Tacoma is surprisingly noisy, so I apologize in advance. So I was asked to bring a presentation to this group about the HL7 Public Health Work Group, present that perspective. It was a relatively long list of potential topics to cover in five minutes. So I am going to try and keep things fairly brief and assume if you have specific questions that we will cover them in a discussion, or you can just ask. So if you can go to the next slide.

What I will just remind folks, as Gillian mentioned, the Public Health Work Group is a part of the HL7 Standards Development Organization, and we are a volunteer group. So we do not, for the most part as a work group, create the standards, but we sponsor project teams that come to us with defined projects in mind, help them through the process of creating, balloting, and publishing an HL7 guide. We do our best to guide them and make sure that things are consistent between projects, but the work group as an entity is there as a forum as much as anything. And so, over the years, we have developed a really broad range of different standards that covers a lot of ground. Most of them are presented here.

This includes a lot of the core specifications that are represented in EHR certification requirements and regulations today. The things that you are all familiar with, case reporting, syndromic cancers, healthcare surveys, laboratory orders and results, healthcare-associated infections. And one you will noticed that is missing from here is the immunization standard, which is not currently an HL7 published standard, but a lot of the same people that participate in the work group have had a hand in that document, as well, myself included.

But the work group is much broader than that. We have standards in a large number of other areas. There is a large number. That center column is really a lot that deal directly with Maternal and Child Health, which is one of the priorities that we are hearing a lot about in public health today. But we also touch on areas such as occupational data, situational awareness, which has been critical for the combating the COVID pandemic, obviously, referrals, and then we do have some immunization work, and we are working now toward the standardization of some of the building blocks that are common between a lot of reporting programs.

And one thing to notice here is that we have a wide variety of topics but also of approaches. In parentheses are the HL7 product families that are represented in some of these areas. And you will notice that it is a very split mix. There are a lot of HL7 Version 2. There is a lot of CDA-based guides, and now as a community we are also looking a lot into FHIR as is most of healthcare. So a very diverse group of standards and a lot of different ways of approaching public health data sharing. You can go to the next slide.

I thought that I would end with what we have found works in public health over the last probably decade or more, is that the HL7 consensus process for creating standards works. We are an active work group. We have a lot of participation. We are largely US centric. That is who shows up to the calls. But for the purposes of this group, that is probably all right. But we do get a lot of input from public health, from EHR vendors. We have undertaken a lot of outreaches over the last few years to make sure that EHRs are represented within our work group because they are a valuable and necessary partner, and we want to hear them. And we have also found that the inclusion of standards in EHR certification requirements has really driven adoption by the HIT vendors. Not a surprise. And that naming standards and programs such as meaningful use originally and promoting interoperability drives implementation in the real world. These have been very successful programs for seeing adoption.

The immunization world -- if you are familiar with that -- is a great example of how we have driven adoption of a standard across the country. But the main thing that we wanted to bring is that we need to continue to raise that bar. We have the core standards that are in certification. Those are largely represented in other regulations, but there is so much more that we can do. Right? And this is a really important driver for public health. And so, again, as I mentioned, maternal and child health is a gigantic topic. It is a priority for a lot of people, and we have standards that have existed in some cases for many years that just have never got the attraction that they need in the real world. Things like newborn screening, birth defect reporting, birth certification, which underlies a lot of other public health programs, so there is a lot more that we can do. But as we do that, we need to be clear on what the requirements are.

We need to be as exact as possible. We understand the dangers of being too prescriptive, but we have learned in the past that ambiguity is not our friend. And so, we need to be careful with our standards and how we reference them to be as exact as possible, and we want to make sure that people understand that we have to adopt the right technology and architectures. I know the world is focused on FHIR, but Version 2 and CDA are mature standard, public health understands them, and they are very well suited to certain public health workflows. And so, we should not overlook those in favor of the new and shiny thing always. FHIR gives us a lot more tools, but it may not always be the right answer. And we want to focus on ways to augment the flow of data that is happening today.

We do not want to rip and replace things that are working just to replace them with a FHIR solution. Right? We want to be looking to expand, not replace. And then we need to have public health reflected in USCDI. We need to promote USCDI+ so that public health needs are front and center there. We need to coordinate activities across agencies. We see a lot of input from CDC, ONC, PRSA to a lesser extent within the work group. Those activities need to be coordinated. And the important thing, the take-home message is that support for implementation needs to be coordinated across all partners. Healthcare providers, public health, community organizations all need to have similar resources and expectations in terms of what their systems can do, how well they conform to the standards. We need to think of it across all partners within public health.

Historically, meaningful use promoting interoperability in some of the funding programs have focused on one side but not necessarily the other in unison, and we need to change that so that expectation and resources are available on both sides so that we can all work together.

The last slide is just the summary. If you have questions, happy to answer them. You can always reach out to me or any of the Public Health Work Group Chairs, or you can just join the calls. We meet every Thursday from 4 PM to 5 PM Eastern, and we invite everybody to join us. Thanks.

Gillian Haney

Thank you so much, Craig. I appreciate your perspective from the work group, and I think your point particularly around Version 2 and CDA not to overlook those is important, particularly in light of the vast difference of resources and capability across public health. Not everybody is going to be able to manage FHIR at this time. So, thank you for that. Our next presenter is Stephen Murphy from the Network For Public Health Law. Welcome, Stephen!

Network for Public Health Law (00:14:30)

Stephen Murphy

Thanks very much, Gillian. And good morning, everybody. I want to just thank the taskforce for giving me the opportunity to speak with you this morning. I am Stephen Murphy, Senior Public Health Attorney with the Network For Public Health Law in our mid-states region, and we focus on data, data privacy, data sharing, and general public health authority work. We were created by the Robert Wood Johnson Foundation to promote and support the use of law and solve public health problems. Next slide, please.

So to advance the (f) criteria, it is essential to address law, since law governs every aspect of data, including as we know its collection use, disclosure, and protection. A law may be a friend. For example, a law establishes public health agencies and grants them power to collect data to protect the public during routine times and emergencies, including deciding the data elements and the formatting needed. Public health also has the power to require reporting of data by race and ethnicity including by subgroups that better reflect the history, language, and culture of populations than those that are captured by the OMB categories, which I know is something that folks have talked about on these calls in the last few weeks. Next slide, please.

So as folks on the taskforce know, for most data reporting, we have a decentralized system with state law establishing reporting requirements. And this decentralized system is based on the US Constitution, which generally vests police powers, and the police powers is the power to regulate for the public good, safety, and health of the community, and so, that is at the state level. And so, state law determines in most

instances who must report, what information must be reported, and which format and manner of reporting. And the resulting variations amongst states and territories and every within the same jurisdiction with respect to different data makes it different to coordinate data. This has presented problems in the context of immunization information systems.

For example, IIS as folks on this call know generally opt in or opt out, and this presents issues where providers or IIS wish to transmit immunization data across jurisdictional boundaries such as through the **[inaudible] [16:43]** gateway, where a state requires consent before its IIS may enter data. This presents problems when providers in other jurisdictions, particularly in opt-out jurisdictions are not required to obtain a consent and certainly do not obtain an expressed consent to enter data into a neighboring jurisdictions' IIS. And so, the IIS jurisdiction in that scenario that has requirements for express consen then encounters legal barriers to entering data because of their state law. Next slide, please.

So I wanted to just spend a few minutes talking about minimum necessary. I know that this is something that this group has talked about in the last few weeks and particularly in the context of electronic case reporting, which was the subject of a previous taskforce meeting. One key difficulty in standardizing systems for a national application from a legal perspective is the variation in law and policy amongst the states. Minimum necessary and how it is applied is a perfect example. And just as a reminder for folks, "minimum necessary" is a standard that is contained within HIPAA, within the privacy rule, and generally requires that a covered entity that is using or disclosing or requesting protected health information use the minimum necessary that is required to accomplish the intended use. And actually, it applies to business associates, as well, so covered entities and business associates.

It applies in some but not all instances in which a covered entity discloses data. It does apply in the context of public health reporting, but a covered entity may rely on the representation of a public health authority as to what is the minimum necessary. And many, but not all, state health departments are HIPAA-covered entities. Some jurisdictions have encountered problems in the application of the minimum necessary standard to trigger codes for reportable diseases as we know exactly which conditions are reportable and which data elements are reportable vary across jurisdictions and where a disease or condition is not reportable in a jurisdiction, some of these jurisdictions have determined that receiving data about these conditions, and most importantly about patients, would be more than the minimum necessary.

And whether or not that information would be more than minimum necessary I think is debatable. Some jurisdictions, for example, include a catch-all provision for unusual cases of a disease or a condition that is otherwise listed in the jurisdictions reporting law, and in those jurisdictions, I think it is very questionable as to whether it would be the minimum necessary to submit data on an unenumerated disease or condition.

Nevertheless, the Reportable Conditions Knowledge Management System, the RCKMS, which one of the previous panelists spoke about during our conversation about electronic case reporting, and which is hosted on the AIMS platform, can determine the reportability of an initial case report and to which public health jurisdiction the initial case report would be sent. So that is one way in which technology can help overcome legal barriers and may help resolve questions around minimum necessary. Another way which I think minimum necessary questions might be resolved is for ONC to work with the Office of Civil Rights, which is the agency that enforces HIPAA to issue some guidance around this. Next slide, please.

And then just with the time that I have left, I will just briefly mention the information blocking rule. That is a rule which also stems from the 21st Century Cures Act in response to concerns that some individuals or entities are engaging in practices that unreasonably limit the availability and use of electronic health information for authorized and permitted purposes. It prohibits healthcare providers and health IT developers of Certified Health IT and HIE and HIMs from engaging in activity that is likely to interfere with access, exchange, or use of electronic health information. ONC issued one frequently asked question, taking the position that a healthcare provider who fails to transmit data to public health where it is required to do so may be engaging in information blocking, and it may be helpful to have additional guidance from ONC on how the information blocking rule applies to transmission of data to public health, or even again, work with the Office of Civil Rights to provide guidance for entities that are subject to both HIPAA and the information blocking rule, again, in the context of transmission of data to public health.

So with that, I will pass it back to you, Gillian, or Arien.

Discussion (00:21:22)

Gillian Haney

Great, thank you so much. I think Arien has his hand up, but I think there is a question in the chat. One for you, Stephen, if you could just speak briefly on how the minimum necessary applies to the uncovered portions of a hybrid entity?

Stephen Murphy

Yeah, good question. So a hybrid is a certain type of covered entity in which the activities -- and it often applies to a public health department where you have parts of the entity that would be subject to HIPAA if there were a separate legal entity and parts that would not be. And so, in the context of a health department, we see this where you might have delivery of healthcare services maybe in the community, and that might put you into the category of a covered entity. And so, in the context of a hybrid, then you can parse out those parts of your covered entity, and kind of wall them off. I know many people on the call know this already, but let us just go over some basics. So that is the context of a hybrid, and so then those other parts of the hybrid -- maybe your surveillance units, or your WIC Program, or what have you, those then are not subject to HIPAA.

So as to minimum necessary, so minimum necessary is part of the HIPAA Privacy Rule, and that means that it applies to covered entities and business associates. And so, if you do not have a healthcare component involved, then really minimum necessary does not apply. Now, I would say that, just with the caveat to keep in mind that when there is a disclosure of protected health information, you have two ends. You have the sending party and the receiving party, and so you might have a covered entity on either side of that equation, which can add a certain nuance to it. But I guess the bottom line would be minimum necessary does not apply to non-healthcare components in a hybrid entity. And so, if there is more detail that folks want to communicate about that specific problem, I would be happy to address those, too.

Gillian Haney

You know, I think that I know that from in my former role in Massachusetts overseeing surveillance for infectious diseases, we were really struggling with how we parse in certain pieces of information that might be coming through on electronic case reports around getting someone's mental health diagnosis associated with their hepatitis A case report. I just personally felt incredibly uncomfortable with capturing that

information in our surveillance system. And so, I know that they were working really hard to try to parse that information out. So I think that even though Massachusetts was a hybrid entity, and we were on the uncovered side of it, I guess, if you will -- excuse my terms of language -- that does not mean that we should be collecting those pieces of information about an individual, and we always try to stick with the minimal necessary for what it is that we are investigating.

Stephen Murphy

Yeah, that is a great point, Gillian. And I think something else to remember in that context in the example that you use with mental health is HIPAA is just one privacy law, and there are many others. And state law often has protections around mental health or in addition to the Federal Substance Use Privacy Part 2, there are also state provisions around that, too. And in the context of surveillance, as well, you have confidentiality provisions around different data types like STI and HIV. And so, people, I guess, need to get out of the mindset that HIPAA is just the floor as we like to say. And so, I think we need to think beyond just HIPAA as to a broader context.

Gillian Haney

Thank you. Arien.

Arien Malec

There we go.

Gillian Haney

You are on.

Arien Malec

[Crosstalk] mute button.

Gillian Haney

There you go.

Arien Malec

[Crosstalk] I was searching in vain for the mute button. So we have a little conversation going on in chat, but the heart of this of the minimum necessary issue in my mind -- and this came up early days in the COVID pandemic and continues to be an issue -- is that a covered entity in particular, a hospital, a provider, etc., who may want to provide data to a public health authority. They want to provide, for example, the whole CCDA to a public health authority easy and legitimate doubt as to whether they are following the law or not. The situation where a public health authority, a local public health authority, estate, locality, etc., provides guidance that the full USCDI or US Core Data or whatever the appropriate subset, that is the subset that the EHR technology the provider uses is medical minimum necessary effectively has no issue.

The issue arises when the local public health authority has not provided that uniform guidance. There is no uniform guidance coming from HHS OCR, and so there is no strong presumption that the format and content that an EHR can readily produce is, in fact, minimum necessary for public health disclosure. So I wonder whether you have recommendations or the notion that we talked about in the Duke Margolis workgroup taskforce was whether OCR as you know could provide some uniform guidance, if you have some

perspective on what the form of that uniform guidance could be. And then the other thing that could be useful is NPHL providing, and it did actually provide a uniform guidance statement that was readily available language that a state or locality could adopt and promote through their local authority.

I am not sure how much uptake there was in that standard language. And so, maybe the question is, how can we better promote the issuance of uniform guidance that creates a presumption that the format and content that EHRs can readily produce for summaries of care is, in fact, minimum necessary when requested by a public health authority?

Stephen Murphy

Yeah, that is a great point, Arien. And a few thoughts on that. I should have started this conversation by saying that I obviously encourage everybody to talk to their legal counsel. What I present here is informational, and it is not legal guidance. I am an attorney, but I am not everybody's attorney on this call. But I know that some folks have the luxury of having legal counsel and some folks do not. I mean, in some smaller health departments they do not. I have used that process myself of issuing standard language that can be distributed to folks that are resisting reporting information, and we have distributed that just in the form of a letter. Or I was at the network, I was at the Chicago Department of Public Health, and sometimes that letter helps.

One of the points that I want to emphasize with the minimum necessary is that the privacy rule states that a covered entity may rely on the representation of a health department or a health authority, as a public health authority as it is referred to in HIPAA, as to what is the minimum necessary, and that is the rule. So to my understanding, the lawyer, that kind of creates a safe harbor or a safe haven for a covered entity. You can legitimately rely on the representations of the health department as to what is the minimum necessary. And then, I mean, I do not see a reason why OCR could not issue some guidance, and perhaps ONC could work together with OCR to do that because I think it is something where there is a gray area. But I think there is some certainty in it. The fact that you can rely on representations of the Public Health Department, that does create some reliability. I know you mentioned, Arien, that hospitals or other private entities might have legitimate concerns. And they are legitimate but, again, if you have a representation from a health department that these are the minimum necessary, the USCDI data points are our minimum necessary, then that is legitimate. I mean, that is enough to say that, yes, [crosstalk] this is the minimum necessary.

Arien Malec

So I just want to follow up on that because I think Chicago was an exemplary Public Health Department that issued proactive guidance and created not just a reasonable presumption but a referenceable letter that clearly addressed the question of minimum necessary. It is my opinion, and I am looking for maybe your perspective on this that if ONC could collaborate with OCR to note that if a public health department, a public health authority requests data in a certain format according to the readily-produced information that is not back to public standards -- national standards like USCDI, but that, in fact, that act itself constitutes a declaration that data is indeed minimum necessary for the use requested. I think that simple kind of guidance from OCR would help a lot in addressing some of the legitimate concerns that a hospital or provider organization might reasonably have.

Gillian Haney

I want to just step in here for a second and just caution against what version that we are talking about with USCDI because it is at this point, woefully -- it is not enough for public health right now. And I think we are starting to trying to address some of that with Version 4, but we are a long way from implementation. So if we just reference USCDI Version 1, we are not going to be getting the information that we need. Arien, I see we got a lot of people with their hands up, so beginning with you, Erin.

Erin Holt Coyne

I think you just addressed it. We talk sometimes about USCDI as this kind of like monolithic standard. But there are Versions and I think different expectations for the implementation of those Versions. And we also have USCDI+. And so, I would question and caution whether or not any one Version, at least now as currently designed and implemented, would support minimum necessary for public health.

Gillian Haney

Thank you. Agree. Bryant.

Bryant Thomas Karras

Yeah. I just want to underline and ask Stephen to confirm it is not HHS or the OCR that ultimately determines. We worked with our assistant attorney general in Washington state, and it is at the state authority. Or in our particular state, it is actually a home rule. It is the local jurisdictions that ultimately determine what the minimum necessary is, and the state is acting on behalf of the local jurisdictions. So I caution you to think that we can come up with one generic guidance that would cover [inaudible] [33:46] cover the entire country in terms of what is needed to respond to a particular on-the-ground outbreak or on-the-ground health situation. Because it may not be a pandemic that we are dealing with now, which I would argue if it did give us a uniform need, but there may be situations that we paint ourselves into a corner if we say that it has to be consistent across the entire country in terms of understanding what the data elements are.

USCDI cannot predict the data elements that might be hidden or necessary in a physician's note. And if we go back to the old days, what happened with a case investigation is shoe-leather epidemiology. Those epidemiologists and the health officer from a jurisdiction would go into the clinic or into the hospital, open up the chart, and review everything to determine what needed to be pulled forward into the case investigation. We need the digital equivalent of that. We are partners in this response. And as our Attorney General said, "You are part of the healthcare team that is seeking to respond to this crisis." We are not a government entity that is just creating a line list tally, we are part of the response. [Crosstalk]

Stephen Murphy

That is a great point. I think it is important to remember that minimum necessary is a very flexible standard. And as you say, Bryant, it is not going to be the same from one place to the next. I think one thing that I have not mentioned -- I think folks on this call already know -- but the provision within HIPAA that permits disclosure of protected health information to a public health authority is pretty broad. It can be **[crosstalk]** frustratingly vague at times, but at the same time, it does permit public health authority to -- rather, a covered entity to disclose protected health information to a public health authority authorized by law to receive the information for a slew of public health reasons, and that gets us into the minimum necessary. But we have that advantage of having that provision within HIPAA that does permit disclosure to public health. So I think

we have a bit of a leg up in many respects. And I guess, yeah. That is where we land in terms of determining what the minimum necessary is from one place to the next.

Gillian Haney

Hans.

Hans Buitendijk

I would like to echo a little bit of what Erin mentioned that USCDI that we have to be careful looking at that. And, in fact, that even today's Version 1, in some areas it is not enough, and in other areas it is too much. When you look at the individual data classes in there, it's not the entire data class in all the instances. There are certain lab tests that are included but not others necessarily. So it really varies, and I would be very careful using CDI or even USCDI+ to really understand minimum necessary in the variations. Rather, I think we need to start to look at the methods that are starting to be used around case reporting with the RCKMS, the knowledge management capability, how can we capture that guidance across jurisdictions in a very consistent non-English in a way, but a very structured, computable way that we can capture that so that there is clarity who is required to report what?

And that where we ground that to understand that USCDI effectively is a scoping mechanism to say for this set of data, we know that there are standards in CCA and FHIR and perhaps in some areas over time, as well. But therefore, we know it can be done in a standard fashion, the combination between that and an RCKMS-style approach, that looks at what is reportable at the trigger of an event, whatever the event might be, very granular, very coarse, whatever. And what are some of the requirements that when you query follow up -- which is much more dynamic, so it might not be as applicable -- is that I think that is where we need to look to help scope and define and understand what is necessary. USCDI is a great tool for general scoping, but it is too blunt of a tool to get into the refined understanding that we need to have to address minimum unnecessary by jurisdiction.

Gillian Haney

Thanks, Hans. Really good points. I also just want to draw your attention to the example that that Erin gave in the shot of the fungal meningitis outbreak that actually occurred in Tennessee. That is a really good example of a little local need for flexibility around their information. Steve, I see your hand. Oh. You are next, Steven, so take it away. Sorry.

Steve Eichner

Thank you. I have three points. I want to echo **[crosstalk]** what Bryant said earlier regarding local control or local government or state government levels of activities, that it may not be sufficient to have something just from OCR because there may be state regulations that apply that may be different in that space and getting way in from either state's attorney general or department counsel or whatever is the right authority for that particular environment really is important.

Secondly, I think as we are looking at a minimum necessary set, it depends really on the purpose behind my data collection. I may need a different minimum set of data for, say, birth defects registry as I might for immunization, and I do not necessarily want extraneous information because I have to account for that. If I store it and I do not need it, it is an unnecessary storage, which is increasing my cost and increasing the

risk of that data being released for unintended purposes and not really respecting individuals with their privacy and security components. So we do have to be cognizant of that, as well.

And thirdly, I am not sure that the USCDI is the right data set to define it. We really do need flexibility to address what is the minimum necessary for that particular purpose? Public health is not in a good position to simply receive a CDA from a provider and say, okay, public health, you figure out what you are supposed to do with this and where you are supposed to populate the different registries or different uses of that data. That runs into the dangerous world of having missing data, or interpreting what is the data really used for? We have different data needs for say cancer registry and immunization. And if we are trying to have a single message that fulfills all needs, then it means that each field would have to be populated for each message to satisfy that minimum necessary for all those uses. So we really need to be careful about where we are going in this space. Thanks.

Gillian Haney

Thanks. Steve. And our other Steve.

Steven Lane

Yeah. In other taskforces, we -- me, Stephen, and him Steve or Ike. But we can do [crosstalk] whatever we need. I just wanted to bring attention to some information that I put into the chat. So early on in the COVID-19 pandemic, at Care Quality we developed a policy trying to address this that basically said that we were happy to utilize queries that were made -- that were labeled as being made for treatment purposes in order to address public health needs. And we got that approved by the participants of the Care Quality Framework. We also said and encouraged public health jurisdictions or states to specify that a query for a CCD could be assumed to be minimum necessary in the context of the pandemic. And we stood that up, and as Bryant points out, we actually did utilize that in at least one case. I am checking to see if there are any others that availed themselves to that.

We thought was a good solution, but I was impressed by how little opportunity was made of that. I think the beauty of the progression towards FHIR, one of the beauties is that it addresses exactly this problem. And I agree with Stephen Murphy that we do not need to use FHIR for everything. We do not just assume it is the right answer. But I think in this case for queries from public health providers, it is a great answer, specifically because we know providers have FHIR capabilities in order to respond, and in this way a specified query can be made, and then a declaration by the jurisdiction can simply say that if we are asking for it using FHIR, that is the minimum necessary. And I do not think we need to keep going back and revisiting that. So I do hope that that is the direction that we will be going in.

Gillian Haney

I really do appreciate that point, but I cannot stress enough that public health may not have the capacity and the resources to send and receive FHIR right away. There are some health departments and state health departments that definitely do have that capability, but there are others that are really under resourced and simply do not have that capability on the ground. So we have to make sure that we build in flexibility to both support the higher performing and what we would like to aspire to, as well as what is actually reality on the ground. Arien is really **[crosstalk]** --

Steven Lane

Listen, Gillian -- actually, before you go on, if I could just say, a question to Stephen as the attorney in the room, is this a concept that a public health jurisdiction could state that a CCD request is minimum necessary for our purposes? Is that a reasonable idea as we move beyond a declared pandemic? And, in fact, was it even a reasonable idea when we proposed it back in 2020?

Stephen Murphy

I think yes. I mean going back to my point about the fact that a covered entity can rely on the representation of a public health department. And I think as long as it is reasonable, I do not perceive an issue with that.

Bryant Thomas Karras

Yeah, and Stephen, our assistant attorney general specifically consulted with the network for public health law in crafting the position and crafting the letter from our state health officer that allowed for that query. But it is still -- I think that Gillian put it really well. Even a high-functioning state like Washington still can struggle with the variety of responses that come back. No two CDAs are formatted exactly alike. Or oftentimes a customized implementation will put certain data elements into some places and not others. So it becomes a tremendous challenge for public health to utilize that information effectively. And if a state like Washington is struggling with it, I can only imagine what states that have been even in greater underfunded are dealing with. So I think maybe part of our recommendations need to be providing that technical assistance, those regional extension centers, to lift up all of the capacity of the catcher's mitt components that Micky Tripathi talked about when they put forward this charge.

Stephen Murphy

And Bryant, actually, I just want to go back to a point you made, I think, a few minutes ago, about in your jurisdiction. You said that it is the local health department that determines the minimum necessary. And is that codified somewhere?

Bryant Thomas Karras

Yeah. We are in a home rule state. The public health authority in Washington state is a county or health district. We have several multi-county consortiums that have a single health officer within a multi-county region. They have the authority in our state constitution for public health response. The state public health agency works under their behalf to gather information.

Stephen Murphy

Thank you.

Gillian Haney

All right. I want to make sure everyone gets a chance to say a word, and then we are probably going to need to move over to the worksheet. So, Arien.

Arien Malec

Yeah. I feel like sometimes we are talking ourselves into circles in this conversation. Clearly, if a state or locality public health authority provides legal guidance, legally enforceable guidance, that does constitute minimum necessary, and nobody argues with that. Number two, the mention of USCDI is purely because USCDI constrains the boundaries of what is readily producible by an EHR. And again, nobody disputes the ability of a public health authority to ask or request an electronic means for more than is in USCDI, but

USCDI does provide the boundary envelope for what is readily producible, and it is going to provide the boundary and envelope for where the floor exists. And then really, the third point is that if we come to the conclusion that FHIR is a scalpel, something like FHIR is the right tool for public health use, but the public health cannot use FHIR, and the USCDI does not provide the data that public health needs.

What we are doing is talking ourselves into a world where we are really maintaining status quo, and that is great if we like status quo. So maybe a little more frustration than helpful commentary. Where I was trying to steer toward was steering toward a land where we have uniform guidance from OCR, which independent and public health authorities does administer HIPAA and it administers HIPAA penalties and penalties for disclosure. A guidance from OCR that if a public health authority asks for something, that request itself is, by definition, minimum necessary for the data that is being requested. And it does seem [crosstalk] to me that in the absence of more specific guidance or legal ruling from a public health authority that having OCR provide that higher level guidance would be useful for covered entities that have some reasonable uncertainty.

That is the proposal that I am making. If that is not a proposal that the workgroup feels is helpful, we can just punt on this issue and move on. But I do caution us not to drive ourselves to a world where we rule out all everything that is possible and only accept the impossible because then we will be in the world that we currently are.

Stephen Murphy

Arien, that is where my mind was going, too, that as we talk about local health departments and state health departments making determinations as to what is minimum necessary, and you used the phrase, "a legally enforceable guidance." The first thing that came to mind for me was at the end of the day for a covered entity, it is OCR that is going to decide whether they are playing by the rules or not. And to be honest, we see enforcement actions from OCR every month. It kind of ebbs and flows. Some years, there is like one every month, and then other times there is not. I have not seen -- I cannot think of an enforcement action off the top of my head involving minimum necessary. And not to say that OCR could not come down hard on it. They could. I mean, they make a very big deal out of the right to access, which they invest a lot of resources in. So, I guess they could invest resources in this, too. But a lot of times the enforcement actions are far more egregious mishaps around HIPAA compliance.

Gillian Haney

I am going to give John the last word while we switch over. Liz, perhaps you can get ready the worksheet for us. John.

John Kansky

Thank you, Gillian. So just looking from Stephen Murphy's perspective on a lesson learned from the pandemic response, which returning to public health authority's broad but authority in many states, not just mine, where I run a Health Information Exchange. Public health authorities wanted to leverage the HIE as an aggregator of data. And the public health authority asked, for example, hospitals to report through the Health Information Exchange and the interpretation of many hospitals was we cannot **[inaudible] [51:57]** a public health authority. So in our state that required a Governor's Executive Order, which was followed by a change to state law before the executive order expired, was this a weird policy barrier that was encountered because it was perceived as fairly common when we spoke to our peers in other states?

Stephen Murphy

That is very interesting. And I think, in terms of public health authority, it does vary from one jurisdiction to the next in terms of what authority is granted to a local health department versus while it is retained by the state. Some jurisdictions are centralized to a state health department. Some are very decentralized. Some jurisdictions have home rule authority. Other municipalities and cities and counties operate under different kinds of authority. So I think it is going to depend on the facts, which I know is an answer that attorneys love to give, but people do not generally like to hear it. But I think it would depend on the authority that we are talking about in any particular instance. I mean, the City of Chicago is going to have different public health authority than the State of Ohio or what have you. So how is that for sitting on the fence, John?

Arien Malec

Nice.

John Kansky

Unfortunately, yeah, that kind of confirms what I thought. Thank you.

Task Force Topics Worksheet (00:53:26)

Arien Malec

Nice. Clear as **[crosstalk]**. Cool. All right. Let us go over to -- so, first of all, just thanks to the presenters. You are welcome to stay on as we go through the sausage making of taking this input and turning it into recommendations transmittal to the National Coordinator. But if that does not constitute entertainment for you, you are also welcome to drop and get on with your day. But again, profound appreciations for the input and the feedback and the engagement.

So, Gillian, you had a question on the status of the transmittal. And so, maybe we can start with a framing conversation about what the transmittal is and what its role is.

Gillian Haney

Yeah, it was more I just want to make sure that everybody is clear about what the process is going to be and the parameters around which comments will be made.

Arien Malec

Cool. So let me give a broad overview of what it is that we produce. So at the end of the day, as a taskforce of the HIT Advisory Committee, we produce a draft transmittal. That transmittal is effectively a letter from the HITAC to the national coordinator that makes certain recommendations. At the end of the day, it is the HITAC as a full deliberative body that passes or does not, that transmittal on to the National Coordinator. So there is clearly a presumption that the workgroup has engaged in this work, and their recommendations are good and strong. But at the end of the day, it is the HITAC that is making the determination to pass the transmittal on to the national coordinator. As I noted, the transmittal is a set of recommendations to the national coordinator, and so we may make appropriate recommendations for the national coordinator to convene with other federal agencies, but it is not our role to make recommendations to CDC, to other federal agencies, or to other entities, including STLTs about what they should do.

The term that we generally use is we recommend that ONC coordinate with or convene or use one of its coordination powers to be able to affect some indirect action on other actors. In terms of the process, we are using the spreadsheet as the input mechanism, so it is a more free-ranging, free-floating place to collect our ideas. And then we memorialize those in the draft transmittal. That draft transmittal is draft until we lock it and present it to the HITAC, and the HITAC makes any amendments that they might make on it, and it moves on. So moving something from the worksheet to the transmittal letter does not finalize that content until we actually do finalize and send it on to the HITAC for a consideration. We just have a lot more flexibility for drafting and editing a worksheet as opposed to drafting in the transmittal.

So when we are in the transmittal mode, we like to keep the content locked down and then use the comment feature to make suggested changes. We will definitely go through the transmittal line by line and make sure that it represents the notion of the workgroup. So showing any other sort of high-level feedback in terms of the process that we are using?

Gillian Haney

No, I do not think so. Liz, did we cover all of the parameters? [Crosstalk] --

Liz Turi

Yeah.

Gillian Haney

Okay. Great. Thank you.

Liz Turi

I just want to add one thing the disposition working document. You will all be getting a link to the disposition working document with this week's homework email, but you will have reviewer access. So that is a suggesting mode in Google Document so that we can capture comments as we go through. And Gillian and Arien, anything that had been green in the worksheet has been transferred over. So anything that is color coded green going forward, we will not be able to make edits in the draft disposition working document.

Arien Malec

Yeah. So for taskforce members, if you encounter something that is green in the spreadsheet and you disagree with it, it is not going to be useful to register that disagreement in the spreadsheet itself. Please move over to the draft transmittal and provide a comment to that effect. So trying to make that actionable for you. We did not quite get through all the overarching comments. So we will go through overarching and scroll to the uncovered items. Okay, Gillian.

Gillian Haney

Right. So this is just sort of a general statement. And I have conferred with colleagues, and we would like to make sure that wherever it said stakeholders that public health and stakeholders that we update that to state STLT public health authorities and their partner organizations, and that gets at the point that you addressed by bringing in CSTE, AIRA, APHL and others.

Arien Malec

Perfect. So we are going to use still public health authorities and their partner organizations as our generic term.

Gillian Haney

Yes.

Arien Malec

It is long, but it is at least -- we can copy and paste, and it is unambiguous. And we will make sure to define it upfront in the transmittal

Gillian Haney

Yeah. I propose that we do not need to go back everywhere within this document. We will just bring it over for language in the transmittal document. **[Crosstalk]**.

Arien Malec

Yeah. That is fine. When we put it over to the transmittal, we will make sure to be using that term consistently. Okay, Kansky.

John Kansky

Yeah. Thanks. So this is actually a really good juxtaposition to adjust rates with Stephen Murphy. Erin, you crafted an articulate row five recommendation -- which I totally support -- that refers to making sure that intermediaries, the flexibility given, I believe is related but different. And it acknowledges that there are State-based small "p" and large "P" policy barriers. Ike and Bryant referenced a couple of these in their comments. And that, of course, gets to the, Well, what do you want? What do you think we should do about it? My question is whether there would be support for a recommendation regarding ONC offering guidance on these policy barriers, noting perhaps what best practices or barriers to avoid. I do not know but interested in whether there is support for that.

Arien Malec

Yeah. Maybe CDC could offer advice to Stilts on what policies Stilts should use. Sorry. That was tongue firmly in cheek as the suggestion least likely to be adopted. Gillian, looking for your guidance in terms of -- this is an area where what I want to say is that accepting and acknowledging that public health authority resides by constitution in our Federalist system in states and localities, and accepting and understanding that the public health authority is broad and jurisdictional. Nonetheless, there are certain ways of using public health authority and associated policy that are useful and some that are not useful. So saying that something is not useful is certainly not saying that a state or locality does not have the right to engage in that activity. Those are two different determinations. All that being said, Gillian, what would be the right recommendation, if any, to make recommendations that help public health authorities achieve their mission while reducing the process-oriented or policy-oriented friction towards mission achievement? And is that an ONC role?

Gillian Haney

[Crosstalk] I think that we could [crosstalk] --

Arien Malec

And is that an ONC role?

Gillian Haney

I do not know that that is an ONC role, but I think that there could be general acknowledgement that these authorities do exist at the state and local level. But wherever possible, public health should come together to develop consensus and speak with a unified voice. [Crosstalk] --

Arien Malec

And so, again, our goal is to make recommendations to ONC. So the way we might want to frame that is we recommend that ONC confer with, convene **[crosstalk]** --

Gillian Haney

Convene.

Arien Malec

Convene, yeah. Okay.

John Kansky

And I would offer that you can certainly focus this. My intent, what I am picking up, you can certainly focus this by addressing the intermediary issues. You want to give public health authority the ensure that they have flexibility to leverage intermediaries when it makes sense. And the policy barriers are often unintended, but I am trying to narrow it and make it more actionable. It is really the use of intermediaries to accomplish these public health missions that I am referring to.

Gillian Haney

I just want to point you to the comment that Erin made in the chat.

Arien Malec

Yeah. And I was about to respond to that. There is a distinction between an EDI engine that a public health authority deploys in order to meet their local mission and the use of an intermediary that serves multiple parties like a multi-tenant intermediary. So APHL AIMS platform would be an example of a multi-tenant intermediary. A single tenant component that is used for by a state or locality to achieve its public health mission would not be in that frame and intermediary. But as we get to next generation architectural vision for public health data infrastructure, we may well be relying on multi-tenant infrastructure to better support STLTs in achieving their mission, and this position becomes much more salient. And then as John is noting, there is a significant need for other intermediaries, maybe state-based like a state HIE, national intermediaries like nationwide query networks such as QHENS. And so, yeah, this position is pretty salient.

I think we have got good guidance. So Gillian, maybe you and I can work on turning this into actionable recommendations text.

Steven Eichner

I want to jump in really quickly. One of my concerns about intermediaries is who then ends up with rights to data through that intermediary for what purpose? People do not usually have an opportunity to opt in to public health reporting or opt out of public health reporting for contagious diseases and the like. People

have a right to not participate in Health Information Exchange. [Crosstalk] So I [crosstalk] -- I do not have [crosstalk] --

Arien Malec

[Crosstalk] Yeah. No doubt. And yeah, again [crosstalk].

Steven Eichner

However, I will clarify that there is no issue in data being routed through an intermediary to public health. We just need to be careful about what retention rights exist for that intermediary.

Arien Malec

Yeah, no doubt. So there should also be no presumption that a public health authority must use an intermediary that does not address the policy goals of the public health authority. All right, let us move on to the next unmarked issue. [Crosstalk]

Bryant Thomas Karras

Arien, I think that you may be oversimplifying that multi-tenant concept in that when an intermediary is operated by an organization like APHL and on behalf of the states, but the funding for that infrastructure comes from a federal agency, who has that ultimate retention or data governance in access. I think we went through an evolution of this with syndromic surveillance, where we had a multi-tenant structure that each state governed its own data, and for cost saving reasons became a non multi-tenant environment operated by the feds. And that begets problems that were unforeseen by the policy and its origin. So I think we need to not oversimplify this.

Arien Malec

Just to be clear, nothing that we are saying is making any recommendations on the use or non-use of intermediaries. All we are saying is that in the context of this transmittal is that the certification criteria and any use of those certification criteria be flexible to allow public health authorities to assemble the technology to achieve the public health mission? And that does include multiple modalities of use. So I think [crosstalk]

Steven Eichner

I think it should be allow but not required to be [crosstalk] --

Arien Malec

Yeah. So if you go. Yeah, if you go back and look at the language that I drafted. Please, please go back and make sure. I think it does address all those concerns. But please go back and relook at that language and make sure that it does indeed address those concerns. We can go back at the end as we have time and go back and look at the proposed language because I did try to write it that way. Okay. So we just marked Gillian's comment as already addressed.

Gillian Haney

This was a different one, actually.

Arien Malec

Okay.

Gillian Haney

This was around developing use cases to reflect real-world testing and having it be done through consensus with the public health and establishment about minimum threshold.

Arien Malec

Okay. So this would want to go along with our general recommendations that certification address not just syntax but also semantics and that there be no gap between certification and **[inaudible] [69:33**] interoperability.

Gillian Haney

Right, and not just the perfect but also the imperfect.

Arien Malec

Yep. Good. So I think we can take this language, move it over, and then I think we are going to have to do an editing pass to make sure all the language reads together. I think it follows as a natural extension of some of the stuff that is already in there.

Hans Buitendijk

A quick question there, Arien and Gillian, particularly Gillian. Do we need to have some consideration in that recommendation on how to work whether to address the variations because certification today is a singular set across all jurisdictions, and then we have all jurisdictions having variations. So I am trying to understand. Are you trying to indicate this is only the real-world testing at the level of certification that currently exists nationally, or that there be that recognition of variations that need to be recognized in such real-world testing?

Arien Malec

I guess, Hans, my take -- and Gillian is free to completely disagree with this -- my take would be we want to make sure that the floor level of interoperability actually is sufficient to meet the floor level of public health mission. And what we have heard in practice on the ground is that the floor level of interoperability as defined by certified standards does not, in fact, address the needs for which those floor level certification criteria and implementation guidance were developed, oftentimes because the data that is flowing through those interfaces is not, in fact, the data that was represented to flow through those interfaces. Gillian does that -- or do you have a different perspective there in terms of addressing variation above the floor?

Gillian Haney

I think that I am agreeing with you. I think what we wanted -- we do not want to just be looking at -- I think what my point was that we do not want to just be looking at the ideal messages that are coming through, which most certification programs currently look for. But we also want to be able to assess what it means when they are missing data elements that are there, or that their people are using non-compliant value sets.

Arien Malec

Exactly.

Gillian Haney

So it is that would be at the minimum standard.

Arien Malec

Exactly.

Hans Buitendijk

Okay. And that is good clarity because that was not totally clear. So are you looking for that real world of the minimum, both sides of good data and bad data and everything, or beyond the minimum for the variations in jurisdictions, as well? [Crosstalk] --

Arien Malec

[Crosstalk] We want the floor to actually work.

Gillian Haney

Yes.

Arien Malec

Shocker.

Unknown Speaker

Because some of the issues may be not so much the data being sent from or to public health but looking at how the data is translated from within the EHR to the outgoing message. If that makes **[crosstalk]** --

Arien Malec

Yeah. No, no. So, oftentimes, what happens in practice is that the certification run and then an EHR goes through is 100% [inaudible] [01:12:51] mocked up data. Everything is entered new. Everything just follows the existing -- the required coding standard, and then you send it out into the real world. And you have got Legacy codes. You have got people loading in noncompliant code sets. You have got people using EHR in ways that were not contemplated in the certification test script. And so, the data that flows out of the EHR does not actually conform to what was certified to. We want to reduce that level of variance.

Unknown Speaker

Right. Exactly.

Arien Malec

Yep. Okay. Sorry, I am doing my initial dereferencing and trying to figure out who J.G. is.

Gillian Haney

That is Joe Gibson from the CDC Foundation.

Arien Malec

Got it. Got it. Thank you. Thank you. Joe.

Joe Gibson

True. These are two related recommendations. And it is about putting some focus beyond the interface between healthcare and public health to looking at transmission within public health and from public health to other partners who are going to use the information. So recommending that we require the systems have some functionality for transmitting subsets of the data within two other public health agencies. And then the next one is about specifically immunizations. There are a lot of partners who can make use of immunization data in making sure that that interoperability is considered in certifying the systems.

Arien Malec

Yeah, so generally agree with the sentiment. My only concern is that our charter is (f) criteria, EHR, catchers, potential public health data receivers, and intermediaries. And so, this would be pushing on our charter a bit which does not mean we cannot make the record elimination, but we probably would not want to acknowledge that it is strictly extra to our charter.

Joe Gibson

Yeah. I didn't realize that limitation, but it is sort of the get into the meaningful use of the data.

Arien Malec

Yep. Any comments in terms of making these recommendations that we also address other consumers in the case, for example of immunization registry or other public health authorities in the case of upstream/downstream use of data? I'm not seeing any major dissent. Let us move on. Did we miss one, Liz? There we go. One up. There we go. So also you, Joe.

Joe Gibson

Oh, yeah. So this is somewhat similar to the prior one, **[crosstalk]** but this is some more specific to the uses of immunization data **[crosstalk]** uses.

Arien Malec

Cool. Good, good, good. Okay.

Liz Turi

Yeah, filtering is not doing what it is supposed to do, so I have highlighted the next overarching one.

Arien Malec

Okay. [Crosstalk] --

Gillian Haney

This is another one of mine.

Arien Malec

Okay.

Gillian Haney

Looking also to improve content and assessment, assessing compliance, and recommending development of new testing tools.

Arien Malec

Okay, so we should put this in that same section. As I said, we are going to have to do an editing pass just to make sure it all reads well together. Okay. So are we all the way through overarching? Oh. We got more overarching. Nice, as you say. So I think we have addressed this one. I am going to see if we can mark this one as a duplicate.

Liz Turi

So this is a little different. I actually just updated it based on the conversation that we just had. I think it is going to be critical for public health and other partners, frankly, to be able to incorporate a combination of technology solutions internal to their organization, so I updated that here in this recommendation.

Multiple speakers

[Crosstalk] --

Arien Malec

I think it is a duplicate of the modular certification recommendation, or it may be an extension to that modular certification criteria recommendation, the number of which currently eludes me. But we can move it over, and then we can do it editing pass and just combine like with like and see if we can do the deduplicate any duplication?

Bryant Thomas Karras

Arien, I think modular certification presumes that the parent product is under the ONC governance, and it may be that an EDI engine may be outside of the healthcare industry tool set and will have no goal or interest in seeking certification. So there is no modular certification that will ever happen. So I think that there needs to be some recognition.

Arien Malec

The general means for solving that problem is a self-certification approach, where if a state or locality, if a STLT is assembling, cost technology to address the issue, and that cost technology, or that assembly of cost technology needs to be certified that there needs to be a path for self-certification of the assembled technology.

Bryant Thomas Karras

Yeah, but there is not a -- unlike the healthcare side, there is no financial incentive or return on investment for that certification. So there is some, I think, sustainability challenges there.

Arien Malec

Right. And again, I think our presumption broadly -- and we have a recommendation to this effect -- is that as we require -- as we include certification requirements in programmatics that we also contemplate the funding associated with achieving certification. But, yes, I think this one also belongs in that same section. So mark it, move it over, and then just make sure that the same overarching recommendation that is there is accommodative of this nuance, as well. All right, Fill. Is Fill on?

Fillipe Southerland

I am here. Hi Arien.

Arien Malec

Hey.

Fillipe Southerland

Yep. So this is basically a recommendation for ONC to coordinate with CMS and SAMSA on defining and incentivizing certified HIT outside of [crosstalk] --

Arien Malec

I think this is outside of our scope. Unless you can convince me that it fits the scope definition that we have for looking at public health criteria. Or are you making the recommendation that non certified -- sorry, are you making the recommendation that health information technology that is in use by organizations that are not currently covered by meaningful use or promoting interoperability also be certified to the public health standards? So, for example, that an LTPAC could access immunization registry data or report on syndromic surveillance or transmit case reports? Is that the intent here?

Fillipe Southerland

That is correct.

Arien Malec

Good.

Fillipe Southerland

So [crosstalk] these alternative settings to use that technology to be able to report on they have criteria.

Arien Malec

Got it. Okay, cool. So we just need to make sure that we limit this recommendation to appropriate criteria. Then I think I understand and, yeah, agree that it does fit part of our mission. All right, Liz. Are we -- okay, cool. We have gone through the overarching. criteria. I do not think we have a good way of marking currently whether something is filtered by color. Is filter by color working? All right. We have eight minutes, but we are going to reserve five of that for public comments. So we have three minutes. We will go through as much as we can of the currently untagged. Okay. And Erin.

Erin Holt Coyne

Yeah. So the next series of items are all in regard to lab tests and results, but there is also included some items regarding orders. And the approach I took with some of these was to include setting a standard or a baseline certification criteria but then also this notion of an advanced criteria, which would allow for entities who may be at a point where they could further adopt new or additional criteria, like adopting new laboratory specifications, for example, would have the ability to do so. And so, this first one is specific to receivers of electronic laboratory results. And what is included is the implementation guide and all of the errata and clarification documentation as documented in the ISA as well as the value set companion guide.

Arien Malec

Okay, so we should have a consensus about how we address specific implementation guidance. Are we going to make a comment on the specifics of implementation guidance that we expect to be in a certification

program or make reference to the certification program itself? I think the way things stand absent this recommendation is that we are making recommendations to public health that public health data systems be certified to the appropriate (f) criteria. We are also making recommendations that ONC work to update appropriate implementation guidance to the latest supported versions. And we are also making recommendations that that be done in ways that are consistent with deployed technology and public health funding.

And I think we have a choice about providing broad-level policy guidance or providing specific policy guidance. And I would prefer that we sort of stick with a broad-level policy framework as opposed to naming specific implementation guidance. But that perspective may well be disagreed with by the members of the taskforce. And I do not feel so strongly about that one that it is a point of religion for me. So my general perspective is that we should be providing a policy framework and giving ONC the flexibility to do the assessment, making pointers in areas where we recognize that there are updates as we do for LRI, but there are updates in LRI that address some of the variations we have seen with ELR. Likewise with some of the other standards. So anyway, just happy that that is a perspective that I have, but happy to have a different perspective if the taskforce believes that this is what we should be getting into that level of detail. Bryant.

Bryant Thomas Karras

Yeah, Arien. I think we are tasked as a taskforce with making recommendations, and the public health members of the taskforce recognize that ONC in a broad guidance has not got to the level of detail and specificity. So I think I intend we do need to get very specific and mention specific standards or specific versions of more releases of standards if we are going to make some rapid response that we very well could have made in advance of the pandemic but did not because the guidance was generalized. [crosstalk] I think we need to be specific, say we need to the [inaudible] [01:26:31]. And I recognize that the dilemma there is they will have to come back to reconvene when new versions come out, but so be it. I think that is the cost of [crosstalk] being impacted.

Arien Malec

Yeah. And we can do it both, and we can provide a broad level policy framework, and we can also make specific recommendations, so there is no conflict in doing it both and --

Hans Buitendijk

And particularly in this area is that least our four of **[inaudible] [01:27:01]** just were published, and they do address the latest capabilities as well as that they have pre-adoption opportunities. And I think that makes it more important to be more specific about the context and the framework to say in the ELR, what is a reasonable way to mix or match or not. And if you mix and match which ones to make sure that the path is as consistent as possible because the amount of variation is already substantial. If we are going to put in more with the variety of guys that you can support or not support. It is going to make it more complicated. We have to keep it simple. And that means **[crosstalk]** --

Arien Malec

I gracefully withdrawal. We have to go to public comments. So we will open it up for public comment.

Seth Pazinski

All right. Hi, everyone. Can you guys hear me?

Arien Malec

We got you.

Public Comment (01:28:09)

Seth Pazinski

All right. We will transition to open up for public comments. If you are on the Zoom and would like to make a comment, please just use the raise hand function, which is located in the Zoom toolbar at the bottom of your screen. If you are on the phone only, you can just press *9 to raise your hand. And then once called upon, you can press *6 to mute and unmute yourself. We will pause for a minute and give folks a chance to get in queue if anyone has any public comments. Okay, no comments, so I will turn it back to Gillian and Arien to close us out.

Next Steps (01:29:09)

Arien Malec

All right. So let us try to see if next week we can get through all of the untagged content and see if we can get to using the transmittal as our -- by the week after using the transmittal as our primary means of input. I think for homework we would like to ask folks to do in effect a close to last call because our time is very limited. Our next meeting is also going to be occupied by a public health systems developer forum. So we are going to have a chance to hear from public health systems developers on their perspectives on certification. So we will have a little bit of limited time in going through the commentary. We will try to keep that session brisk, and then it is really crunch time. So for homework, I would just encourage taskforce members to do a last pass, last call for worksheet input. We will go to the transmittal and clean the transmittal up to make sure that it represents the will of the taskforce and something that is clean and actionable for ONC to reference. And with that, I think we are one minute over, so we should end. And looking forward to next week.

Gillian Haney

Thanks, everyone.

Arien Malec

Thanks, all.

Hans Buitendijk

Take care.

Seth Pazinski

Thank you, everyone.

Adjourn (01:30:43)