Transcript

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

November 2, 2022, 10 AM – 12:30 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
Aaron 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	Task Force for Global Health	Member

Name	Organization	Role
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Elevance Health	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

Call to Order/Roll Call (00:00:11)

Michael Berry
Good morning, everyone. I am Mike Berry with ONC. I would like to thank you for joining the Public Health Data Systems Taskforce. All taskforce meetings are open to the public, and your feedback is welcomed, either in the Zoom chat or during the public comment period that is scheduled about 12:20 Eastern Time. I am going to begin with roll call for taskforce members. When I call your name, please indicate that you are here. I will start with our cochairs. Gillian Haney?

Gillian Haney
Present.

Michael Berry
Arien Malec?

Arien Malec
Good morning.

Michael Berry
Rachelle Boulton?

Rachelle Boulton
Here.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Heather Cooks-Sinclair? Erin Holt Coyne?

Erin Holt Coyne
Here.

Michael Berry
Charles Cross? Steven Eichner?

Steven Eichner
Good morning.

Michael Berry
Joe Gibson will be joining us a little bit later. Raj Godavarthi? Jim Jirjis? John Kansky?

John Kansky

Good morning.

Michael Berry
Good morning, John. Bryant Thomas Karras?

Bryant Thomas Karras
Present.

Michael Berry
Steven Lane?

Steven Lane
Good morning.

Michael Berry
Jennifer Layden? Leslie Lenert? Hung Luu? Mark Marostica?

Mark Marostica
Good morning, everybody.

Michael Berry
Aaron Miri?

Aaron Miri
Good morning.

Michael Berry
Alexandra Mugge?

Alex Mugge
Good morning.

Michael Berry
Stephen Murphy?

Stephen Murphy
Good morning.

Michael Berry
Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry

Jamie Pina?

Jamie Pina
Good morning.

Michael Berry
Abby Sears?

Abby Sears
Good morning.

Michael Berry
Vivian Singletary?

Vivian Singletary
Good morning.

Michael Berry
Fil Southerland? Sheryl Turney? All right, thank you, everyone. Now, please join me in welcoming Arien and Gillian for their opening remarks.

Arien Malec
Good morning. We are in crunch time. We have what I feel is a pretty good rough draft. We need to turn that into a good, clean copy that we can hand in to the HITAC next week. So, I think we are in relatively good shape. Today, I would like to make sure that the current words that we are saying are the words we want to say. We will go through a process after this of accepting or reverting comments. There will be some weird artifacts, and we will get those cleaned up. We will send via email the then-current draft and have taskforce members review it.

If there are major substantive issues, we will take the meeting before the HITAC to reconvene and dispose of anything there. Hopefully not, because we like to give the full HITAC ample time to pre-read the recommendations prior to the HITAC meeting, and this is a long and important report, so I would like to see if we could dispose of all of our major wording issues today. It is a lot to go through, and a few people have to leave a half hour before the end of the meeting, so we are going to be ruthless and merciless as we march through the meeting. We are unfortunately plagued in this taskforce by COVID. I came down with it about halfway through, and Gillian now is suffering through, so we will not ask her to talk too much, but she will be there and ready to contribute as we pull her in. Hopefully, we do not have a lot of disputes that only Gillian can help us resolve.

So, with that, any questions, first of all, about the status of where we are or about the task at hand today? I also should note that some people may have seen a letter that Annie Fine cosigned by most of the major organizations that support public health sent to both ONC and CDC, both praising the activity of our work and also picking up on a number of themes that we have been working through, and then, ONC prepared a little bit of a primer in terms of our role, which I think really recapitulates some of the major work that we had been contemplating and some of the tension, frankly, that we have been contemplating as we work

through this work, such as the notion that we are going to be focused on modular certification, that we are going to be focused on interoperability, but also the notion that, to some extent, the programmatics to which the certification criteria will be attached are not our charter and mandate, and actually are not ONC's charter and mandate.

They are the purview of other federal agencies, and so, we are putting in language to make sure that, as I am sure everybody is aware, you cannot just roll out a certification program with a public health system that is fully in flight, and you also cannot roll out a certification program that does not have funding attached to it that funds both the modernization and the ongoing work of keeping the system certified. So, the ONC folks have sort of picked up on a number of themes that we have been working through, so I think we are all headed in the same direction and know the dance, but again, I am happy to address anything. Gillian, you have your hand up. Sorry to force you to talk so early.

Gillian Haney
No, no problem. I just would like to go back to the letter that was cosigned by some of the major public health organizations and encourage the taskforce to review it. There is a lot of really good language that was very thoughtfully written, and I would also suggest that perhaps we may want to actually use some of the language or suggestions that are in there if, of course, we are all in agreement because it was extremely well thought through and written.

Arien Malec
Yes, absolutely. I think we did send it out to the full taskforce.

Gillian Haney
I believe it went out in an email earlier this week.

Draft Disposition Working Document (00:07:50)

Arien Malec
Perfect. Anyway, that is it in terms of the up-front matter. Any questions in terms of our charge today? All right. Let us get to it. Liz, are you on? Let's go through the document. All right, so, Steve did a really nice job of writing some up-front preamble, and then I did some editing cleanup to have it flow into the overarching work. Abby, go ahead.

Abby Sears
Hi. As I was reading this, I just had a quick request. If there is any way to maybe speak a little bit in the introduction just about health equity, the point of health equity, and the focus on that, not leaving anybody behind, I would just really appreciate it. Otherwise, I thought it looked really good.

Arien Malec
Okay. If you have some places to insert, let us know, otherwise we can just take a pass at that in the editing cleanup. Absolutely agreed. All right. So, as I said, Ike put a lot of thought into the up-front, putting in many of the themes that we talked about, framing them, and as I am thinking about this, I actually think it would be useful for us to frame that public health data systems have, in fact, worked better than one might have expected in COVID times, that our surveillance systems actually worked as designed. We saw a signal very early on that some of the publicized issues that we had in regard to ELR to case tracking and person

identification were clearly there, but on the other hand, we were getting, by and large, electronic ELR. We had many issues early on with paper-based case reporting, and then we responded with ECR, which we partially rolled out.

We almost completely got immunization data into immunization registries, which I consider to be a minor miracle, so it also might be worthwhile just to do a preamble paragraph that notes that all is not doom and gloom, and in fact, we are building on a public health data system that matured quite rapidly in response to COVID, and I think it is worthwhile calling out the large degrees of special effort that went into it, and part of our call is to lower the special effort for both the routine work for public health and future public health crises. Okay, cool. So, let's make sure that we put a placeholder that we are going to add health equity by design and note that we want to talk about how the public health data systems actually performed in the first major, major crisis that we have had in public health since the flu pandemic.

All right, let us go on, because a lot of the fireworks start below in terms of editing wars or just wordsmithing. Huh, I thought I de-bulleted these points. I guess not. We should de-bullet these. So, we start with our overall recommendations, and Ike, I think you used the words "receipt intake," and I changed it back to "exchange, access, and use" because that is the language that ONC has used and that is the language that is enshrined in 21st Century CURES. That phrase was used by design.

Gillian Haney
I think we wanted to have specific language in there that demonstrated that it was not so much… We wanted to be able to receive the information, we wanted to be able to then turn it into actionable information and then take response, so that is one of the reasons why it is like this. I thought I edited some of this last night, and I am not seeing it.

Arien Malec
Yes, as I said, I think there were some edits I thought I made that might not have gotten through.

Steven Eichner
The rationale that I was using was that we focused the certification or discussion on the taskforce really about the interoperability functions, not the other functions that IT can certainly provide, but they are **[audio cuts out] [00:13:06]** in scope, and I wanted to make sure that we were reflecting that focus here because public health is not going to use the data on the back side, but we wanted to be sure that we are focusing the certification components on the ability to receive and do that initial processing, and not interpreted that we were looking at any certification of other function with the technology.

Arien Malec
I definitely agree with that. And then, you and I have a back and forth in this document on "efficiently" versus "effectively" or "efficiently to serve the public health mission." I am understanding that a lot of your comments are focused on how we are not actually certifying public health systems, we are not certifying public health authorities, and I think I am focused on the same point that Gillian raised, which is that we want to not only make sure we are receiving the data, but also that the data are useful for the public health mission, that they actually can be used effectively.

So, it is this boundary condition on interoperability that I think we are wordsmithing around, and I want to say that I think we both agree on each other's points. I agree that our focus is on interoperability. I think you would agree that efficient interoperability of data that public health does not need, does not want, or is not useful is not the goal. So, I think we generally agree on the boundary condition, and I think we would generally agree that our goal is to get data into systems in ways that actually serve the public health mission, and then, we are just trying to find the language that artfully articulates both points. Is that correct?

Steven Eichner
Well, there are two or three things to work through. There is not a single public health mission. Look at the diverse set of activities that public health is engaged in. You could certainly say the single mission is to improve public health, but that is not a singular aspect to do that. You could just say it is controlling infectious disease, but public health is much more than that, so, looking at having a mission statement without defining what the mission is could easily be…

Arien Malec
Cool, cool. I am not interested in… I think we are saying the same thing, that we both agree that the focus should be on interoperability, that the data that we need to interoperate both needs to be efficient and effective, that "effective" is parameterized on the purposes to which public health needs to put that data, and that we are not certifying the functions, activities, etc. of the data systems for public health authorities themselves in this work. And so, I am open to finding the right language that articulates both those points.

Steven Eichner
Absolutely, and still recognizing, as I put in the preamble, that public health, like generality in healthcare, has an overall concept of improving health, but there is not a singular message or singular mission within that. So, psychologists have their area of specialty and folks that are working with chronic disease control and cancer have their specialty on the public health side, so again, it is not a singular mission, making sure that we are not trying to evolve to a single healthcare message that satisfies…

Arien Malec
So, again, I am just in the position where I am going to make too interruptive here. I think we both agree that all we are doing is finding the right words to memorialize our agreement, and I am happy to get input from the field on it.

Gillian Haney
Arien, there is some language below that might be appropriate. Let me just check and see which. It is in the first recommendation. **[Inaudible – crosstalk] [00:17:57]**

Steven Eichner
I will be quiet for the rest of the morning.

Arien Malec
No, you do not need to be quiet.

Steven Lane
Please do not, Ike. Your input is invaluable.

Arien Malec
No, that is absolutely not the point. If we agree and all we are trying to do is find the words, let's focus less on the disagreement and more on finding the words that artfully articulate what we are both saying. If we disagree, then clearly, let's either have it out or punt that issue.

Steven Eichner
Appreciated.

Liz Turi
Gillian, is this the recommendation that you were thinking of that has the wording you were looking for?

Gillian Haney
Yes.

Arien Malec
We will get to this when we talk about measurement, but the additional point is we also want to make sure that the data we are interchanging is useful for the plurality of missions of public health for which the data is applicable. Cool. Let's go back up, Liz, and go to the preamble. Getting the preamble is right because many people go read the preamble and do not necessarily take the time to read every single one of our recommendations. There will be people who will read every single one of our recommendations, and I am sure Micky and Don will read every single one of our recommendations, but there will be people who will read the preamble. So, I think we can just accept Bullet 2 as is. Let's not go through the mechanics here on the fly. Go ahead.

Hans Buitendijk
On Bullet 1 and the note that I made about if we want to clarify that we have in our conversation a fair amount about if we are certifying and validating organizations/PHAs or focusing on HIT, the bullet is focusing on the data systems.

Arien Malec
Yes, thank you. Good add.

Hans Buitendijk
Do we want to acknowledge that discussion and say that it is out of scope, or save the recommendation for later to consider it as well, but separately? That is currently what would not happen for providers either.

Gillian Haney
I think we want to be very clear that we are not…

Arien Malec
Not doing that.

Hans Buitendijk
Then I think we should just…

Arien Malec
We did not say that. So, after "public health data systems," or just at the end, we should say something to the effect of "or the activities of public health authorities," or how public health authorities use the interoperable systems.

Gillian Haney
Or "public health authorities," stop.

Arien Malec
Yes, stop, period.

Bryant Thomas Karras
[Inaudible] [00:21:07]

Gillian Haney
Bryant, we cannot hear you.

Bryant Thomas Karras
My laptop is dying. Sorry, folks. Can you hear me?

Arien Malec
Yes.

Bryant Thomas Karras
I think we need to make sure that this taskforce does not fully blame or indicate that the only folks that need measurement or certification are on the public health side.

Arien Malec
Sure.

Bryant Thomas Karras
There is a significant partnership requirement for this to work.

Arien Malec
That is also a good point. So, again, in our preamble, we note that we need to do work on the outbound as well as the inbound interfaces. Fair point.

Hans Buitendijk
Quick clarification: If we say "or the activities of public health authorities" and we put that in the first sentence, that would seem to imply that certification is done on both public health data systems and on public health authorities. I thought that was the thing not to do.

Gillian Haney
Agreed.

Arien Malec
Agreed. So, we will find the right language to say **[inaudible – crosstalk] [00:22:15]**.

Hans Buitendijk
It is not the public health activity/authority, something like that.

Arien Malec
We are not going to repeat some of the understandable but ultimate missteps of Meaningful Use early on. All right, cool. So, I do not think the second bullet requires a ton of different wording. This is just about the difference between our task and the recent Adopted Standards Taskforce. Bullet 3 focuses on the notion of a common floor, the notion of public health authority, that we are not trying to circumscribe or override public health authority, but that we are trying to create a useful common floor. Steven is coming in and doing some editing work on the fly. Fantastic, cool.

Steven Eichner
It probably should say "healthcare providers," not just "providers."

Arien Malec
Oh, thank you.

Steven Lane
Well, the value of saying "providers" is that it also can incorporate social care.

Steven Eichner
Okay, not to have discussion, but that might be a new term we want to define or standardize early on.

Arien Malec
Where we use the term "provider," we mean inclusive of mental health professionals… We mean "providers" as defined in…sorry, I was going to go to the Congressional Public Health Act.

Gillian Haney
How about we say something to support the exchange of data between or inclusive of all providers and public health, including methods?

Arien Malec
Yes, good. Perfect, thank you. The fourth bullet is our admonition that we are only dealing with certification, but we are addressing certification under the assumption that there will be new funding sources that are sufficient to fund modernization. We probably should use "public health authorities and their partner organizations" where we say "public health authorities."

Gillian Haney
Please, yes.

Arien Malec

We should spell out "PHAs" to "public health authorities" in that sentence. Sorry, I did not catch that one. And then, in the one below, "federal partners, public health authorities," that one should also include a reference to "and their partner organizations." Cool. Good, good, good. So, with that objection, we will move on. So then, a little bit of our term definition. And so, I split the definition of "public health authorities" and "public health authorities and their partner organizations" because sometimes we refer to public health authorities, sometimes we refer to public health authorities and their partner organizations, and so, again, hopefully there is no controversy here. I spelled out what we mean by "public health data system."

And then, there is a callout for ONC to add a definition of "modular certification," so that would be useful. Now we get into the meat. Good, good, good. All right. Okay, first recommendation, which is confusing with Recommendation No. 7, but we will clean up the ordering. "We recommend that ONC establish a certification program." Okay, this is one where we are using "ability to receive intake and respond to." I did not get to this one. We probably should use "exchange, access, and use" just because, again, it is the language that is in 21st Century CURES, but we should use the same language here, and as above, let's move on to the next one because I do not think there is any…

Gillian Haney
I do want to call out a comment I put there about the F criteria and whether we want to limit ourselves to just the F criteria because there are other vital records, SANER, and other things that we want to fall under the umbrella here.

Arien Malec
No, I think we are good, because structurally, this point says to include the F criteria, and then, we explicitly say, "In addition to the F criteria, we also recommend," and then list those recommendations. So, the intent here is this one says, "Hey, let's do certification criteria that matches the existing F criteria," we explicitly call out public health access to TEF query, and then have a section on other additions in addition to the F criteria, including vital health statistics and SANER. So, I think we are okay. When we get to that section, if we do not feel like we make that point explicitly enough, let's look at it again.

So, here is another one where Ike and I went back and forth. Sorry, go back up, Liz. Here we go. This is about metrics, and again, I think we agree. So, Ike struck "measures of utility of data transmitted," and I would argue that we want to put that back in, but we want to put that back in subject to restricting to just the data that is interchanged for interoperability, but I think we would both agree that we not only want to interoperate efficiently, we also want to interoperate effectively, so I will be eagerly searching for people who have proposed language. Otherwise, I will try to wordsmith it myself.

Gillian Haney
So, what is the concern around the striking here?

Arien Malec
Why am I concerned that it was stricken?

Gillian Haney
Yes. What is wrong with the language that exists?

Arien Malec
So, if I am going to advocate for Ike, Ike's point is…

Gillian Haney
I was actually the one who struck some of this.

Arien Malec
Ike struck it as well. So, Erin, you have your hand up.

Erin Holt Coyne
Presumably, "measures of the utility of the data transmitted" would be defined by whatever specification we are using for that particular interface, so are we attempting, then, to assess the applicability of the content of those standards in this certification process?

Arien Malec
Yes. So, again, I will fully acknowledge that the words that I use can be misunderstood, but I would also believe that we would all say that it is important that the interoperability be efficient and effective, and that "effective" is defined as the ability of public health authorities to use the data that is transmitted in order to serve the plurality of missions for which that date is applicable. I am happy to entertain the right language. I think we would all agree that the data should be interchanged efficiently, and also that the data should be effective.

Gillian Haney
I like that.

Hans Buitendijk
I have a thought that I might be typing while you keep on going.

Arien Malec
Go for it. So, again, as a taskforce, I think we agree on what we want to say and we are struggling with wordsmithing, which I think is a good thing. It is much better than disagreeing on what we want to say. So, Hans is going to…

John Kansky
Sorry. Before we move on, "other relevant stakeholders" crept its way back in there, which seems to imply that public health authorities are stakeholders.

Arien Malec
Okay. I do not think that implies that. I do not think there is anything wrong with…

John Kansky
So, what is the other modifier?

Arien Malec

We enumerate a list of organizations that ONC should work with, and then we contemplate that that list may not be exhaustive, and that there are other stakeholders who may have a relevant interest that ONC should work with.

John Kansky
I would say that public health authorities are stakeholders. They may be more than that, but they are part of the set of stakeholders.

Bryant Thomas Karras
Well, we are more than the stakeholders. We are the holders.

Arien Malec
That is right. "Stakeholders" is not intended to be a pejorative term.

Bryant Thomas Karras
But it is.

Arien Malec
Cool. Again, I am happy to entertain… In cases where we agree on the spirit and we are searching for the words, I am happy to suggest or get edits. Hans, I am looking at this. I do not think that is exactly the point. I think the general point is a metric should capture how efficiently we are exchanging data and that the data that is being exchanged is actually effective for the specific purposes to which public health puts that data.

Hans Buitendijk
And I think on the last part, on the effectiveness, it has that part that certification is the floor, but there is that additional aspect that it impacts the effectiveness of the total picture.

Arien Malec
Yes.

Hans Buitendijk
But that needs to be twisted a little bit more.

Arien Malec
Okay, good. We are in the range, we are in the ballpark. As I said, I am super happy if we get to a point where we agree about the spirit and we are arguing about the wordsmithing, and words are important, and it is our job to make sure that what we agree on here is interpreted downstream appropriately, but to me, we have good victory if we are marching on a common understanding. All right. So, here, we need to spell out "public health authority" and "public health data systems."

Liz Turi
As a note, do we need to spell it out here as well, since we have spelled it out in the preamble and there is an appendix?

Arien Malec

I think it is useful to spell it out. Either abbreviate it consistently or spell it out consistently, and since we spell it out sometimes, I have defaulted to spelling it out all the time. I also recognize that the language can be read by people who know what a PHDS and a PHA is, and that is easy for people to read, but for other people, it is actually useful if it is spelled out. Let's see. I think I got a comment on this one. "It does not need to be certified for use of…"

Gillian Haney
Yes, I edited this last night to give it more flexibility as well as to try to strengthen the language.

Arien Malec
I guess my take on this is that we are in this fine thing where the programmatics are out of our bailiwick, but we do want to make sure that the certification requirements are pretty darn clear, that they are certification requirements for interoperability. I think generally, through the rest of it, we are good.

Gillian Haney
So, I also added language that use of third-party testers as well as self-certification should use common testing criteria.

Arien Malec
Perfect. Good, okay. Let us move on. I think we are good here. Any objections to the language as it currently reads modulo strikethroughs?

Gillian Haney
Again, I updated this one to include the standard code and value sets, so this is actually one that I think we wanted to discuss today because we do call out the inability of public health to match on patient demographic information when reports first come in, but it is really much broader than that. That is just really the first pain point in the entire process. And so, I want to make sure that we do not limit the standardized code and value sets to be reflective for just demographic information, but that it is also inclusive of things like LOINC and SNOMED, and eventually, when USCDI becomes more useful, all of that as well. So, perhaps we actually want to break this into two recommendations. Maybe you could scroll through a little bit, Liz, as I cannot remember what my comment was yesterday.

Arien Malec
Liz, are we seeing comments in your view?

Gillian Haney
Sometimes I see mine, and other times I do not. It is kind of weird.

Liz Turi
So, if I scroll down to look at all the comments, I move past… There is no way to separate…

Arien Malec
I see, I got it. Let's just make sure that as we are doing this review, we are picking up comments.

Steven Lane

We should also refresh the doc now and then in case people are adding comments as we go.

Arien Malec
We are 42 minutes in, so we have to chunk through.

Gillian Haney
If people are in agreement, I am happy.

Arien Malec
I think people are in agreement, and I actually agree with you that we probably should split it into two. I have the same queasiness about how we specifically reference patient matching, but it is broader than that.

Gillian Haney
I will take that on, then, to split that into two and wordsmith it later.

Arien Malec
Good, okay. All right. Let us go to our next recommendation. So, this is the one where we have a nice preamble, a heavily edited preamble, and this is the one where we are saying we need to expand certification to include the ability to update value sets dynamically and operating rules for the updating of value sets.

Gillian Haney
Sorry, Liz, my brain is just foggy. Can you scroll down to what my comment was here? I had a question about what we are meaning by "dynamically." I think we need to be a little bit clearer. Are we talking about the timely implementation of said value sets, or are we talking about updates of value sets? I think those are two different issues, and I would also be careful. If we are talking about the… Sorry, I went on mute again.

Arien Malec
I am with you. "Timely" is the intent.

Gillian Haney
Right, and I think the use of the term "dynamic" could be problematic if we are talking about updated value sets dynamically because if it is automatically coming in, then there is no way IT will allow us to do that, and we also have to do a lot of…

Arien Malec
I am good on it. I am good. So, again, we can just use the word "timely" here rather than "dynamically." The goal here is that certification should include the pathway by which value sets are updated, and that value sets can be kept up to date, and that we need to make sure that we do not have systems in the field that are trying to interoperate with value sets that have not been updated for a year. That is entirely the point. It is not prescribing that the value set update be automatic, background, and transparent. It is that the systems have the ability to do so periodically and timely, and that the real-world certification includes the ability to update in a timely manner. So, can we just replace the word "dynamically" with "timely"?

Alex Mugge
Can I ask a question about how that works in practice for what ONC is trying to do? How does one produce a regulation that supports dynamic updates?

Arien Malec
So, No. 1, it is perfectly feasible to have a certification criterion that demonstrates the ability of a system to update its value sets, and then… This one should not be "stakeholders," it should be "federal authorities." But, as an example, CMS actually delegates the construction of the operating rule, per law, to an organization that defines operating rules for the use of clearinghouses, but CMS has some authority over that space, and those operating rules are enforceable. The programmatics by which operating rules would be enforceable would be something for ONC to work through, but this could be part of, for example, ONC's real-world certification program.

Gillian Haney
Can I just clarify, again, that the intent of this recommendation is around the timely ingestion of value sets, not the timely updating of value sets by public health or other authority?

Hans Buitendijk
Wouldn't we want to do both?

Gillian Haney
I think we do want to do both, and I think that this language smushes them together, and I think that we may want to separate them out.

Arien Malec
"Access and update," or…? Do we like "access and update"?

Bryant Thomas Karras
It depends. Are we describing updating the reference tables in our systems or the standards bodies and authorities updating the standards themselves?

Arien Malec
Reference tables in the system. So, the problem we note is that value sets were out of date, and that those value sets being out of date impeded interoperability, and so therefore, it is valuable that there be systems to make sure that value sets are up to date.

Bryant Thomas Karras
Right, but you are misunderstanding. Some of the value sets were out of date because local systems had not pulled down the latest version of tables.

Arien Malec
That is the problem.

Bryant Thomas Karras

But, there is also the issue that some of the references had not been updated in 10 years, so they were out of date.

Arien Malec
That is also a problem, but that is not our problem to solve. Our problem to solve is where the standards development organizations have updated value sets, there need to be mechanisms to keep the value sets up to date in the systems. Hans, you have your hand up.

Hans Buitendijk
Yes. Also addressing Alex's question, if the focus of the criteria is on the ability of the systems, respectively PHDS and EHRs, and that they have the ability to support timely updates to the content, leaving blank whether those are automated updates, manual updates, or whatever approach it is, but that they support it, and I think that is as far as you can go focusing at the systems without focusing on the organizations and what they need to do. So, it is the ability of the systems respectively…

Arien Malec
Yes, that is what certification is focused on, and then, the operating rules are focused on that the systems that are deployed are actually kept up to date.

Bryant Thomas Karras
I am still having trouble with how ONC cannot have a service-level agreement with state agencies.

Arien Malec
No.

Bryant Thomas Karras
So, are we talking about… Who are the relevant partners?

Arien Malec
Generally, CDC. It could be CLIA, it could be CMS. There are a variety of federal organizations that may have a role to play.

Bryant Thomas Karras
Can ONC actually enter into service-level agreement with those partner federal agencies?

Arien Malec
No. ONC is creating operating rules that are inclusive of SLAs for timely updating of the value sets.

Hans Buitendijk
Should we, then, add there "encourage provider organizations and PHAs to validate the operating rules"?

Arien Malec
Yes.

Gillian Haney

I like that.

Arien Malec
So, Hans, can you make that edit and we can move on?

Hans Buitendijk
I will just use "PHAs."

Arien Malec
That is fine. We can de-reference. Recommendation No. 4. Okay, there are a lot of edits here. So, I struck Jamie's language on "contingent on the collection" because that really gets into the actual collection, but "focused on ONC work with public health authorities, partner organizations, CDC, and other federal agencies, etc., to update relevant V.2, consolidated CDA, and FHIR-based implementation guides to reflect the updates to USCDI," and we should probably say "latest versions" rather than V.3, although V.3 is where most of the SDOH and SOGI data fireworks have taken place. "Latest version of" is probably best.

Steven Lane
So, I had a question. Is it the latest version that was published or the latest version that was SVAPed?

Arien Malec
It is probably the latest SVAP version.

Steven Lane
I agree, but I think we should specify that.

Arien Malec
Yes.

Gillian Haney
Please. That is a really good point.

Arien Malec
Perfect. Now we have to define "SVAP." Cool.

Hans Buitendijk
One comment there is that in that construct of SVAP, and some comments were made as part of the Updated Standards Taskforce as well, we have to be very careful within SVAP on which versions are referenced where, and if one organization takes the latest version permissible in SVAP, but the other side of the coin does not, that may lead to some interoperability challenges, so I think we have to be very cautious on how we introduce it, that yes, it is in SVAP, but at the same point in time, both parties then would have to adopt it.

Arien Malec
Yes, I hear you. Edits are welcome.

Hans Buitendijk
Yes, it is a hard one.

Arien Malec
Also, there is a level of fractal clarity that we can provide, but we have time limitations, and sometimes staying high-level is useful. Again, edits are welcome. I am struggling with the last sentence here. "Guidance must also include expectations for the method by which possible responses are provided to responders to ensure consistency in question presentation, e.g., a list of response options are provided to respond in." I do not understand…

Gillian Haney
I did not write this, but I think the issue, and I will just call it "USCDI" there, is something like pregnancy, that is listed, but it is not how the question is phrased or how the information is gathered and what response options are.

Arien Malec
Got it.

Gillian Haney
I think. I do not know who wrote this, but that is a thing that I have found.

Arien Malec
That is right. So, generally, USCDI will either point to a defined value set or a LOINC-enumerated set of questionnaires in the case where there are assessments to be made, and there are some cases, alas, where USCDI seems to indicate that there should just be a field without any definition of structure for the field, but I would just encourage us to strike this sentence.

Gillian Haney
But how can we get at that issue, though? Because it is a real problem.

Arien Malec
So, if the problem is that the interoperability specifications themselves do not specify the level of detail that is required, I think that is covered by "ongoing development of USCDI and/or USCDI Plus, taking into account the needs of public health," and maybe we could add "and the needs for exchange of structured information."

Gillian Haney
That would be good.

Arien Malec
Okay, cool. So, maybe "the needs of public health inclusive of exchange of structured information," and we strike this whole last sentence. Okay, so, we want to say "the needs of public health inclusive of exchange of structured information." Cool, all right. Here is our point about health equity by design. I think there are good edits here. So, at the last one, maybe somebody unstruck it, or maybe I just put a comment on. So,

the last sentence here in this paragraph, not the last paragraph, but the last sentence in the current, extant paragraph… This one is firmly out of our scope.

Gillian Haney
Can we add something in the preamble, though? Because I do think it is really important. The fact that the U.S. Census does not gather data so that we can have appropriate denominators renders a lot of stuff useless, so it would be really great if we could include that sentence as something in the preamble.

Arien Malec
Cool, that makes sense, or we could also say, "Although out of our charge, we note that any change, to be effective, must be reflected across all government programs." That would be another way to handle it. I completely agree with the point.

Gillian Haney
Wherever it will have the most impact.

Arien Malec
Yes, good. I agree, let's repeat this point in the preamble so that people who just read the preamble pick it up as well. All right, let's keep going. I think we are actually good on this one. There are a lot of really good edits. I would say unless there is any objection, let's move on. I think I updated this one, so I think we are actually okay here. I think I did the update to address my and Hans's concerns. Let's just make sure people can read this and actually agree with it.

So, the point that Hans is making is that we have a set of point interoperability implementation guides, but we have not necessarily looked at crossed data flows, and it is important that "ONC, in collaboration with public health authorities and the partner organizations, as well as with SDOs, look at the standards and implementation guide's guidance to address harmonization and use across separate data flows where data eventually need to be integrated and used together by public health authorities," and I provide some examples. So, the basic point is it would be weird if the specs for reportable labs differed materially from the specs for ECR in ways that rendered the ELR data and the ECR data effectively non-combinable or difficult to combine. Same thing for immunization data, where that data needs to be combined to create a longitudinal record for case investigation. Any objections to this? Okay, let's move on.

Gillian Haney
Hans?

Hans Buitendijk
Yes, just a quick note, Arien, is that as we move it into "overarching," I think we need to keep the distinction between what the role of USCDI is on aligning on the data definitions and vocabulary, and then you have the data flows that are finding the optimum way for subsets of the USCDI in workflows and reporting to get that to the right spot. The comment that you made does not belong in "overarching," but should it harmonize to USCDI Version 3? I think we need to keep those somewhat separate as we do that because they have different roles.

Arien Malec

I think so, and I think we are okay with the language, but if we are not, then edits are welcome.

Hans Buitendijk
Are you going to move it up as is?

Arien Malec
I think we are going to keep it right here. It is already up, it is already where it needs to be, so we did the move up, it is where it wants to be, and I think we are okay. All right, let's move on. There is a comment here. This is the "efficiently and effectively." Good point. So, whatever language we use for "efficiently and effectively," let's do it. At this point, let's go with "efficiently and effectively." If we have better language, we can go for it. **[Coughs]** Sorry.

Gillian Haney
We are quite a pair.

Arien Malec
Quite a pair indeed. I think we are okay with this one, unless there is any objection. There is a comment on it. Good points on who we would be certifying, and I think we are okay at this point because that is firmly in the future, but it is probably worthwhile mentioning future certification, and maybe in paragraphs, potentially, of systems that have not yet been subject to certification, such as inventory management. Okay, cool. Liz, can you put a note? So, after "future certification," we can put in parentheses "potentially of systems that have heretofore not been certified, such as inventory management," just to acknowledge that when we are talking about certification, we are not talking about the usual EHR certification program. Cool, all right.

Gillian Haney
This is a question that I meant to ask at the beginning. So, a lot of our recommendations are like Recommendations 1 and 2.

Arien Malec
We are going to reword them. Liz has already noted that we are going to do a pass of making sure numbering is consistent.

Gillian Haney
All right. Is it going to have some sort of language that summarizes the issue?

Arien Malec
If there is language that summarizes the issue, we are the ones that need to create it. I have tried to add where it is useful to have preamble text to frame the problem and then the solution. I have tried to add that ad hoc, but if there are areas where it is important to add some preamble, let's do it.

Liz Turi
Yes, and do not worry about the numbering here. There is a specific numbering convention as I transfer them over. "Recommendation 1" is going to have no meaning once it gets transferred to the final document.

Gillian Haney

Right. I appreciate still keeping it in the references to the spreadsheet, though, so, thanks for that.

Liz Turi
Yes, those will be removed by the time it gets in the final.

Bryant Thomas Karras
Will there be some type of subtext or title name associated with each of the…?

Arien Malec
It will say "Recommendation Blah blah blah," it will not have wording that summarizes what the recommendation is.

Bryant Thomas Karras
In last year's taskforce, we had categories.

Arien Malec
Yes, we do have categories.

Liz Turi
There are categories. So, these general recommendations, recommendations on new standards, transmission to immunization…

Gillian Haney
Okay, that is good.

Liz Turi
So, these are all going to be consistent…

Arien Malec
Those will be categorized. There will be a table of contents where you can access each of the detailed recommendations, but the detailed recommendations themselves will just have consistent numbering attached to them. All right, let's go. Next one. There are lots of good edits on this next one. I think we are good on SANER. By the way, this is a section where, as I noted previously, we recommend certifying to F criteria, and then, this is the section where we specifically recommend adding additional standards implementation guidance and turning them into certification where appropriate.

Steven Eichner
I just want to be clear on the SANER piece. Texas is working on proof of concept. We are a long way, I think, from actually looking at certification.

Arien Malec
Yes, and I have been diligent in making sure in these areas that we develop the standard implementation guidance, that we test it in the real world, and that at the appropriate time, we turn it into a certification program.

Steven Eichner
Yes, certification for it at some point in the future would be a fantastic thing, but there is a lot more work to be done in figuring out how to get the data out of different systems.

Arien Malec
Yes, that is why subsequent to develop of testing, we believe it would be an appropriate avenue for future certification. Anyplace where we have not said that, we really should say it, because it is an important point. All right, next one is on vital health statistics.

Steven Eichner
That was separating out vital health statistics from the other pieces because in the original draft, vital statistics was mixed with something else, and they are really two different subjects.

Arien Malec
Yes.

Steven Eichner
Blood spot.

Arien Malec
Got it. So, then, I was questioning what the point is of making the last sentence here "Technical standards with successful and complete exchange are separate from legal and policy guidance reflecting data availability."

Steven Eichner
Looking at that, the technical exchange is separate from any legal balance on accessing data. Vital statistics data is one of those data classes from public health that may have various specific limits on who can access and for what purposes.

Gillian Haney
Erin?

Arien Malec
Erin, go ahead.

Erin Holt Coyne
In reading this, I am struck by the use of the word "vital statistics," and it made me wonder if we were talking about standards around birth and death reporting or standards in communicating specifically vital statistics data, say, to NCHS, but reading this over again, I am wondering if we are not talking about the whole continuum of communicating this data. I feel like I am missing something here.

Arien Malec
Yes. So, I think the point intent of this paragraph is timely updates to birth/death, where birth/death is recorded in EHRs or other key lifetime indicators.

Steven Eichner
This is Steve. I had made edits specifying that it was birth and death data.

Arien Malec
Yes, it is right here: "…such as identifiable line-level birth and death data."

Gillian Haney
Yes, and it is "to produce vital statistics." I think that is what I missed.

Arien Malec
"Data used to produce," yes.

Steven Eichner
It is there in Line 4, Erin.

Arien Malec
Good edits. So, I think we are okay with this paragraph. And then, we note that there are other areas where EHRs are the source, and it would be useful to expand standards implementation guidance, newborn screening…

Steven Eichner
For newborn screening, do we also want to point back around to the Data Standards Taskforce?

Arien Malec
I do not think so here. I think we are okay.

Bryant Thomas Karras
Vital records, birth certificates, and newborn screening are not the same thing.

Arien Malec
No, they are not. I do not think we are saying the same thing.

Bryant Thomas Karras
We are being lumped into one recommendation here.

Arien Malec
No, I completely agree. We split them out, different paragraphs. So, I think we are okay.

Steven Eichner
To Bryant's point, it should be a separate recommendation because if we are saying, "Hey, we like Recommendation X" and they are in the same bucket…

Arien Malec
Got it. Liz made the comment. I think it is right. Sorry to be interruptive, but we have to charge through. All right, let's move through to the next one. Is this TEF query? All right. There is a comment here on these

queries to take advantage of. Or, is that an edit? No, it is a comment. What is the comment here? Oh, "Addresses part of recommended…" Cool. Any objections to this as currently written? So, this is one where we say… Go ahead.

Gillian Haney
I will wait. I have an issue with the third paragraph.

Arien Malec
Okay, good.

Steven Eichner
To a certain extent, what are we testing, or what is being certified here? This is not really public health receiving data, this is really looking at TEFCA or a HIN's ability to produce data.

Arien Malec
No. This is public health's ability to use the TEF to query for data.

Steven Eichner
The certification piece is on the HIN, not on public health.

Arien Malec
So, "yes and." So, rather than "HINs, and HIE, and participants," I think we want to say "QHIN" here. There we go. Strike "HINs and." Cool.

Alex Mugge
If we want to be really specific, we should say "QHIN participants and sub-participants."

Arien Malec
Awesome. Let it be. So, it is a "yes and." Public health data systems would be able to query, would be able to issue queries, their QHINs would appropriately address those queries to other QHINs to be able to create nationwide data access…

Steven Eichner
It is not just QHINs, because public health or the entity may not be connected directly to a QHIN. It is all the way through, so it is…

Arien Malec
Well, by definition, if you are using the TEF, you are connected to a QHIN, so I think we have contemplated in the past that there are going to be QHINS that are specially constituted to address the needs of public health. One could imagine that APHL would create a QHIN, or somebody might create a QHIN that is focused on the needs of public health. There is obviously work to get this done, but yes, we are recommending that the certification criteria would be inclusive of public health data systems and their QHIN partners. So, there we go. "We recommend that ONC, subsequent to testing the implementation guide for public health TEF query, establish certification criteria for public health TEF query inclusive of the major actors who participate in such queries: Public health data systems, QHINs or local HIEs, and EHRs."

Steven Lane
On Line 4, the word "incremental" does not add value for me. I do not know what it means.

Arien Malec
Hans?

Hans Buitendijk
I can see why it might not be a good word. The intent was additional queries beyond the feeds. So, you have ECR, ELR, whatever kind of feeds, and this would be incremental queries for additional data.

Arien Malec
I think Hans's point is you are getting an ECR…

Steven Lane
No, I get the point. I think the word could confuse people.

Hans Buitendijk
Yes. I am totally open to a better word.

Steven Lane
Maybe spell out the phrase.

Arien Malec
No, it already says, so I think we are good. Let's delete the word "incremental."

Steven Lane
Yes, it says "beyond the data."

Hans Buitendijk
That might have been added a little bit…

Arien Malec
That was added. It is a better add. Okay, cool. Let's get to Paragraph 3, which is the one that a number of people have objected to. Gillian, you had an objection here.

Gillian Haney
Yes. This may not be very popular, but I am going to go ahead and put it up for discussion anyways. I am concerned that we really do not have any demonstrated proof that FHIR is actually going to work for public health. I see it says "might or may provide," but I am uncomfortable with the language around specifics of case investigation for emerging public health threats. It really implies that all the data the public health needs are in healthcare data, and it is not. There is an enormous amount of data that we get from contacting the cases themselves. So, I am really uncomfortable with both calling FHIR out here, as well as…

Arien Malec

I am open to striking the entire paragraph. The point that this paragraph, which I wrote, wants to say is that when you get a C-CDA, you get a C-CDA, and you get only the data that the EHR packaged in the C-CDA, and that creates two problems. I think we addressed how OCR has, in fact, provided guidance that if public health asks for something, then providers should be able to rely on the fact that public health asked for it to be able to provide it, so I think we are actually okay there. But, one problem has historically been that you are getting a whole bunch of data, and there is a question of if you actually need all the data that is traditionally packaged in the consolidated CDA, and does that address the needs of minimum necessary?

The second is if there are data that public health needs that are actually in EHRs that are not packaged in the consolidated CDA, is there a more efficient way to get there electronically, and if there is, a FHIR-based query could provide a means to do that. Again, I totally acknowledge your point that in some cases, you have to go read the notes, you have to go interview… There are many other ways of getting at data than that, but that is the entire point that this paragraph wants to make, and I am totally okay with…

Steven Lane
I would not strike it, Arien. I think it makes a very good point, and I do not think it threatens what Gillian is saying. Sure, there are going to be other needs as well, but this is a really good point to make.

Gillian Haney
I really appreciate the issue around minimum necessary and the limitations of CDA around that.

Arien Malec
So, let's strike the word "better" and say "additional."

Erin Holt Coyne
Yes.

Bryant Thomas Karras
Yes, thank you.

Steven Eichner
This is Steve. I think most of the text in yellow can get deleted for several reasons. One, an awful lot of public health reporting data is not collected through a C-CDA today. It is collected using specialized messaging that is intended to collect the minimum necessary data set for the specific purpose. Secondly, there is the language in HIPAA that public health can define what it needs and providers can rely on that description as satisfying HIPAA requirements for minimum necessary.

Arien Malec
As I said, in fact, OCR has said that if someone asks for something, then just give it to them. That actually satisfies the definition of…

Steven Eichner
Right, exactly. So, most…

Arien Malec

Again, this is not a hill I want to die on. I am okay deleting this phrase.

Gillian Haney
I am much more comfortable with "additional."

Arien Malec
Cool.

Hans Buitendijk
I have a suggestion. I have not sure whether it is very feasible, as it is in the color, but I highlighted between "and" and the word "like," along the words of Ike's suggestion. If that is struck, then that might be sufficient to indicate that there are additional opportunities, and I agree we need to keep something about FHIR in there that, for additional data, can have more pointed and targeted opportunities to get data than the bigger once-size-fits-all C-CDA. So, if we strike that, would that be sufficient?

Steven Lane
And satisfy providers' concerns about minimum necessary. I would not strike that on here.

Steven Eichner
We can refine, but we need to address the minimum necessary pieces because I do not want to get ourselves…

Arien Malec
You do not want a pregnant assumption that asking for a consolidated CDA does not address the needs of minimum necessary. I hear you.

Gillian Haney
Can we just call this out for wordsmithing, then?

Arien Malec
Yes, call it out for wordsmithing.

Gillian Haney
I am in agreement that it should stay with wordsmithing.

Bryant Thomas Karras
Arien, perhaps, to your comment, which would reference a sentence that OCR has recognized that public health is allowed to request anything they want under HIPAA, because otherwise, minimum necessary being ratified in this recommendation makes it seem like we are saying the provider cannot do beyond if asked for.

Arien Malec
Yes, that is right. All right, the next recommendation has not attracted any comments, so let's just move on. Same with the next. Non-certified actors…let's just say "other actors." Cool. "…and study certified HIT uptake."

Gillian Haney
What is LTPAC? Is that long-term care something?

Bryant Thomas Karras
Long-term post-acute care.

Arien Malec
This is in an area where those of us who have been in it for a while are using acronyms, and those of us who have been in public health for a while are using acronyms…

Gillian Haney
Yes, our acronyms for that are different, but I really support that.

Arien Malec
Good, cool.

Bryant Thomas Karras
And then, my comment there was in reference to how we have not studied uptake at all in these industries since 2013, so it would sure be helpful to have some data around that.

Arien Malec
"Study and align"?

Bryant Thomas Karras
Sounds good.

Arien Malec
Cool. Moving on.

Gillian Haney
Can I just clarify again? Long-term post-acute: Does that include nursing homes?

Arien Malec
Yes.

Gillian Haney
I want to make sure that we are including…

Arien Malec
So, LTPAC traditionally includes live-in facilities, SNFs, stepdown units, etc.

Gillian Haney
Got it, good. If that is the correct acronym, then I am fine with it, but I want to make sure.

Arien Malec
That is the acronym the LTPAC community uses, which is a self-referential use of acronyms, which is fantastic. Cool. So, there is general agreement. Okay, cool. Next one, move to "overarching."

Steven Eichner
My personal take is that 17 could pretty much be struck. Most privacy is framed in public health under state law, so you are not going to necessarily…unless you are looking at modifying state law…

Arien Malec
We should strike the "streamline privacy policies wherever possible."

Bryant Thomas Karras
Okay, because it is the same thing. The patient does not have to consent going from their facility to the public health.

Arien Malec
It depends by jurisdiction.

Bryant Thomas Karras
No, it does not.

Arien Malec
Opt-in versus opt-out of participation in state immunization information systems varies by jurisdiction.

Hans Buitendijk
So, does it really, then, focus on establishing that there is recognition, there are variations, but it needs to be easier to get access to those in a computable way so it is easier to share data?

Arien Malec
I think if we just strike "streamline privacy policies wherever possible, work with," to use our terms of art, "public health authorities and their partner organizations to establish a privacy consent management infrastructure that enables automated sharing," though we can probably strike "automated" as well," across jurisdictions within established privacy consent policies and directives." There are places where, because there is jurisdictional variance, there is sometimes reduced cross-jurisdictional data query or information sharing, and there are sometimes cases where provider organizations who need to interface with multiple jurisdictions struggle with how to set that up in a way that addresses all parties, and that is all this point is making.

Gillian Haney
Should we limit to just "sharing across jurisdictions"? Because that is also with federal authorities.

Arien Malec
"Sharing across jurisdictions and with federal partners"?

Gillian Haney

Yes.

Steven Eichner
And again, I would feel better about there being some description about what data is involved.

Gillian Haney
Yes, I think this is not just about immunizations. There can be limitations on HIV and that sort of thing as well. So, is this inclusive of that, or is this intended to just be around immunization registries?

Arien Malec
Intended to just be around immunizations. It showed up under "immunizations." We recommend that it be moved up to "overarching."

Gillian Haney
I think it should be in "overarching."

Arien Malec
Which is where it is right now.

Gillian Haney
Sorry, go ahead, Bryant.

Arien Malec
We have yet to get to a single F criterion.

Steven Eichner
I would think that you need to call attention to immunizations or call attention that it is overarching, and I can tell you it is going to be problematic on implementation because, again, it is really looking at state law, not a matter of…

Arien Malec
We struck the points where we are suggesting modifying state law. All we are talking about here is when there is interjurisdictional data sharing, or there are providers who need to share with multiple jurisdictions, or there are jurisdictions that need to share with federal partners, it would be pretty darn useful if we had a communicate and share the…

Steven Eichner
Looking at privacy consent management infrastructure, again, looking at consent management, the only big area where DSHS Texas collects patient consent is looking at immunization data, where we are looking at public health's role as an HIE-like entity because that is the other place where you get into some complicated environments.

Arien Malec
There is also lab data, lab data sharing, there have been… Anyway, in some sense, if this is a flytrap for discussion, I would be happy just removing it because the likelihood that anything is going to get done here

in this space generally approaches nil, in my experience, and we have so much more in the report to go to, but I know this sort of came up from Hans as an issue, where it has been problematic in the field.

Steven Eichner
Leave it to wordsmithing, but I think there are advantages of providing, at least, some examples of what data might be subject to **[inaudible – crosstalk] [01:25:08]**.

Hans Buitendijk
I think examples would be helpful.

Arien Malec
Cool, let it be.

Bryant Thomas Karras
If we have it moved from "immunization" to "overarching," we need to make a recognition that privacy and consent policies may not be applicable to all the F criteria.

Arien Malec
Bryant, I think we are having trouble hearing you. Maybe you can work on your audio issues, and if you cannot, feel free to type it into the chat. The next recommendation is on general policy barriers, and here, we put a little preamble noting we are not limiting the ability of public health authorities to develop and enforce local policy, identify policy barriers where barriers…recommend ONC coordinate definition and promulgation of standard best practices, period. We are not changing anybody's policies, we are just saying, "Hey, it would be cool if, in areas where there the same policy outcome can be achieved, here is the identified best way to do it." No objection? Move on.

All right, immunization. Let it be adopted and include standard mechanisms for transport. Good wordsmithing around "to the same standards" on both sides. Done. Any concerns? We will move on. HIMSS/AIRA IIP. By the way, I did find out where the term "HIMSS IIP" came from that I used. It is actually coming from the published ONC test methods, so all we are doing is saying, "Here, we heard from AIRA that there are some variations with differential handling of local inventory control and local consent policies, and ONC should coordinate with yada yada to do a rev of the immunization implementation specifications, and if necessary, underlying standards to better support predictable variation in these areas." Boom. Move on.

Bryant Thomas Karras
Can you guys hear me?

Arien Malec
Yes.

Bryant Thomas Karras
I wonder if, on Recommendation 2, we need to specify that the certification on clinical side currently does not certify the transport mechanism.

Arien Malec
That is already addressed. That is on No. 1.

Bryant Thomas Karras
Okay.

Arien Malec
Cool, let's move. Two current test methods: We are recommending that we recognize the HIMSS/AIRA IIP as the standard test method. Done. A lot of deletes here, so let's make sure, if we are suggesting deleting something, that this is not something that you think… In most cases, we are deleting things because they are duplicative. So, with this one, there is a lot of wordsmithing here. Hans and I went back and forth via comments. Here, the point is we want to make sure that the data that is received in an immunization query/response is incorporable into the EHR, into a longitudinal patient record, without special effort. So, I think we wordsmithed it to the point where it is in submission. Any objection?

Gillian Haney
Still reading. Hold on. Okay with me.

Arien Malec
For those of us who worked on "automatic incorporation of data into systems," the problem you often find is that you query twice, and you get data, and you are not sure if the data that you are getting is the same data or new data, and so, it is useful, when you query for data, to have a persistent identifier, some notion of provenance, and consistency of patient identity so that you can automatically incorporate and reconcile.

Bryant Thomas Karras
I do not know what "special effort" means. It might be good to use a more specific term there.

Arien Malec
"Special effort" is defined in law, or it is used in law, in the 21st Century CURES Act.

Bryant Thomas Karras
Okay, that is fine.

Hans Buitendijk
A particular example here might just be EG reconciliation. That is a special effort that somebody has to manually do.

Bryant Thomas Karras
That is a good answer, but I do not think we are going to be able to eliminate that need when we are talking about cross-jurisdictional IIS queries.

Arien Malec
It says "reconcile without special effort," and there is reasonable effort, like there is no way that computers can substitute for human beings, and then, there are areas where you are like, "Really? You are asking me to review this thing that you already provided me, and it is exactly the same?"

Hans Buitendijk
Yes. From a provider perspective, that is the same data across different sources, and the more that we have provenance, good identification, etc., and it is the same on the PHA side, the less human effort there is to get it together.

Arien Malec
Yes, that is all we are saying. Good. Move. I think we can delete this one, so I think we addressed it above. Any objection to deleting? So, we addressed it in Recommendation No. 1. Cool, done. Let us move on. Deleted, deleted… So, this is the area where we say that "across multiple settings of care that are providing updates to immunization registries, it would be useful to have a standard policy floor for timely and accurate information." Objections? Cool. Next one. "We recommend that ONC work with CDC to certify…" CDC and probably APHL, right?

Gillian Haney
Wait, why is APHL listed here?

Arien Malec
Doesn't APHL run IZ Gateway?

Hans Buitendijk
I do not think so.

Stephen Murphy
This is Stephen Murphy. APHL administers one of the agreements related to IZ Gateway. They administer the data use agreement.

Arien Malec
Okay, then we can strike it at this point, relative to modular certification. I think we are suggesting deleting this one. I think we addressed it. Oh, no, this is outside of our mandate. We cannot use certification criteria to make sure that we are addressing policy outcomes. These are all good things, they are just…

Gillian Haney
Joe, was there something that…?

Joe Gibson
I just got a little hung up. We are talking about data exchange, and this is around data exchange and having standardized data exchange. This is not between healthcare and public health agencies, but it is where the rubber meets the road in terms of getting value out of a lot of this.

Arien Malec
I think we addressed this above.

Joe Gibson
Yes, we do in a very generalized way up above.

Arien Malec
Okay. Are you okay with deleting this or reviewing what we did above and making sure…?

Joe Gibson
Well, I do think there is a potential benefit of recommending the development and testing of standards for matching.

Arien Malec
We do say that. We are good there.

Joe Gibson
But you are recommending deleting it.

Arien Malec
We are recommending deleting this section. Matching… I am not sure I understand.

Joe Gibson
Where do we address matching? Elsewhere somewhere?

Arien Malec
Yes, in "overarching," we recommend that we improve the transmission of data to support patient matching.

Gillian Haney
It was the one that needs wordsmithing around value…

Arien Malec
We need some separation because we have two different things, one that is specific to matching, the other where we want to address value sets.

Joe Gibson
I guess I am not clear about the scope of this group.

Bryant Thomas Karras
Thanks, Joe. I do not think that the one that was above addressed algorithms and standards for matching, it addressed inclusion of demographic information on the individual.

Gillian Haney
Correct.

Bryant Thomas Karras
It did not address the gap and absence of **[inaudible – crosstalk] [01:35:33]** matching in the same mechanisms.

Arien Malec

Yes, yes. There was one that I deleted, which we could bring back, but the only reason I deleted it is that ONC has been asked so many times to improve algorithms and test methods. I have been a participant in multiple ad hoc groups to address data collection and standards, the standards committee has called multiple times and the advisory committee has called multiple times for ONC to publish, so it is sort of well-trodden ground. I am happy to include it back. This particular thing that we are proposing deleting does not talk about matching.

Steven Eichner
This is Steve. I think 11 needs to go. Sharing aggregate data? Maybe, but this looks like unfettered data access.

Arien Malec
That is right. Standards implementation guidance for the use of data is not… We are talking about standards and interoperability of certification criteria. I guess my summary would be that good policy outcomes are not our bailiwick.

Joe Gibson
Right, and I know this is **[inaudible] [01:36:49]** what is the standard that would be used to transfer data between a public health agency and a school?

Arien Malec
I think we addressed that. Maybe we did not.

Liz Turi
Didn't we address it earlier in discussing future standards and talking with…?

Joe Gibson
Yes, it is referred to very generally at the top. I could go either way. Whatever the group thinks, it would be nice to reach beyond just the public agency to healthcare standardization if we are talking about certifying these systems.

Arien Malec
All right. Oh, boy. We are going to need the other meeting.

Steven Lane
Yes, we are.

Arien Malec
Fun, fun. Okay, cool. Let's just delete this one and move on. Syndromic surveillance. So, our basic syndromic surveillance recommendation is that we recommend expanding the settings for syndromic surveillance.

Steven Eichner
Just to clarify, it is required under Promoting Interoperability from ED, just to clarify.

Arien Malec
What's that?

Steven Eichner
It is required from EDs under Promoting Interoperability.

Arien Malec
Oh, thank you. Good add. Liz, can you make that? No, we are good.

Steven Eichner
And again, here, I think the focus also needs to be… Because the first paragraph lays out public policy. I think we need to make sure that we focus on the certification component.

Arien Malec
Okay, cool. "Set up HIT systems for certifications available and assess appropriate incentives to adopt certified technology, and in particular, we recommend syndromic surveillance certification of systems used by primary care, urgent care, and LTPAC."

Steven Eichner
Isn't it currently a modular certification anyway for syndromic surveillance?

Bryant Thomas Karras
It is, Steve, but most of the products that are used in long-term care facilities, for example, did not elect to do that modular certification course.

Steven Eichner
So, I think the recommendation needs to be something different about the certification. In other words, greater adoption, something in that kind of space, if we can go there, because, again, I am not disagreeing that it has not been well adopted or well certified, but that is a different question than if there are certification criteria in the first place.

Arien Malec
I think we are saying that above. "Expand the set of HIT systems for certifications available." I think her point is the certification may well be already available for those systems, who are using them, "and address appropriate incentives to certify and adopt certified…" Maybe we should say "address appropriate incentives to certify and adopt certified technology."

Steven Eichner
Yes, because otherwise, the last sentence is just saying "recommend it be certified," but we have already said that it is.

Arien Malec
Cool, good, okay. So, Liz, I think what we are saying is "address appropriate incentives to certify and to adopt certified technology." All right.

Bryant Thomas Karras
Is there anything we can say here to get vendors to reassess which modular components they certify to?

Arien Malec
The real truth is that at the end of the day, vendors certify to the technologies that their customers are required to use, and the art here is we are trying not to make policy recommendations, only certification mechanisms, but what are the incentives to get certified? It is because you have to use it. So, I think we are tiptoeing around an issue that we are not supposed to be tiptoeing around, and that is okay. I agree with the edits, this is an area where we all agree, and I would suggest we move.

Hans Buitendijk
As long as the certification criteria are modular enough, **[inaudible] [01:41:36]** can be done, and the challenge comes in when it is not. But in this case, in public health, they are reasonably modular at this point.

Arien Malec
Again, the policy outcome we are looking for is that we want to cast a wider net, it would be useful to cast a wider net, and we are kicking the ball over to ONC to figure out the appropriate mechanisms to cast a wider net. All right, let's go. Next one. Oof. This is one we have to discuss.

Hans Buitendijk
I think there is a lot of clarity from the conversations that we had that we need to clearly distinguish between deidentified flows and identifiable flows, so that is one point. On the identifiable flows there is still the notion that because it is identifiable, are we really having optimized data flows for those? They are a little different than ELR versus ECR and syndromic versus ECR. Yes, they have different trigger events, there are different sets of data that are of interest, but the flows are essentially analogous, and very consistent in that regard, yet we have different methods, different approaches, etc.

So, this is looking for opportunities to enhance on that as part of aligning and optimizing the data flows in the identifiable space, and then, deidentified space has its own challenges and needs, etc., and I think it is clear we need to distinguish those, but even syndromic surveillance has identifiable flows. As recently as in August, we got from a jurisdiction "Can you please add identifiable data to syndromic surveillance that can allow them to match them up better?" So, once you do that, you are in the space of asking how that fits with all the other reporting that is identifiable.

Gillian Haney
Sorry, Hans, I really do not understand the issue here. Syndromic surveillance is a completely separate… It contains different data elements, it has a totally different use…

Arien Malec
If I am interpreting where Hans has been going, that is the intent of syndromic surveillance. There are local jurisdictions for which syndromic surveillance is line-level, PHI-containing, and because it is a pipe that is open, some jurisdictions have requested that we add information into the syndromic surveillance flows to better address things like timely identification of cases.

Bryant Thomas Karras
Yes, but it is not adding it in the specification…

Arien Malec
Bryant, you are underwater again.

Bryant Thomas Karras
It is in the implementation guide. We are not adding something new.

Arien Malec
Sorry, it is in the implementation guide that you can…?

Hans Buitendijk
Perhaps we need to leave this recommendation out, since we cannot align on it.

Arien Malec
If this is going to be a 10-hour discussion, we do not have time for that, so maybe we should just delete this.

Hans Buitendijk
It remains an align-and-optimize issue from a provider perspective on how data flows in a suboptimum way at this point in time.

Gillian Haney
I respectfully disagree, Hans.

Arien Malec
Yes, that is why we are deleting and moving on.

Hans Buitendijk
Yes, that is fair.

Arien Malec
Good. I think we agree that we can delete this one, Hans.

Hans Buitendijk
I am okay deleting it and leaving the debate for elsewhere.

Arien Malec
We are deleting Recommendation 3 for the same issue. Are we keeping Recommendation 4, or are we deleting? This is where we are re-memorializing the previous HITAC recommendation.

Gillian Haney
You are going too fast for me, sorry. So, can we address Erin's point around lifecycle and expectation/adoption of new standards?

Arien Malec
I think we have above, in "overarching." So, in "overarching," we note that the certification program needs to be phased in, needs to have adequate funding, needs to understand that there are existing data flows that should not be disrupted.

Gillian Haney
Okay, then I am fine. Erin, does that satisfy you too?

Erin Holt Coyne
It does, and I have to keep reminding myself that we are attempting to establish floors, and at some point, there may be a recommendation that a new floor is needed, but at least starting at a floor is appropriate.

Gillian Haney
I think that language will stand, and we can remove the comments. There we go.

Arien Malec
Yes. We are going to keep the language, we are going to remove Erin's, because we have addressed it above, and we are going to go forward with this language. Cool. Oh, we have 10 minutes. All right, let's see how far we can get in the next five minutes.

Gillian Haney
I know we have people who have to leave at 12:00, but we are actually scheduled to 12:30.

Arien Malec
Oh, good. We are going to go to 12:30. Let's do it. All right. I think we are okay with this one, Recommendation No. 1. My overarching preamble thing here is… Liz, just reorder the stuff after editing because right now, it goes very detailed, to overarching, to very detailed, so we want to make sure we get the right flow.

Gillian Haney
This language is very convoluted at this point, and I am not quite sure what the intent is.

Arien Malec
This has been a point from Hans for a while. The intent is there are cases where we are adding information into ELR that is clinical context in nature, and in a world where we have ECR deployed, ECR is probably the appropriate mechanism for publishing the clinical context, and ELR should be focused on the results. Clearly, the ELR feed needs to include everything that is required to make the result interpretable, but ECR should be the mechanism for publishing case detail information. And then, the appropriate add, which I think was from Ike, was what if you have a walk-in clinic and that lab is the only point of capture for clinical detail, or you go to urgent care that has an attached lab and that is the only point for additional detail and capture? I think the point here is where that is true, that point-of-care organization is taking the role of the ordering provider as well as the resulting organization and should capture any of the additional context.

Hans Buitendijk

And report accordingly.

Arien Malec
And report accordingly.

Gillian Haney
I agree with that principle. I just want to make sure that this is not going to detract from our need to get full patient demographic information from laboratories in the initial report.

Arien Malec
We call out very specifically the need to get demographic and contact information. So, we will get there.

Joe Gibson
This is Joe Gibson. I have a really hard time seeing how you… On the public health side, laboratory reporting is essentially case reporting for so many conditions. We do not get data, except from laboratory reports, so, saying that we are going to delineate it from case reporting strikes me as kind of crazy.

Arien Malec
In a context where ECR is widely available.

Bryant Thomas Karras
Which it is not.

Joe Gibson
Yes, give me that context. So, I would not back this recommendation until we have context because we are not ready to delineate between those two on the public health side.

Bryant Thomas Karras
These recommendations are for today, right? Not five years from now.

Hans Buitendijk
I thought they were in-between, directional.

Arien Malec
That is right. This is the floor that we want to establish, and so, we are proposing establishing a floor that includes ECR.

Hans Buitendijk
If we are pushing ECR out, the base by which you have the data through that channel electronically is expanding.

Joe Gibson
I would not be for this recommendation until that ECR exists. I know that at the local level, it does not, and we depend entirely on electronic lab reporting for a lot of the disease surveillance that we do.

Erin Holt Coyne
This is Erin. I would say we have experienced something similar, but I do not necessarily know if that is what we want. I think we want the corresponding case report from the provider side in addition to the laboratory observation.

Joe Gibson
Right.

Gillian Haney
Could we say something that recognizes that ECR is still being expanded, and as it comes to widespread adoption and use, that it is differentiated from laboratory reporting?

Hans Buitendijk
I think some clarification along those lines would be helpful.

Gillian Haney
I agree with Hans that the ECR should be containing that information where it is appropriate, and LIMS systems should not be sending…

Arien Malec
Should not be collecting it, right? It is just problematic. This is an area where this calls for a little bit of preamble context-setting.

Gillian Haney
So, I think it needs some additional wordsmithing, and maybe Joe and Hans can sort that out.

Arien Malec
Yes.

Hans Buitendijk
We have seen problematic adoption of getting the data onto the workflow in the lab, or not in the lab, but on the order side.

Joe Gibson
Yes, I agree with that.

Arien Malec
It is actually worse than that because sometimes the order does not contain any information, and then you are asking the lab to go retroactively get the clinical information. I think we all agree on what the issue is, but how do we memorialize the language? I am proposing deleting Recommendation 2. Hans, tell me I am wrong.

Hans Buitendijk
Hold on. I need to switch over to that one.

Arien Malec
This is not a certification requirement.

Hans Buitendijk
That is fine.

Gillian Haney
Okay. So, does this mean that Mass General Hospital is going to have to report through a centralized hub and cannot report directly to Mass Department of Health?

Arien Malec
That is why we are deleting it.

Gillian Haney
Oh, sorry.

Hans Buitendijk
That was not the intent of the meeting, but yes.

Gillian Haney
Sorry, COVID fog.

Arien Malec
No problem. I think we addressed this one. Either we addressed it or it is like goodness. It is either "overarching" or it is just motherhood and apple pie.

Hans Buitendijk
I think it is "overarching" just as a general…we should align… It goes a little bit to that superset/subset. Have a floor, but we also need to figure out how we can make the variations above it as easy as possible.

Arien Malec
I think we do. I think we comment about the establishment of floor. I think we comment on the need to test for optional data, and I think we specifically comment, where there is specific variation, on the need to reduce variation.

Hans Buitendijk
This can be merged in, or it is taken care of fully above.

Arien Malec
Move to "overarching" or delete.

Hans Buitendijk
Yes.

Arien Malec

Cool. Here is the actual big one. So, our recommendation is "We recommend that ONC adopt certification programs for public health data systems to receive ELR." I have adopted "baseline" and "target" as opposed to "standard" and "advanced" in these areas. Erin may have an objection to that, and Erin does indeed have her hand up. Go ahead.

Erin Holt Coyne
No, I like that, I was just going to say that that last statement in the recommendation, where it says "with standard and advance syntax and semantics," you want to update those.

Arien Malec
Yes, a sliding target. And so, we want to acknowledge that there is a baseline that is in use and acknowledge that there is a target we want to get people to.

Erin Holt Coyne
There is one question I have in regards to the value set companion guide. Maybe this is a question for Hans. Do we need to be that prescriptive with the specific STU version?

Hans Buitendijk
I think we just have to be cautious because the version that is out there is 4, and the value set guide is able to move independently, but that has been moved up as well, so you want to make sure that you use the latest one. I think a general question here is going to be with a baseline target in either direction, where do we strike the balance between adopting pieces of them where folks have already implemented working LOI/LRI-like exchanges, but they need the additional capabilities where we can standardize on that, but what would it take for what to value to…

Arien Malec
Hans, this is absolutely critical work. I think we have addressed it above in "overarching," where we are calling for a phase and incremental plan to roll into the target. I think all we are doing here is acknowledging that there is a baseline that is in existence and acknowledging that there is a target that we want to get to without defining the timeframe, the incentives, or **[inaudible – crosstalk] [01:57:54]**.

Hans Buitendijk
Okay.

Arien Malec
I addressed the optional requirements in "overarching" already. I do not know if people caught that, because we were going pretty quickly at that point, but when we talked about testing, the point is that the requirements for testing need to require testing the optional elements. So, as we see that, we will strike those. I do not think there are any major adds to this one. Boom. Let us move. Okay, cool. I think we want to say STU 4. I think we can delete the last two comments because we addressed them.

Bryant Thomas Karras
I still have concern that modular implementors will only read the recommendations that apply to their system and are not going to review recommendations in "overarching" or preamble.

Arien Malec
Well, ONC and CDC will clearly read the whole thing.

Gillian Haney
Also, can we go up above here? Is "including both CLIA and CLIA-waived" public health laboratories? It is not public health laboratories, it is CLIA-waived laboratories.

Arien Malec
Okay. Do we want to say "CLIA-waived and PHLs"?

Gillian Haney
It is not PHLs at all. It is "includes PHLs and CLIA and CLIA-waived laboratories."

Arien Malec
So, do we want to say "including public health labs"?

Gillian Haney
"Including public health labs and CLIA and CLIA-waived."

Arien Malec
Perfect.

Steven Eichner
In some ways, that is doublespeak, but we do want to call… Most public health labs are also CLIA-certified, but we do want to call attention to how public health laboratories are included here.

Arien Malec
Yes. Good, okay. Next one. What was my comment here? Oh, yes, this was "send results and EHRs to send results," and I do not think we want to be saying that EHRs are sending results.

Gillian Haney
We want them to, though. That is the issue.

Arien Malec
Why do we want EHRs to send results?

Gillian Haney
Go ahead, Erin.

Erin Holt Coyne
Well, I do not know if it is necessarily the EHR, but I think this was an attempt to align existing certifications for ELR from hospitals to public health.

Gillian Haney

I think we also wanted EHRs to be able to accept… In order for ECR to be useful, they need to be able to accept the LOINC and SNOMEDs and send it to us.

Arien Malec
Yes. So, the flow that I am trying to delineate is we have sometimes used the EHR certification program to capture certification requirements on the hospital lab itself, but it is actually the hospital lab that is the one that is sending ELR data. The provider is sending the order to the lab; the lab is sending the data to public health.

Erin Holt Coyne
Sure. I think it is the "update the certification program," not "create a new certification program," so whatever the certification program is today or has been, update it to reflect this standard, baseline, and floor. That is what the intention was.

Arien Malec
Got it, okay. So, we want to update the certification program requirements for ELR. Okay, cool.

Steven Eichner
The benefit, Arien, is that both a hospital's EHR and public health would have an easier time ingesting data from a LIMS system.

Arien Malec
Yes, I am being super pedantic, and I will stop being pedantic. I think Erin has this right. We have an existing program that captures the hospital labs, and we want to update the requirements for that program. Again, we want to say "baseline" and "target" both here and above, and we can resolve my comment. Cool, all right. Moving on. This is the LOI. Again, some wordsmithing. There has yet to be a certification program that requires electronic lab orders and receipt of electronic lab results, and so, we are recommending that ONC adopt, or in some senses, re-adopt, and I think we got three with four. I think we are okay. I think with the companion set, we want to say three here. Right, I think we want to say three here. Is that right? Hearing no objection…

Erin Holt Coyne
I had just put a comment on some of these, that you probably need to reference "the latest" as opposed to a specific release.

Arien Malec
"The latest," yes. Okay, and then, this one: "A threshold to establish use of LOI/LRI via portal ETOR should be established by…" I did not understand separate certification being established for web entry. I did not understand any of this.

Gillian Haney
So, this is the reality, that many public health laboratories and others still have web entry for test orders.

Arien Malec
I hear you. Do we want to establish certification criteria for web entry?

Gillian Haney
Yes. It is not going away anytime soon.

Arien Malec
What would a certification criterion for web entry look like? You could certify the web entry system as a certified system with the ability to send orders and receive results, or send results. I can wrap my head around that. I am having a hard time understanding certification for web entry.

Steven Eichner
The certification, at least to my mind, would look at replicating the ability to take in successfully consistent with the implementation guide.

Arien Malec
Yes. So, I totally agree. If there is a web entry system, it must be a certified system, in which case it needs to certify to the appropriate implementation specs, and I do not think we need to say anything about it. I certainly do not think we need to say anything about "establish use of LOI versus web entry."

Steven Eichner
The goal here is severalfold. One, public health would certainly, in many ways, prefer full electronic and interoperable submission of data. There may be some small providers for whom it is economically inefficient for them to establish interoperability on their end, so providing the opportunity for lower-cost manual entry via a web portal makes sense, but again, ensuring that public health is still getting all of the data that it needs to process the results becomes important, so certifying that interface so that it is consistent with the IP, in other words, performing the same function, same capability, and same level of detail **[inaudible – crosstalk] [02:06:39]**.

Arien Malec
Got it. So, this feels like a separate recommendation… For the self-certification point, we should have a separate system that says where, effectively, legacy web entry systems…

Steven Eichner
It is not even looking at a legacy. It may very well be a new offering, but again, looking at trying to support providers with different capabilities. If it is a small, eight-bed hospital, it may not be practical for them to spend $30,000.00-50,000.00 or whatever it costs per year to maintain an interface.

Arien Malec
I think we are just acknowledging that there may be web entry systems out there that will be certified, so we should punt it out of this recommendation and create a new recommendation. But, I do not think the threshold to establish use of LOI/LRI versus portal ETOR is a recommendation that we want to make.

Steven Eichner
Right. Well, that should be certified.

Arien Malec

I think we are agreeing. Where web entry is used, it should be certified.

Steven Eichner
Yes.

Arien Malec
Okay, cool. I do not think it is a separate certification, I think it is the same certification. So, I think what we are going to say is where…

Steven Eichner
Same certification, different test.

Arien Malec
Where web entry is used, those systems should be certified to the appropriate certification criteria. Cool, all right. Okay, and then we can wordsmith, delete, and clean this up. Last one. "We are recommending that ONC add LIMS and their supporting intermediaries to list certified health information technologies, adopt a certification program, and work with federal agencies to receive electronic lab orders and send electronic results."

Gillian Haney
I feel like this is a hugely important one.

Arien Malec
It is so important.

Gillian Haney
Maybe it should be up front, one of the first within this.

Arien Malec
Yes, this is the thunder strike from above. I think we want to say STU 4 for this one, because there is not one. Sorry, I got it. LOI 3, LRI 4. Do I have that right, Hans? Has Hans dropped? Okay, I think we are good. I think we have addressed the other two, so we can punt and delete. Okay, cancer. Maybe my comment got deleted. I am not sure. I thought I put a comment here. In any case, what I heard in the cancer registry meetings testimony that we heard was that, by and large, cancer registries are not using the implementation guide or are partially using the implementation guide, and what most of them are using in practice is something like an OMOP reference data model, a research data model.

Bryant Thomas Karras
That is only at academic health centers. That is not what registries are using.

Arien Malec
So, the question is whether the public health cancer registry implementation guide as it currently stands is sufficient for use and is widely adopted and used by cancer registries.

Gillian Haney

Can you say that again, please?

Arien Malec
Is the existing cancer registry implementation guide widely used and sufficient for use by cancer registries?

Erin Holt Coyne
This is Erin. I do not know if I can comment specifically on widespread adoption. I can say that our cancer registry here in Tennessee is using the cancer registry electronic case report, as well as the other laboratory-related interfaces that come in. If I remember correctly, there is also some work in the MedMorph project and elsewhere looking at the creation and promulgation of FHIR-based standards to support, but where that is in adoption, I do not know.

Arien Malec
That is right. So, MedMorph was also aligned with OMOP, if I recall. I feel like we want to say something here, and maybe it is in our second paragraph. We are just recapitulating the existing HITAC recommendations. Maybe we want to say something about potentially aligning to MedMorph and reference models such as OMOP.

Steven Eichner
I think Texas gets most of its data using specifications developed by NASIRE, not the HL7 IG, but I would have to confirm that with our program.

Bryant Thomas Karras
I believe that there are some suffering with modular and this not becoming one of the required criteria. As the people could pass to public health reporting with only two measures, cancer fell off, and our cancer program has had tremendous difficulty getting people to implement it.

Arien Malec
This is the classic “nobody is driving on the bridge that does not exist, so we do not need a bridge” issue. Let’s maintain as is, and note that we need to do future work for MedMorph/OMOP or reference data modules, etc., to better support cancer registries. Okay, ECR. So, here is another area where we need to reorder because we start with highly detail things like OID registries, and then, at some point, we should pull in that we really should certify to ECR, which is actually our second recommendation. Why don’t we go to our second recommendation first, and then go up? So, Erin, go ahead.

Erin Holt Coyne
I just wanted to say I did confirm we should go with the STU 3.1 guide, as opposed to the earlier version.

Arien Malec
Perfect, excellent. Thank you, Erin. So, “We recommend that ONC modify the existing certification criteria for case reporting to require certification for ECR,” and I just deleted a bunch of details, “and establish associated test methods, recommend a basic set of capabilities for consumption of EICR using 3.1, and optionally following the FHIR implementation guide.” Cool, good.

Erin Holt Coyne

Do we want to use the same baseline and whatever language from above here?

Arien Malec
Yes. So, there is another place where, because there is no baseline, we want to align to a target. The baseline is self-certification/functional certification as opposed to technical certification.

Erin Holt Coyne
Sorry, I was referring to the STU 3.1 versus the FHIR because we say "and optionally following."

Arien Malec
I do not know that we want to say that the CDA one is baseline and the FHIR one is target in this case, as much as I want to align the whole world towards FHIR, because I think most adoption has actually been on the CDA version.

Erin Holt Coyne
Yeah, I would agree.

Arien Malec
Okay, that is our base one. I think we have another one that we pull in later around reportability response, so when we pull that in, we want to move that one up. Oh, do not delete that one, please. Oh, you are moving it down. I see, got it. Thank you. Cool, all right. "We recommend that ONC work with CDC to establish a national public health organization directory, including OIDs and other clinical identifiers, for relevant organizations/facilities enabling consistent use and lookup." Erin?

Erin Holt Coyne
Why the reference only to public health organization directory? Because that is needed across the board.

Arien Malec
Yes, I had the same thought, to establish an organization directory. We want to say "organization." Potentially, that might be aligned with the CMS efforts to establish a provider directory, etc.

Steven Eichner
This is Steve. I think "and other stakeholders" should go in that space. So, we probably should include RCE and everybody else in that framework because we do not need…

Arien Malec
We do not need 10 directories that all say the same things. CDC, CMS, RCE…

Bryant Thomas Karras
APHL has an **[inaudible] [02:17:27]** directory.

Arien Malec
What's that?

Bryant Thomas Karras

APHL has had to build one out because it did not exist.

Arien Malec
And public health authorities and their partner organizations. Liz, can you just delete the HB colon above? There we go, thank you.

Steven Eichner
And I would include states.

Arien Malec
Yes, "public health authorities and their partner organizations."

Steven Eichner
No, but also include state Medicaid agencies. I would call them out specifically.

Arien Malec
Cool, good.

Bryant Thomas Karras
I would put the state Medicaid agencies right behind CMS.

Steven Eichner
They are wonderful partners. I would want to make sure they are included, not just CMS.

Arien Malec
Cool. Makes sense. Good, okay. I think we got this one. Yes, we got this one already. Yes, good. Delete. We are recommending that ONC work with public health authorities and partner organizations, as well as SDOs and technology developers, to ensure the certification programs and associated test methods are robust enough to reduce and eventually eliminate paper-based…" Okay, I think we already have standardized test sets addressed above, so we can delete that one. I think we want to delete this one because we already have a reportability response recommendation. Is this duplicative?

Bryant Thomas Karras
You went by too fast. Could you scroll back up to the last one you just deleted and let me finish reading it? So, you think this was added into the ECR one?

Arien Malec
So, we have a recommendation, which I think we are about to get to, that includes the use of the reportability response. So, we are certifying to the reportability response.

Erin Holt Coyne
Yes, there should be a separate one that is specific to the reportability response.

Arien Malec

So, if there is anything we want to pick up… Okay. Is this one duplicative? But this is the only one where we talk about reportability responses.

Erin Holt Coyne
Well, the next one is EHR-related receivers of a reportability response. That is right below it.

Arien Malec
Cool, thank you. So, the first one is EHR certification. Sorry, thank you. Cool. Though I forget which recommendation number it is, we need to include that first one and also see to the reportability response, right?

Liz Turi
I am confused. Are you talking about this one that we just deleted?

Arien Malec
Not the one we just deleted. Scroll up.

Liz Turi
Oh, this one.

Arien Malec
No, the one above. The real one above. So, we need to include reference to the reportability response, and this actually should not be "consumption," this should be "transmission." So, we want to transmit an EICR and consumer reportability response as an EHR, correct?

Gillian Haney
Yes.

Arien Malec
Liz, you have already made the note that we have to include…

Liz Turi
Yes.

Arien Malec
Okay. This one is public health data systems. Now I am situated appropriately. Here, I think we want to align on the target. Sorry, go up one more. There we go. So, now we are focused on recommending "ONC adopt a certification program to receive and send reportability responses." Cool, correct verbs. I think we want to delete the standard and just advance on the target.

Gillian Haney
Yes.

Arien Malec

Cool. I guess we have already addressed that one. Good. Oh, okay. Here is where we talk about "EHR vendors to receive reportability responses." Good, okay. So, we just want to move this one inclusive with the first one.

Erin Holt Coyne
Then the IG needs to reference 3.1, not 1.1.

Arien Malec
Yes.

Erin Holt Coyne
When you say "inclusive of the first one," what do you…?

Arien Malec
Okay, we are moving fast and furious. We have two basic recommendations, two overarching recommendations, foundational recommendations for ECR. The first one states that ONC will update the existing certification requirements for EHRs to explicitly certify to ECR, and where ONC will certify to ECR, they will certify both to transmit EICR and to receive reportability responses. So, we are taking this text here, which is around EHR receipt of reportability responses, moving it up into the EHR side, send EICR, receive reportability responses. The second major recommendation that we have is on the public health data system side, to receive EICR and send reportability responses, and then we have some additional recommendations around OID registries and the like. Cool. Okeydoke.

Gillian Haney
Would you mind scrolling back up just a second?

Arien Malec
We can remove "advanced." This is "optional" rather than "advanced." Cool.

Gillian Haney
There was a comment in the chat about "just receive a reportability response or receive and absorb process," and we probably want to make sure we are leaning towards "absorb and process."

Arien Malec
I got a reminder that we are out of time and we need to go to public comment.

Public Comment (02:26:20)

Michael Berry
Yes. Can we put up our public comment slide? If you are on Zoom and would like to make a comment, please use the hand raise function that is located on the Zoom toolbar at the bottom of your screen. If you are on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. So, let's just pause for a moment and see if anyone raises their hand. I am not seeing any hands raised, Arien and Gillian, so I will turn it back to you to close us out.

Next Steps (02:26:44)

Arien Malec

Cool. We will need the last meeting, though we made tons of progress today, so, hopefully, what we will do is take everything we chunked through, get to non-red-line, clean versions of the text, make sure that the usual things that happen when you accept red lines… If stuff does not flow, we will clean all that stuff up and submit fair, clean copy for review, and then, subsequent to the HITAC meeting, we will go through the last bits of our recommendation that we have yet to get to, get those cleaned up, and alas, we will send over the HITAC material late, and I do not know what to do about that. That is not what I like to do, but at this stage, I feel like that is where we are. I think we are pretty darn close to having a fair, final-draft copy for the HITAC's consideration.

All right, so, the fun will continue on 11/9. At the end of 11/9, we are shipping it, and the HITAC is getting it. So, let's make sure that we do the work between then and now to reduce variation and make sure we are close. As I said, I think we got through the most material stuff. Okay, we are over time. I thank you so much for all of your hard work and effort. I especially thank Gillian for persevering through COVID. I know how that feels. Thanks, everybody, and we will reconvene on the 9th. Thank you.

Adjourn (02:28:28)