Transcript

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

November 7, 2022, 10:30 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 (00:00:05)

Michael Berry
Good morning, everyone. I am Mike Berry with ONC, and I would like to thank you for joining the Public Health Data Systems Task Force, and this might be our last task force meeting, and I just want to take the opportunity to thank all of our task force members, our cochairs, and all of you for quite a bit of work over the past few months, so, thank you so much. All of our task force meetings, of course, are open to the public, and your feedback is always welcomed, either in the Zoom chat or during the public comment period that is scheduled later in the agenda. I am going to begin with rollcall of our task force members, so 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
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Heather Cooks-Sinclair? Erin Holt Coyne?

Erin Holt Coyne
Good morning.

Michael Berry
Good morning. Charles Cross? Steve Eichner?

Steven Eichner
Good morning.

Michael Berry
Joe Gibson? Raj Godavarthi?

Rajesh Godavarthi
Good morning.

Michael Berry
Jim Jirjis? John Kansky?

John Kansky
Good morning.

Michael Berry
Bryant Thomas Karras?

Bryant Thomas Karras
Present.

Michael Berry
Steven Lane?

Steven Lane
Hello.

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

Mark Marostica
Good morning.

Michael Berry
Aaron Miri? Alex Mugge? Stephen Murphy? Eliel Oliveira? Jamie Pina? Abby Sears? Vivian Singletary? Fil Southerland? Sheryl Turney?

Sheryl Turney
Good morning.

Michael Berry
Good morning. We may have some people joining us late, and this was a last-minute scheduled meeting, so some of our task force members could not join us, but thank you so much, everyone, and now, please join me in welcoming Arien and Gillian for their opening remarks.

Arien Malec
Good morning. Gillian, I will be the vocal person, just to save you from having to talk too much, but feel free to pipe up, as I know you will. We are landing the plane. We actually have the plane on the runway, we are braking hard, and we are hoping that we do not get the plane off the runway and actually get it straight to the destination. We have a pretty good draft. It has a fair number of edits on it after our last review. This is

our last review session prior to the full HITAC, so at this point, either we agree on the content or we cut it, and I think we are at a place where we have some pretty good recommendations that will help advance the public health agenda, and we would be desirous of just making sure that we close out all the language.

So, since last week, I guess since last Wednesday, we have been hard at work in editing a bunch of language, so in the first part of this, we will go through all the language we did edits in over the last few days, and then, we got almost all the way through the content last time. I think we stopped at cancer registries, and so, we want to go back and make sure that we have addressed all of the topics. Most of the topics with significant meat were already addressed, and so, we just want to make sure we get through the edits. So, if we can show the document… All right, thank you, Liz. Okeydoke.

Gillian Haney
Make it a little bit bigger, please.

Draft Disposition Working Document (00:04:44)

Arien Malec
All right. So, let's see. We did some wordsmithing of the introduction. For the first section, we just tried to highlight motivating the work that we are doing in terms of how we had a lot of information exchange during the COVID-19 pandemic, and yet, a lot of work remains, and so, this is now the time to go address it. I will let people look at the edits to this paragraph. Again, this is mostly stage setting at this point. Gillian, I am interested as to why you struck the sentence with "early detection and awareness of COVID-19 from existing syndromic surveillance speeds."

Gillian Haney
Because we really did not.

Bryant Thomas Karras
Arien, it was astute clinicians and astute patients, mostly.

Arien Malec
Got it. I am sort of thinking of Farzad, looking at the New York stream in early…

Gillian Haney
So, syndromic surveillance definitely became very useful as the pandemic went on and we were able to use it much more for situational awareness, but it really did not provide us with any early warning.

Arien Malec
Got it, okay. Fair point. As I said, I am anchored on Farzad, looking at the New York feed and seeing ILI signal in early March, before anybody knew that COVID was hitting, but yes, absolutely fair, so we will move on. So, basically, just motivating that it is a good time to move. Generally, edits for clarification in the next paragraph… Let's keep moving. Keep moving. So, we have holistically moved from certification of public health data systems to certification of public health technology. The justification for this is that by and large, we are not intending to have the system certified, we are intending to have modular interoperability components or technologies certified, and so, this is really in keeping with our general call for modular

certification, allowing public health authorities to assemble technology to create the systems in order to address their programmatic needs and policies.

So, you will see some wholesale revisions of public health data system certification to public health technology certification. Again, nothing has changed in terms of any of the wrapper. We just felt that that term provided better clarity for what it was that we were certifying, so here, you will see certification criteria for technology used. This should be "establish certification criteria" rather than "a certification criteria." Thank you.

Gillian Haney
Steven had his hand up. Steven?

Steven Lane
Sorry, I hesitated a little bit. Just the way you said that Arien… We are talking about certifying the systems that are used within public health, right? And so, call them systems, call them technologies; I guess that does not matter. However, are we still envisioning that, similar to what there is with EHR, there will be certification criteria and there will be systems that become certified against those criteria, and we will be able to say that California has certified health IT supporting their public health system? The way you phrased it…

Arien Malec
That is actually not the way it works, Steven. So, by and large, a provider attests to using certified technology by, in their attestation, naming the technologies that were certified for the criteria. In some cases, if they are using all-in-one technology, they name one system. In other cases, they may name multiple systems that add together to address the certification criteria. So, Hans, you might have some enlightenment here, but I would imagine this program would work similarly.

Hans Buitendijk
But, I am then hearing the same between you, Arien, and Steven in that, as a result, a public health agency/organization can state that they are or are not using certified software. So, whether their software is self-developed or bought from a vendor…

Arien Malec
Right, certified technology. They are using certified technology that addresses the criteria in the programmatics that they are attesting to.

Steven Lane
The fact that it is modular means I am using certified technology for ECR, I am using certified technology for ELR, etc.

Arien Malec
Yes, that is right, for the interoperability functions. Just to be super clear, the distinction that we are making here is that we are not certifying the end-to-end systems that are used by public health, and in particular, if we think about case tracking, or case reporting, or contract tracing, we are not certifying the functional

behavior of those functions as used by public health authorities, we are certifying that the technology they use has the capability of electronic case reporting.

Hans Buitendijk
We may have to put something in the document that it is indeed modular enough, granular enough. We know from firsthand experience in early days, particularly and possibly coming back up again with more complex workflows, that if it is not modular enough, that would create problems for providers and system developers alike because they are required to do more, so I think the modular part is critical to make sure that it fits.

Arien Malec
Yes. Hans, I think we addressed that. So, if we look farther down in our recommendation on modularity, we are very clear that the intent is for public health to be able to assemble technologies that address this.

Hans Buitendijk
I am comfortable with it. I just want to make sure that when Steven looks at it, it is indeed expressed as modular enough. Otherwise, it will not work, and we have seen that in the past, and we are hoping to avoid it in the future.

Arien Malec
Okay. So, we also did some work, which I think Liz is highlighting, to make sure our charge is in here.

Liz Turi
Yes. Actually, that is what I wanted to bring up. We actually have a specific section in the final transmittal where it actually calls out the specific charge, so I do not know that we actually need this paragraph there.

Arien Malec
Okay, that is fine. So, let's keep going. Again, just be very clear. This notion of "efficient and effective," and again, just reclarifying we recommend certifying the programs of public health authorities. Okay, no changes here. Let's keep moving. All right, public health technology and our definitions. A couple changes to definitions. No. 1 is where we use "provider," we use the definition provided in 42 U.S. Code, Section 300JJ. This is super geeky, but if you de-reference U.S. Code Section 300JJ, the term "provider" there is all-inclusive, all-encompassing, it includes physicians, hospitals, labs, therapists, home health, and long-term post-acute. It is a pretty all-encompassing definition. Again, "public health technology/certified public health technology," so, again, trying to make that clear. So, those are the changes to the front line.

Bryant Thomas Karras
Arien, I believe in those same 42 U.S. Code regulations, public health authorities are capitalized and referred to as "PHA," not lower-case.

Arien Malec
I am happy to upper-case "public health authorities." If we do that, we should do it globally. Anyway, let's not do the wordsmithing right now. Okay, let's keep going.

Liz Turi

The background section here was added to, again, provide context.

Arien Malec
Perfect. So, basically, grounding this in terms of the CDC Data Modernization Initiative, and then, we are going to put in an enumeration of all the hearings that we held just to show that we did our homework. All right, good. Next one. Okay, let us go to the edits that we did. So, again, just mostly wordsmithing. Here, "public health authorities in support of exchanging data for public health purposes, including those defined in the existing F criteria." So, again, all general wordsmithing.

Gillian Haney
So, I want to just draw attention to the comment I made on the right. There was some language that was removed around the optional data elements and the implementation guides that need to be required that we had embedded within specific F criteria as appropriate, and it got removed, and so, I would like that to be discussed and added back again.

Arien Malec
It is there. When somebody has actually gone and whacked it, it should be addressed in… Liz, I do not know if you can find… More to put it in the correct place. There we go. "Certification processes should include testing against public health defined use cases, establish a minimum threshold for conformance, inclusive of values marked as optional, that are relevant and critical to the public health mission."

Liz Turi
I am confirming that is in the general recommendations.

Arien Malec
Yes.

Liz Turi
Okay, though it might be worth calling it out in the introduction to general recommendations.

Gillian Haney
I would be in support of that. I think it is a really critical point.

Arien Malec
Yes.

Bryant Thomas Karras
For the sake of the documents, I am willing to conform with moving it from each of the individual sections where it is relevant to "overarching," but from past experience, in the translation from recommendations into actual guidance, measures, and testing criteria, those details often get lost in the shuffle, so we may want to have an appendix or have an ability to come back and, on a regular basis, say which measure is ELR, syndromic, or immunization, and whether some of those optional data elements need to be implemented in certain jurisdictions, therefore, the testing needs to allow for that.

Arien Malec

John, you have your hand up.

John Kansky
Arien, you had an artfully worded recommend about ensuring that these guidelines offer public health authorities the flexibility to use intermediaries. Is that **[inaudible] [00:18:40]**?

Arien Malec
Yes, it is there.

John Kansky
Okay, just making sure. I thought I had missed it. Thank you.

Arien Malec
Okay, so, let us keep going.

Bryant Thomas Karras
There were some changes that I am not seeing here anymore that explained the nuance that "optional" in HL7 language is not the same thing as what we are talking about here as optional, so maybe that is spelled out later in the general recommendations.

Hans Buitendijk
Later on, that is relevant and critical.

Arien Malec
I do not believe I ever saw that language, but again, I agree that the nuance of how different SDOs use the word "optional" is not the point. I think the point is that there are items named in standards and implementation guidance, some of which are named mandatory, some of which are named optional, but the ones that are optional, we need conformance testing against optionality to ensure that the systems have the ability that, when optional elements are named, that data actually transmits correctly, which is sort of the general point.

Steven Eichner
Added onto that is that "optional" does not mean optional to be implemented, but rather, "optional" means the submission of the data is optional, and I know it was written in there at some point.

Arien Malec
Again, that text that we just noted is that we recommend having our certification criteria test against fields that are marked as optional, so the certification test includes the ability to turn on and turn off optional data flows.

Steven Eichner
Right, but I think the second piece is also for providers to pay attention to public health authorities, looking at directions about reporting data.

Arien Malec

Again, just to be super clear, our mandate is on the certification criteria, so what we can do to affect that is make sure that the certification criteria include optional data elements so that EHRs or certified health information technology is capable of transmitting data that is marked as optional in the implementation guides. Whether the provider organizations implement the technology appropriately or capture the data are all real-world issues, but not the subject of the certification program.

Steven Eichner
Except that it does tie into testing the systems in real-world scenarios as deployed.

Arien Malec
Yes. So, again, I want to go through hands raised. We have Erin, who has her hand raised.

Erin Holt Coyne
I think if you went back to the comments that Gillian had made, it was a pretty lengthy comment. I believe that language that is being referred to is in that comment, if I remember correctly. Maybe not.

Hans Buitendijk
I was going to comment there as well. Recommendation 10 is where it says "not just marked as optional," which can mean a variety of things when you are in standards land, but it finished with "are relevant and critical to the public health mission." I think that should be enough indication to SDOs that they may need to make a distinction between optional that is relevant and critical and optional because it is in the standard and is not necessary otherwise. So, I believe it is sufficient in here, but we need to make sure that the SDOs follow up on that and mark accordingly in the guides.

Steven Eichner
I would like to change that text right there to "as defined by public health." I do not want to get into a discussion about who is defining what the public health mission is.

Arien Malec
Yes, health authorities and their…

Steven Lane
Well, is public health the only one who is defining criticality here? There is the whole provider world that is burdened by the challenges of public health exchange, and if there is one thing I have noticed on these calls, it is that sometimes we have different perspectives on the value of pushing forward.

Steven Eichner
The text that I am suggesting is consistent with current language on HIPPA, which basically says public health can define what it needs to achieve its goals.

Steven Lane
Okay, that is fair.

Arien Malec

Steven, let me just give an overarching view as we have drafted these requirements. Our goal is to achieve a floor level of interoperability that reduces burden for both parties. Because there is necessarily jurisdictional variation…

Bryant Thomas Karras
No. The charge is not to just make a floor, the charge is to make recommendations that improve our country's ability to have a public health response.

Arien Malec
Yes, absolutely fair.

Bryant Thomas Karras
A floor is not enough.

Arien Malec
The goal of a certification program is to raise the floor to create a public health data exchange that is both efficient and effective, and part of that goal, and again, we will see language specific to this, is to make sure that out-of-the-box EHR technology can be deployed to address predictable and common variation between jurisdictional variation. So, Steven, the intent here would be that we reduce the burden on the provider organizations as well as reducing the burden on public health authorities by making sure that the certification out of the box includes actual data elements that can be configured and deployed. Now, just to be super clear, that does not mean that there will be some jurisdictional variation that is outside of the floor that will create special effort, and to some extent, that is unavoidable, but our goal is to raise the floor to address the efficient and effective interoperability that improves the public health mission. Let's keep going.

Bryant Thomas Karras
I think Erin made a motion to pull Gillian's comment into the text, and I did not…

Arien Malec
That is right. I think we have already agreed.

Bryant Thomas Karras
Did it get pasted in, though?

Liz Turi
I made a note to include her note here so that we can paste it in.

Arien Malec
Right. All right, let's keep going. Sorry, Gillian, there is something to discuss here. Was this your edit up here? Go on up.

Gillian Haney
Where are you?

Arien Malec

This is the one where you said to delete.

Gillian Haney
At that last call, there was some wordsmithing from the paragraph above, and I tried to edit it down a little bit to make it clear, so perhaps we do not need that edition any more, but that was my suggested edit, and I did not think we needed to get as granular as that.

Liz Turi
So, strike what I have highlighted here?

Gillian Haney
As long as people feel that it is covered in the previous paragraph's edits. That now addresses the issues that were raised last time. So, hearing nothing, I say yes.

Arien Malec
Okay, cool. All right, so, here is the modular certification point. "We recommend certification criteria be modular; that is, public health technologies by public health authorities or partners does not need to be certified for use unless the," and again, we should spell out "public health authority," "is using that particular technology for the purpose for which certification is applicable. It should be noted that public health data systems may have multiple applications and functions. It is therefore necessary to certify the functionality, not the system itself." So, again, we are certifying the interoperability, not the end-to-end system.

"Any certification program must provide public health authorities with maximum flexibility in selecting and implementing certified technology," again, making the point that Hans did about the need that modularity needs to be flexible enough to allow public health authorities to mix and match. "These technologies may be owned or managed by the public health authority," there should be a comma here, "shared between or among public health authorities or consumed as a service, and/or through intermediaries such as HIEs, APHL, and others according to the legal policy and procurement practices and rules governing public health data systems and the relevant jurisdictions. Pathways to use certified technology should include the use of third-party testers as well as the capability of public health authorities to self-certify. Both must use the common set of testing criteria." So, again, I think this addresses the comments that have been raised in terms of modularity of certification. Steven?

Steven Lane
Two points. One is I would update the text to say "HIEs/HINs," just so that there is not confusion about that being a more restrictive definition, and then, I did put a note in earlier, back in 51, in the chat, and I think this is a section where this would belong. We keep talking about modular certification, but are we defining in this document what are the boundaries or the list of those modules? Do we assume that those modules match the existing F criteria, or are they yet to be defined?

Gillian Haney
So, do you mean specifically public health systems outside of the F criteria that are not listed, like vital statistics, for example?

Steven Lane

Module 1, Module 2, Module 3: Do those track exactly with the existing F criteria, and/or are they going to be different or are they going to be potentially more than that?

Arien Malec
So, the intent would be that certification would be to the interoperability criteria and the F criteria, and that… Again, we are presuming that at some point, let's say CDC, in procurement, requires the public health authority that is procuring a system that CDC is providing funding for to use technology that has been certified for ONC criteria, blah blah blah, and that the criteria would be to the interoperability requirements associated with that criteria. So, modularity is defined by the criteria.

Steven Lane
I think we should state that explicitly.

Arien Malec
Well, we are saying the criteria… "We recommend that any certification criteria of public health technologies be modular."

Steven Lane
And then, that the public health systems will certify to those… So, the modules equal the criteria, the modular certification on the public health side.

Arien Malec
Any certification program must provide public health authorities the maximum flexibility in selecting and implementing certified technology, and then, multiple pathways to use the certified technology.

Steven Lane
I still feel like we are missing this point, and maybe it is just me. When I say that I certify to a module, that I have a modular certification, that it is for F1, F2, etc., but those define the modules.

Arien Malec
I think you are saying what we intend to say. So, if there is a friendly edit, I think we would be happy to consider it and make that edit. All right, let's go to Recommendation 2.

Bryant Thomas Karras
Arien, was it Steve that was making the point? Steve, I think that when we get down into the specific F criteria recommendations, there are several of them that we try to become more specific about what we mean by the implementation guide that the modular certification needs to be updated to the latest guide.

Arien Malec
Right, and in some cases, our revisions to F criteria actually include multiple tests and multiple certifications, and so, again, I think we would want that to be modular. Okay, let us keep going. Recommendation No. 2. I think we have split this one into multiple… Okay, "Ensure the data used in F criteria reference the standardized code and value sets. We recommend that an order improve patient matching." So, we did Paragraph 2 to be specific to patient matching. Paragraph 3 is specific to value sets.

Gillian Haney
And is intended to be broader, yes.

Arien Malec
We provided context for Recommendation 3, which is about modifying the certification program to make sure that we do conformance testing and real-world testing for the ability to update value sets. We put in a header that noted that failure to update value sets impeded interoperability and created issues, so we recommend, in the first recommendation, "certification programs demonstrate the ability of technologies to include and regularly update relevant standardized value sets without special effort for competable semantic interoperability, technology to adopt standardized vocabularies and terminologies," and then we reference LOINC and RMS.

Bryant Thomas Karras
Arien, on that last point, ONC just did a presentation here at the AMIA conference analyzing some survey data from providers and their ability to include standards like LOINC in their messages to public health, and it is worse than we thought, so I think we might want to reference that report and…

Arien Malec
If this is something Liz can help us do, if there is a readymade reference that is published, I am happy to do it.

Bryant Thomas Karras
There was a panel that had both the ONC presentation and the HIE STAR findings.

Arien Malec
Yes. We are in crunch time, and so, we are going to drop stuff if we do not have clear language for it. Okay, Gillian, I think you added the last sentence, and I am proposing striking it because it is addressed down below, but there are two issues with the sentence. 1). It is out of place here, as it is actually addressed in the lab recommendations, and 2). We do not do recommendations to HHS; we do recommendations to ONC. So, anyway, this one was out of place and somewhat problematic in terms of our authority. I totally agree with the point.

Gillian Haney
Isn't there somewhere else in the text where we did recommendation, though?

Arien Malec
We do. It is in our ELR section.

Bryant Thomas Karras
Can't we recommend that ONC coordinate with HHS to make sure that the other federal partners…?

Arien Malec
We do, yes.

Bryant Thomas Karras

So, I do not think it is out of scope.

Arien Malec
Liz, to clarify this one, can we jump down to the ELR section and make sure it is in there? Okay, cool. Here we go. "We recommend that ONC follow relevant guidance provided by the interoperability standards workgroup and approved by the full HITAC regarding laboratory orders/results, particularly those addressing transmission/receipt of orderables and results sufficient to trigger reporting criteria, transmission of minimal demographic and contact information, comprehensive use, and normalization at the source of key terminologies, including LOINC, SNOMED, UCUM, UDI, and others relevant to public health data flows, adoption of latest LOI and LRI implementation guides. We note that addressing those concerns solely via certification of the ELR interface, laboratory to public health, does not address the upstream workflows or where data necessary to the public health mission originates."

And then, we probably should put in… Well, actually, all these implementation guides we are referencing include, by reference, LOINC and SNOMED, so the coding systems for all the implementation guidance that we reference, where we are actually making recommendations to certify EHRs for orders, labs for both orders and results, public health data systems for results, all reference LOINC and SNOMED. And then, the report that we reference, if people have not read it, goes into great lengths about exactly these points, about the need to standardize at source, the tools available to standardize at source, etc.

Bryant Thomas Karras
But to make these changes actually happen, there needs to be some kind of lever, and ONC is not going to be able to influence that. It is going to need to be HHS.

Arien Malec
That is correct. So, if we look at the lab section…

Bryant Thomas Karras
I thought I just saw the HHS stricken.

Gillian Haney
Yes, the second one.

Arien Malec
Hold on. Liz, if you go down to Recommendation 6, we will see if that is the one.

Gillian Haney
Would it make sense to lead with that one in this section? Because it is pretty critical.

Arien Malec
Yes. So, Recommendation 6 recommends that "ONC adopt a certification program…" There is the issue of what the incentive structure is, and again, if you read the report and recommendations that we issued, we make specific recommendations about incentives, so, Liz, maybe we can go to Recommendation 3, I believe. No, not Recommendation 3. Which one is it? Maybe 4? No, not 4. There it is, Recommendation 5,

right here. So, maybe we can say, "We recommend that ONC follow the relevant guidance, particularly those addressing…" Let me just add some text here into the chat.

Bryant Thomas Karras
Can you explain to me why you wanted to strike it out above?

Arien Malec
Because where it was, it was about certification criteria, and so, incentives to CLIA labs in the context of certification criteria was misplaced. The second issue is our recommendations are to ONC to work with partner agencies, which is a point I completely agree with.

Bryant Thomas Karras
After striking it, I am not seeing where it goes, and if we only put it in the ELR section, then it is not applying to case reporting, and syndromic, and all the other areas that we need it to report.

Arien Malec
That is right. So, case reporting lab data is going to come via the ELR requirements, or come via the requirements we are making in ELR, which include certification for labs and include certification for ordering.

Steven Eichner
But it also applies, to Bryant's point, to other data for other messages like syndromic surveillance and other messaging that includes SNOMED and LOINC codes.

Arien Malec
Yes. I completely agree. I guess my only point is that the way that data comes encoded is via ingestion of either sending of an order or ingestion of a lab that has been appropriately encoded.

Steven Eichner
No, it does not. It comes in **[audio cuts out] [00:42:50]**. It comes in through a syndromic surveillance message. It does not include a laboratory order or a result. As an example, it could very easily come in through a trauma message that does not include laboratory result information, so there are lots of places where that data could come in that is not a laboratory order or result.

Arien Malec
Right. So, in those cases, that would come in through the coding of the patient for their chief complaint.

Erin Holt Coyne
It is my understanding that LOINC, SNOMED, and other standardized vocabulary could certainly be used for other observations in the medical record that would be used to contribute towards a case report, so it is beyond lab orders.

Arien Malec
That is absolutely correct. Any assessment could have a LOINC code. Clearly, a diagnosis or chief complaint could be mapped to SNOMED, so in those cases, that coding is already addressed via the certification program.

Bryant Thomas Karras
But it is not. It is in the guidance, but it is not actually tested for in the certification.

Arien Malec
That is right. So, again, we are recommending…

Bryant Thomas Karras
And that is where we need the certification program effectively has a recommendation from ONC that there needs to be a reopening of the process to go a little deeper, because as we found out in COVID times, we did not get what we thought we were going to get.

Arien Malec
Yes. Liz, we should wordsmith this one. "We recommend that ONC coordinate" rather than "in coordination."

Steven Eichner
The problem here, Erin, is that while the EHR system or the lab bench may be saying the LOINC or the SNOMED code, the difficulty is that once it is in the field, it is often deployed in such a way that providers are not using LOINC or SNOMED codes natively, or they are not getting converted to LOINC or SNOMED codes on the send-out, which means public health **[inaudible – crosstalk] [00:45:16]**.

Arien Malec
That is right. So, there are two issues I want to be clear about. One is with respect to lab transmission, we have a subset of labs that are not using LOINC or SNOMED for encoding of lab data, and so, data comes in coded to proprietary codes, and it is not available for trigger conditions. In the report, the incentives or the certification program for CLIA and non-CLIA labs and the ability to address the full chain from order, to result, to transmission to public health labs is the lever that we are including here. The second issue that is mentioned, which is that it may be the case that an EHR is certified to be able to collect, for example, a problem list via SNOMED, but physicians use other terminology in practice, is addressed through the real-world testing provisions in these recommendations.

Anyway, I am trying to land the plane here. I think we agree here. Okay, let's go to the next section, which is something that Gillian had some concerns about. The intent here is that not only is the certified health IT certified to be able to update value sets, but that value sets are, in fact, updated on a timely basis. And so, the specific recommendation here is that we recommend that ONC create operating rules inclusive to service-level agreements for timely updating of such value sets. Gillian, you had a concern about this one.

Gillian Haney
Yes. I do not think we can recommend anything about SLAs because those are done in coordination at the STLT, no?

Arien Malec
So, the intent here was that we should have baseline expectations of what timely updating of value sets looks like, and that real-world testing should be able to address timely updates. I am more than willing to

accept or look at friendly amendments to make that point better, and if we disagree about that basic point, then we should strike it, but the intent is there should be a floor level of timely updating to value sets.

Gillian Haney
I agree. It is the language around SLA that I am having issue with.

Arien Malec
Okay. We can strike "inclusive of SLAs."

Gillian Haney
Steve, do you have language?

Steven Eichner
I do not have language. The concern about standardized operating rule, in part, they need to be influenced by public health, is that changing things like trigger codes impacts things like case counts, so, from a timing perspective, it becomes critical on the public health side that there be an identification of timing. Another concern is that there are different security protocols that are in place, looking at automatic updating, that an automatic update would drive our security folks…

Arien Malec
We are not talking about automatic at this point. We already struck "automatic," and we are just talking about "timely."

Steven Eichner
But it comes down to looking at the build of the operating rule, who is building it, and if you wrote that into it on the back side, you have reintroduced the problem without public health sitting at the table to design those operating rules.

Arien Malec
Let's just note "in conjunction with relevant partners, including public health authorities and their partner organizations."

Steven Eichner
I would suggest "public health should develop."

Arien Malec
No, because these operating rules are inclusive, not just of public health concerns, but also provider organization concerns, so value sets are not used solely for the purpose of public health authorities, they are also used for clinicians performing clinical practice.

Bryant Thomas Karras
Now, I am going to say that is out of scope, Arien. This is a public health data systems task force, not a clinical response task force.

Arien Malec

I got that, I understand, but if we say that public health authorities are the only relevant parties for operating rules for updating of value sets…

Steven Eichner
They are certainly relevant for updating the operating rules for updating data sets relevant to public health.

Arien Malec
Yes.

Gillian Haney
Yes, I was going to say, why don't we put in a caveat to say "appropriate"?

Arien Malec
All I am saying is that "in conjunction with relevant partners, including public health authorities and their partner organizations, create operating rules," and then we strike "inclusive of service-level agreements," "for timely updating of such value sets."

Steven Eichner
"Supporting public health reporting." I want that to be a key piece in it as well because it is not helpful from…

Arien Malec
That is fine. Okay, perfect. That should be "in support of public health" or "supporting public health," but not "in supporting public health." Sorry, Liz. It is frustrating to edit in real time. Perfect. Okay, cool.

Gillian Haney
Do we need this now? Oh, that is "incentives." Never mind. All right, with this one, I was having trouble understanding what we were trying to actually say here. Could you scroll up a little bit more?

Arien Malec
So, this is the point that we have jurisdictional variance in terms of optional data, so, in terms of data that is transmitted, and it would be desirable that the implementation guidance that we use is able to be used across multiple jurisdictions. We have specific examples, for example, for immunization reporting, where AIRA noted that different jurisdictional rules for consent and for inventory handling caused local customization of the immunization standards to address jurisdictional requirements. As we update implementation guidance, it would be good to make sure that we have updated predictable variation, jurisdiction by jurisdiction. Again, there is a floor that works out of the box.

Steven Eichner
How do we tie that back to certification?

Arien Malec
This one is a recommendation that "ONC coordinate to update and align relevant HL7 blah blah blah and other guidance to map to USCDI, and then, as part of the alliance, we recommend that ONC work with public health authorities to ensure that standards implementation guidance address predictable policy-

based blah blah blah," and so, presumably, which I think you are calling out, we would then update certification criteria or update SVAP-based certification criteria to include those changes.

Steven Eichner
Okay, that makes sense, thank you. I think that is a valuable addition. A concern I have about SVAP, which I think we touch on later, is that vendors updating to an SVAP protocol that is not backwards compatible can break certification if SVAP technologies do not have to be certified before they are deployed.

Arien Malec
Yes. So, the way that SVAP theoretically works is that you certify to the floor, and then optionally certify above that, and yes, I completely agree that SVAP needs to be backwards compatible.

Steven Eichner
And certified.

Gillian Haney
That is addressed later.

Bryant Thomas Karras
Earlier, this recommendation had race, ethnicity, and preferred language specifically expanded out under SOGI.

Arien Malec
Second paragraph.

Bryant Thomas Karras
I worry that SDOH is not necessarily the thing to call out a need for a more granular race/ethnicity.

Arien Malec
Second paragraph.

Bryant Thomas Karras
All right. **[Inaudible] [00:54:45]** to better… Okay.

Arien Malec
Cool. Okay, minor edits for "public health authorities and their partner organizations." Gillian, this one came from Joe Gibson, recommending deleting it.

Gillian Haney
There will be very distinct data flows, and I think there is still some discussion about if there is redundancy there.

Arien Malec
Oh, this one. Got it, cool. This one came, then… Okay. Let me just orient correctly. This is Hans's. Over time, we should align implementation guidance to make sure that where data needs to be integrated, we

actually are modeling data the same way, so that where we want to, as an example, incorporate electronic labs and then integrate with ECR, we should be making sure that the data requirements for those two things are aligned.

Gillian Haney
Can you comment on my suggested addition and replacement language?

Arien Malec
Sorry. I am struggling with the user interface here. "We recommend that data elements needed to support the current and future F criteria should be included in adopted versions of U.S. Core Data for Interoperability to ensure…" Yes.

Gillian Haney
I am more comfortable with that language than with the previous one, versus "that data will be integrated between lab case and administration flows **[inaudible] [00:56:52]**." The integration is done on the public health side.

Arien Malec
Yes.

Hans Buitendijk
What I have is the reference to USCDI, because here, the intent was…

Arien Malec
It is not "U.S. Core Data," it is "USCDI." That is right. "U.S. Core Data" is sort of legacy.

Gillian Haney
Okay, please edit.

Arien Malec
"U.S. Core Data for Interoperability" is USCDI. Okay, sorry. I think that is right. Hans?

Hans Buitendijk
I am just comparing the thing that Gillian is suggesting to drop. I am trying to figure out where that goes.

Arien Malec
I think Gillian's point is that we should not be presuming or recommending data integration by public health authorities, we should be focused on the interoperability requirements to make sure those data are integrable, and I think that is saying the same thing.

Hans Buitendijk
Not quite, because USCDI would not be able to address part of what it is trying to address. So, I understand if you are saying that the recommendations should not go into the public health architecture of their HIT and how they share it, yet, at the same point in time, optimization on the provider side that is sending the data would benefit from aligning in two ways. One is that data definitions are consistent, and USCDI can

help in part, but USCDI is currently not addressing everything that is in this standard, so we still have to look at the standard itself, that there is consistency of the data being used in either one, wherever they are used, it is the same data if it is meant to be the same data. The other part is the optimization of the flows from a provider perspective. There is relevancy to that because data is flowing in suboptimal ways at this point in time, and we need to figure out how we can better balance that without judging exactly on which need what needs to be done. That is fair in this, but it is still an area to look at because the current flows are not optimal.

Gillian Haney
I agree with everything that you have said. I just do not want there to be anything that suggests this redundancy. I am just uncomfortable with that last sentence specifically: "Data will be integrated between lab."

Arien Malec
Yes, just strike that last sentence.

Hans Buitendijk
If you strike that…

Arien Malec
That was just for purposes of example.

Hans Buitendijk
I am not necessarily seeing that the part before requires and imposes on public health to align their data structures, etc.

Arien Malec
It also does not imply that the data are redundant.

Hans Buitendijk
Keep on going through the others and see whether we can **[inaudible – crosstalk] [01:00:18]** wording.

Arien Malec
Yes, let's keep going. Can we agree that this wording is good enough right now, with that language stricken?

Gillian Haney
Yes.

Arien Malec
Okay, cool. Let's keep moving. This was just reflecting previous commentary. We will capitalize "We recommend eventual certification program." We note that certification criteria for TEF query includes both public health ability to generate and receive data as well as potential responsibility to process and respond to the query. There are more targeted and nuanced FHIR-based requirements that do not… Okay. So, this is the one, Gillian, that you recommend deleting. This is the one that is from Joe.

Gillian Haney
Yes, I think this is a highly aspirational comment there. That is my concern.

Arien Malec
I have no strong feelings about this. I know that Joe felt strongly. He is not on the call. Does anybody else feel strongly enough about this one to argue for keeping it?

Michael Berry
Joe is here. We will get him to do *6 and do the last four of his number.

Joe Gibson
Can you hear me now?

Gillian Haney
Is that Joe? Bryant?

Michael Berry
Joe, what are the last four digits of your cell phone number?

Gillian Haney
Are they trying to get Joe on the line?

Michael Berry
2701, if you can promote the phone…

Liz Turi
You can just talk.

Michael Berry
Go ahead, Joe. You can just talk.

Joe Gibson
Sorry, I am trying to catch up.

Liz Turi
It may not pick up because of my headphones.

Arien Malec
Okay. So, Joe, if you are able to talk, we have this recommendation that originally came from you, which is about transmission of data between public health authorities themselves, so, between states, for example, or between counties of a state, and in between public health authorities and other actors, inclusive of schools. So, we have heretofore addressed recommendations that are specific to the F criteria between EHRs and public health authorities. This was a recommendation that "ONC coordinate with public health authorities and their partner organizations, SDOs, and other stakeholders to develop and test standards that address inter-public-health-authority transmission of data as well as public health authority

transmission of data and non-EHR actors." So, I think Gillian's point is this is aspirational, out of scope, and could potentially derail things, and I think you were the one that felt very strongly about this one.

Joe Gibson
If we are going to move data from healthcare to public health, I believe it is going to involve moving some of that data within public health agencies.

Gillian Haney
I am sorry, I could not hear Joe.

Michael Berry
Here, Joe. Use some of my earwax.

Joe Gibson
Sorry, I am on my headset. If we are going to transfer data among public health agencies, or if we are going to get data from healthcare to public health agencies, some of that data is going to go between public health agencies. It is not all going to go from healthcare to public health.

Bryant Thomas Karras
This is Bryant now. I think between public health agencies…

Arien Malec
We are getting feedback.

Bryant Thomas Karras
…we are going to get some pull-off, but I am nervous that adding schools as example makes it hard for us to regulate.

Arien Malec
Okay. We can do two things here. We are an hour in. We have to close this document.

Bryant Thomas Karras
So, did you hear…?

Arien Malec
I did hear the point.

Bryant Thomas Karras
Okay, if we can take out schools, he would be okay with it. Would that make it less aspirational?

Arien Malec
Gillian, would you be okay with whacking "other actors," whacking the whole last paragraph as well as "between public health authorities and other actors"?

Gillian Haney

I think that is vaguer. That is fine.

Arien Malec
Cool. Let it be done, let it be whacked. We are missing a period now. Cool, thank you. All right, let's move. Okay, so, we want to work with public health authorities and other partners to explore how TEFCA consent practices might be leveraged to enable sharing across jurisdictions. So, this was maybe more specific. Rather than establishing a privacy consent mechanism, I think Gillian recommended looking at the TEFCA consent practices. Objections? Let's move on. So, Gillian, you had a concern here that we are really talking about law and regulation, so I think this is Hans's point that where there is policy variation, it would be useful to start to file it down by establishing best practices.

Gillian Haney
I am trying to read through this.

Arien Malec
My sentence was "without limiting the ability for public health authorities to develop and enforce local policy, we note that where equivalent alternative approaches achieve the same policy outcome, it is helpful to establish policy uniformity." Again, this could be a little bit of a trap.

Gillian Haney
Yes. What is ONC going to do, work with every state legislature?

Hans Buitendijk
It is **[inaudible] [01:07:38]**, but you are just creating friction at times where it would be helpful for there to not be, while still recognizing the needs and the rights to have individual policies, but where we can encourage alignment out of that collaboration, it would be great. I agree, it would not just be ONC, it would be working with whomever: CDC, ONC, appropriate parties, all the states, all the STLTs. Is there a way?

Bryant Thomas Karras
Yes, Hans, but virtually, it is not the STLT health authorities that you would need to work with. You would have to hire lobbyists in every single local congress and senate to change rules and regulations. Changing constitutions of states is not going to happen overnight.

Arien Malec
We are hard pressed for time, so, whack it?

Steven Lane
Crap, sorry. If this goes back to that Kansky-esque comment about trying to have guidance on policy best practices…

Arien Malec
I think it was that damn Kansky guy.

Steven Lane

Yes. We are not trying to imply that you need to work with every public health authority. We are trying to imply that, to the extent possible, ONC do something to help public health authorities understand that there are either best practices or policy barriers to avoid in their state in general.

Hans Buitendijk
There are probably two levels. There is the policy level, awareness and otherwise, and there is the implementation of policies that, even though the policies are the same or similar enough, that standards are being implemented differently. So, I think there are two layers that sit in here that, wherever possible, we need to find ways to minimize that.

Arien Malec
There are two paths at this point. 1). We can delete it and move on, or 2). We can keep it and move on.

John Kansky
I am on Team Keep, but I may be outnumbered.

Hans Buitendijk
I would join you, John, but we still might be outnumbered.

John Kansky
Well, Team Keep is the one speaking up, so we win.

Gillian Haney
Good luck with that.

Hans Buitendijk
We are running into it frequently.

Arien Malec
Let's keep going.

Steven Eichner
Arien, I would note it as an issue that we could not resolve in the report. Again, acknowledge that it is a potential, but not resolved.

Hans Buitendijk
No clear recommendation for it.

Steven Eichner
Correct.

Hans Buitendijk
That is reasonable.

Arien Malec

Cool, let's do it.

Bryant Thomas Karras
I would argue we could make recommendation; we just need to be realistic that it will take 10 years for it to change. I do not want to make our committee seem unsuccessful, as we have recommended the impossible.

Steven Eichner
I would refer to it as an idea to be acknowledged that requires more…

Arien Malec
Not a recommendation.

Hans Buitendijk
Ten years still might be before my retirement.

Arien Malec
Right, good. Let us keep going. Now we are up to the actual F criteria. Okay, let's keep going. I think we are okay here. We did not make any changes. Syndromic surveillance… Again, mostly just edits for clarity. This comes from the previous HITAC recommendations. Again, I think this was from the previous HITAC language, where somebody noted that laboratories are not an actor that submits syndromic surveillance.

John Kansky
I think there may be a newly updated draft of the syndromic surveillance implementation guide, but it is not draft. Weren't there some unresolved comments that we were waiting…?

Liz Turi
That is just part of the STU process.

John Kansky
We could make a recommendation that ONC work with CDC to make sure that it keeps maintaining, that comments are resolved in a timely manner.

Arien Malec
That is too detailed.

John Kansky
It is a coordination job.

Arien Malec
Yes, I know, but "we recommend that ONC work with CDC to resolve comments" is one level detailed in terms of recommendations.

Steven Eichner
It is not resolving comments, it is pushing to get them resolved.

Erin Holt Coyne
Or maintain standard reference if they have a lifecycle.

Arien Malec
So, we recommend that ONC coordinate adoption…?

Gillian Haney
And maintain.

Arien Malec
So, not here, Liz. I think what we are doing is "We recommend that ONC phase out and replace the reference to the version of the syndromic surveillance standard included in the CURES final act, and coordinate publication of the most current version during the next relevant regulatory update."

Bryant Thomas Karras
I think somebody said "maintenance."

Arien Malec
Yes, "publication and maintenance." Cool. So, "publication and maintenance," and then strike the sentence after this sentence.

Bryant Thomas Karras
I think the challenge here is that HL7 relies on folks contributing actively to the maintenance, and when the CDC dissolved ISDS, there was no longer a body of academic and technical workforce that was evolving that standard. It died with the funding cuts.

Arien Malec
So, why don't we strike "laboratories" because the comment is not relevant. Okay, done, move on. All right, lots of deletion here. So, basically, Liz, just note we need to reorder… Where are we now?

Liz Turi
I just moved over to the rewording that Hans and Joe did.

Arien Malec
I thought we were at ELR at that point. Oh, is this ECR? This is ECR, got it, cool.

Liz Turi
Yes, we just moved it to ELR.

Arien Malec
Thank you, sorry.

Liz Turi
But, this is the rewording from here.

Arien Malec
Okay, got it. Sorry. This is detail focus. This is on the transition from ELR only to ELR plus ECR, and this was edits to my up-front language and recommendations. So, "In the current state, when ECR is in its early stages of adoption, ELR has to carry additional information to make available to case investigators. However, capturing this information on order or at the performing laboratory may require updates to legacy systems and is burdensome.

As ECR becomes more broadly deployed, much of the additional data needed for public health is more appropriately captured during a clinical encounter, better communicated through electronic case reporting. ELR data should be focused on the data set required for interpretation of the results, as well as for contextual, demographic, and contact information required for patient matching and jurisdictional assigned for follow-up. Therefore, we recommend that ONC support and coordinate with public health authorities and partner organizations, CDC, and standards development organizations to continue to delineate laboratory-based reporting from electronic case reporting. In context, where ECR is widely available, the ordering provider will often be the most appropriate to submit contextual data. Where laboratories perform walk-in testing, they play the role of ordering provider, and thus should use electronic case reporting for observations collected at the point of collection." That is our recommendation. Objections?

Gillian Haney
I like it.

Arien Malec
Let us carry it forward.

Bryant Thomas Karras
I do not object, I just want us to realize that a lot of drive-through testing facilities were operated by public health agencies. We do not have the tools in place to do ECR from a drive-through or pop-up lab testing environment, so it may continue to need to be ELR.

Gillian Haney
Noted.

Arien Malec
Okay, let's keep going.

Bryant Thomas Karras
Or, unfortunately, Redcap and flat files.

Arien Malec
Okay. "We recommend that ONC adopt certification criteria…" Now we are ELR. Did we move off of ECR?

Liz Turi
Yes.

Arien Malec
Got it. Thank you, Liz. I am now situated appropriately. We want to make sure that we start with the certification program for ELR, and then we insert that consensus language below these foundational requirements. Cool. Now we are talking about updating or creating certification criteria for public health technology for ELR. These are the foundational requirements that we previously mentioned, where we are proposing certifying all of the actors, inclusive of public health technology, EHRs, and laboratories, as well as normalizing at source. All right, I think we are okay, Hans, in terms of STU 3.

Hans Buitendijk
There is actually STU 4 just published.

Arien Malec
Yes, STU 4. The target is STU 4. I think we are okay. Baseline, STU 3, target, STU 4. Okay.

Steven Lane
Should we comment that it will continue to advance as the standards advance? The target is keeping up, right?

Arien Malec
Yes. As much as people want to get into the SVAP conversation, it feels like we do not have enough time to craft finely honed SVAP language.

Hans Buitendijk
Other than, perhaps, an overarching statement that you just have to be careful.

Arien Malec
Yes. If somebody has good overarching language that they want to propose via chat right now, I think we can consider it. Otherwise, we are going to have to punt.

Hans Buitendijk
The only other part that came up that we can perhaps leave out is that the more current guides that were written that acknowledge that systems are supporting older versions of the standards, but they need to add new things to it because of the pandemic and otherwise, etc., and that they have been written that you can modularly accept pieces of the new guide to ease the path. I am not sure whether we want to get that granular.

Arien Malec
We have half an hour.

Hans Buitendijk
Yes. That is what the comment is.

Arien Malec
We have half an hour. We have zero time. We are done. If we do not resolve something, we delete it, and if we do not like that we deleted it, we should get to it. Let's keep going.

Bryant Thomas Karras
Do we still have Wednesday on the books?

Arien Malec
We can, but what we are doing at that point…

Bryant Thomas Karras
Just explicit, little, all-agreed-upon insertions.

Arien Malec
The reason we wanted to move it to Monday is that we are not giving the HITAC the ability to read it.

Bryant Thomas Karras
Understood, but if we have that for things that need just a touch more clarification, they could have the near-penultimate draft, and then, with an understanding that there will be a couple of additional red-line insertions the day before their meeting.

Arien Malec
Sure. It would just be good for us to get through all of this language in the next half hour.

Bryant Thomas Karras
Keep going. I am not suggesting we do it now.

Arien Malec
So again, here, just to be clear, we are making recommendations. We have already reviewed this text. This is all just edits. We are making recommendations for certification criteria for public health technology used by public health authorities, EHRs, and labs, inclusive of order, result, and ELR, and each of these notes the terminology sets. It is inclusive of LOINC and SNOMED, and we are also incorporating our previous recommendations that we include the ability to update terminology.

Steven Eichner
To clarify, in terms of LRI and LOI.

Arien Malec
LRI/LOI, and LRI also includes ELR.

Steven Eichner
Just clarifying.

Arien Malec
Yes. So, we are doing ELR using the LRI standard. Okay. All right, we added a recommendation for web entry system. Certification criteria will be sufficiently flexible to certify essential electronic results capturing systems. We recommend certifying LIMS for LOI and LRI.

Bryant Thomas Karras
We are trying to unmute Erin.

Erin Holt Coyne
Regarding labs, did I understand you correctly, Arien, that the floor was going to be LRI, and not the ELR implementation guide?

Arien Malec
No. Baseline is ELR, target is LRI.

Erin Holt Coyne
LRI, okay, thank you.

Arien Malec
Which is inclusive, but again, I think the question was is LRI inclusive of ELR, and the answer is yes, the LRI guide includes both reporting of labs from lab to the ordering provider as well as reporting the lab to public health in the target state. Okay, we are done with labs. All right, transmission to cancer registries. Our recommendations are "to maintain the reference and recommend that ONC collaborate with public health authorities receiving cancer data, public health professional organizations, CDC, NACCR, and other stakeholders regarding future updated standards for the exchange of cancer-related information. We note that many advanced organizations report using pCORI or OMOP-based reference data models, and that foundational work," not "works," that is my typo, "is being performed via MedMorph." Okay, that is cancer.

Bryant Thomas Karras
So, we heard from a couple of academic cancer research institutions in the testimony, but I think that when we heard from the cancer registry, there are hurdles and barriers to them certifying their system, many of which are a CDC-provided system that does not do what it needs to be able to do to receive true interoperability, and those state agencies were all flat-funded or had funding cuts as a result of the pandemic. Are we really going to be able to see this F4 criteria evolve?

Steven Eichner
The difficulty is not so much on the receiving end. The difficulty seems to be in a way that many of the vendors had developed the supporting technology or the messaging, and the IG was not generating expected results from provider systems. The data was in the provider systems, it just was not being extracted in the expected way, looking at the certified technology, and I think it is unclear even at this point exactly where those stumbling blocks occurred. There was not a singular resolution.

Arien Malec
My understanding is the root of the issue is that we have modular certification, but we actually had much of that being optional, and so, not many people actually certified to the cancer registry standard, and so, we do not even have a fair test as to whether the F criteria addresses interoperability for cancer registries.

Steven Eichner
Well, where it was implemented in the early days of PI, providers had the technology as certified, but it was not generating expected or useful results from the…

Arien Malec
So, the question is do we have recommendations at this point that address that problem?

Steven Eichner
I think the closest you could do is potentially look at MedMorph.

Arien Malec
Right, which we are referencing.

Steven Eichner
I would be hesitant to look at the F criterion in that space, coming out of the certified technology, using what is currently certified technology.

Arien Malec
So, you want to strike the first paragraph, "maintain the reference"?

Steven Eichner
I think so.

Arien Malec
Objections?

Bryant Thomas Karras
Hold on one second.

Arien Malec
Right now, we are saying "maintain the reference and work with yada yada yada to create future update standards for the exchange of cancer-related information with reference to OMOP…"

Steven Eichner
What I think you would want to do in there is work with NACR, public health, academic institutions, and providers to reevaluate cancer reporting and related standards.

Bryant Thomas Karras
Yes, and in the ONC report that was just provided today, they identified that there were a large number of providers that cited the extra cost, that although the cancer module existed, it cost extra. They could add the ELR, syndromic, and immunization for free, but they had to pay extra if they wanted to do cancer, and they would not do it.

Arien Malec
Just to be clear, we cannot address that via certification requirements. So, the question is do we maintain the current cancer registry implementation guide or make recommendations to maintain…?

Bryant Thomas Karras

I would argue that ONC says, as part of the 21st Century CURES Act, or not the CURES Act itself, but the information-blocking provision within it, that having an additional cost for a public health reporting module is an unacceptable fiscal barrier, and those should be eliminated from all EHR vendors that say they have a certified system. They need to take away those modular costs.

Arien Malec
This would not be a point I would argue with, but from a certification perspective, it is running afield of where we are making recommendations.

Steven Eichner
I think the safer place is to look at recommending a revisit of the criterion.

Arien Malec
Yes, which we are doing. So, the question is do we strike the first paragraph or do we maintain the first paragraph, acknowledging that we make recommendations in the second paragraph for making updates?

Steven Eichner
I think we eliminate the current reference.

Arien Malec
Okay, strike the first paragraph. Any objections? So stricken. Next.

Steven Eichner
I am looking at the second paragraph. We are going to collaborate with public health agencies for sending… Do we have enough stakeholders? Do we have providers in there as well?

Arien Malec
Yes, we should include provider organizations. Cool. ECR. I think we have reportability response. I think all this stuff is addressed, it is just an ordering problem. Here we go.

Erin Holt Coyne
That comment was left from before last week, so I removed it.

Arien Malec
Here we go. Standard reporting…good. Liz, go up. I think we need to strike that "standardize expectations for EHR-related receivers of RR" because we have it right below. Let's bold "we recommend," just to be consistent. So, just to repeat, "We are making recommendations that ONC modify the existing certification criteria for case reporting to require certification to ECR and establish associated test methods, where we are recommending initial case report, EICR, and reportability responses." This is for EHRs, for provider organizations. Next recommendation. "We recommend that ONC adopt a certification program for public health technology," which should be "technologies." I missed this one. "Technology," cool. "…to receive electronic case reports and send reportability responses for reporting reportable conditions with syntax and semantic criteria defined below." Boom.

Bryant Thomas Karras

Arien, I think we need to go back. It is not the public health authorities that would be sending the reportability response, but the APHL AIMS…

Gillian Haney
Yes, but ultimately, it is the public health authority.

Arien Malec
Nothing here says anything about public health authorities. Is it above?

Bryant Thomas Karras
It just refers to technology? Okay.

Arien Malec
Yes. All right. Did we miss recommendations for F6 and F7? What was F6 and F7?

Liz Turi
No, they got moved.

Arien Malec
We got everything, cool. Are we done?

Liz Turi
We have two more in F5 that we did not touch last week, and then F6 and F7, and F7 has nothing.

Gillian Haney
Can you go back up, though? I think there is a "public health authority." Scroll back up, please. All right, that is all fine. Next, F7. Wait, now you are saying it is higher? I thought this was the beginning of EHRs.

Arien Malec
No, it is one more. This is Recommendation 2 here, in F5. Okay, above, Recommendation 5, so, the first one. Good?

Gillian Haney
Okay.

Arien Malec
Liz, take us home.

Liz Turi
All right. These are now the ones that we did not touch on last week at all. So, we have two more in F5, two in F7, and nothing in F7. Last are if you wanted to review those that got pulled for deletion.

Arien Malec
I do not think we have time to review those.

Liz Turi
Right.

Arien Malec
If you did not review it and object, then it is gone. Okay, so, this is about "certification **[inaudible] [01:35:26]** for standard adoption of FHIR distribution of trigger codes." Yes. This is going to go in the ECR section. Should we not say "standard adoption of distribution of trigger codes"? We tend to not name specific technologies. "Standard adoption of distribution of trigger codes to EHRs following the implementation guide." Liz, did you get that?

Liz Turi
Yes.

Arien Malec
So, "We recommend," in bold…

Liz Turi
Sorry.

Arien Malec
Sorry, Liz. And then, strike "of FHIR." So, just say "standard adoption of distribution of trigger codes." Sorry, do not strike "of," just "FHIR." Boom, perfect. "Standard adoption of distribution of trigger codes to EHRs following the HL7 FHIR implementation guide, Electronic Case Reporting V.1.0.0 STU 1."

Liz Turi
This was a question that came up.

Hans Buitendijk
It has to be "problems." You can add to it "or then-most-current."

Steven Lane
Yes, I agree. Otherwise, this becomes quickly stale.

Arien Malec
"Specifically to electronic consumption of ESRD for trigger code implementation. In an emergent regime case, use cases should be included in certification." And again, the point here is ECR is fantastic infrastructure, but it is worth nothing if you cannot update trigger codes. That is a little extreme, but it is limited in use if you cannot update trigger codes to respond to emergencies. Cool. The next one is about the public health.

Gillian Haney
You need to bold "recommend" there.

Arien Malec

We will bold "recommend," and I think we want "certification program of public health technology," or "relevant to." We want to strike "system." Just strike the whole word.

Hans Buitendijk
I am noticing that it is very similar to what we just talked about, but that we did not mention the knowledge around the content. So, for the trigger events, one thing is to communicate the trigger events, the other part is what content for what trigger events, and we did not see that here, nor anywhere else. It might be too late, but just as a…

Arien Malec
I think the issue that we heard on the content side was relative to value sets, and I think we have already addressed updating value sets. For LOINC and SNOMED, I think we have already addressed reportable labs, addressing that information at source. Is there more information that we are missing?

Hans Buitendijk
Potentially, because it is not only the value sets for those codes, but it would be, as an example, for this particular trigger event, do I need the last 10 days' worth of lab results, or the last three months'?

Arien Malec
It sounds like a good concern. We do not have recommendations at this point. We are not going to create them in the next 13 minutes.

Hans Buitendijk
Just so we are sure, then.

Arien Malec
Okay, cool. That is ECR. F6. All we did here was pull in the previous HITAC recommendations.

Gillian Haney
I think that should be… Hold on. "ONC collaborates with CDC and public health authorities to…" instead of "NHSN."

Arien Malec
Sorry, below. No, that is okay. "Collaborates with CDC and public health authorities and their partner organizations." And then, rather than "seems premature," we will just say "is premature." Done. This one seems out of place. I think we addressed this one. This was our recommendation on "Our target is to reduce or eliminate paper-based reporting," so I think we are good. We just addressed healthcare surveys.

Liz Turi
No current recommendations.

Arien Malec
Wasn't the one just above healthcare surveys?

Gillian Haney

No, that is for NHS and HII.

Bryant Thomas Karras
There was a comment that I had in there. Part of the data that goes from hospitals to CDC for the antimicrobial-resistant is not shared back with the states by CDC. Should we make a recommendation that information be bidirectional and shared with the underlying jurisdictional authorities?

Gillian Haney
Where would you want it to go?

Bryant Thomas Karras
Under 6. I am trying to see where my comment was.

Gillian Haney
How about "bidirectional NHSN reporting" in that last sentence before "under such a letter"?

Arien Malec
It can be used for certification and bidirectional…

Bryant Thomas Karras
Again, this is another one of those… In the implementation guide, there are optional data elements that are allowed. Washington state asks hospitals to send them, CDC collects them, but then only shares the required ones back to us. Their system did not implement a way to share the optional…

Arien Malec
Again, I think we are consistent in making recommendations that our certification criteria test for optional elements.

Bryant Thomas Karras
CDC is not going to see that section above in the overarching as applicable to NHSN.

Gillian Haney
Can we just copy and paste that language and bring it down three from above?

Arien Malec
Let's just say "bidirectional NHSN reporting inclusive of optional values."

Gillian Haney
That is good.

Bryant Thomas Karras
Thank you. We have been asking for it for 10 years.

Arien Malec
No doubt. Did we get through everything, Liz?

Liz Turi
Yes.

Arien Malec
Ship it!

Liz Turi
Sure!

Steven Lane
Arien, this is Steven. I did throw in a suggested friendly amendment in the chat back at 40 minutes after the hour.

Arien Malec
Oh good, thank you. I have to go find where my chat interface is. Where is my chat interface?

Steven Lane
I sent it to everyone, so anyone should be able to find it.

Arien Malec
I understand. "Show chat." There we go, boom.

Steven Lane
Up at 8:40 our time.

Arien Malec
I have no objections to this.

Liz Turi
Where should this go?

Steven Lane
The first part is on Page 4, and the second part is under Recommendation 1, as noted. I just think it makes it clearer what we mean by "modular."

Gillian Haney
I have a question. The language references just EHR certification. Isn't this supposed to be broader than that?

Steven Lane
That is what I am trying to clarify. We keep saying "modular" as if it is self-evident what that means and what the modules would be.

Arien Malec

"By the term 'modular certification,' we mean a provider is certified to be able to certify a single criterion or multiple criteria aligned with the current certification program."

Steven Lane
Right, current EHR certification program.

Arien Malec
It is not just EHR, because I think we are **[inaudible – crosstalk] [01:45:37]**.

Steven Lane
Health IT, okay.

Gillian Haney
That was my point, yes.

Hans Buitendijk
The other way to describe it is that modular certification is where one or more dependent interoperability capabilities are part of a certification criterion, so that it is not many independent ones under one criterion, they are really, really dependent. They could not work unless they are together, and that it could be split across HIT, so that is a complicated definition.

Steven Lane
And valuable.

Hans Buitendijk
Yes. Well, it is the combination. They have to be very dependent, but even if they are dependent, if you can be split across HIT, you should not have it as one criterion.

Steven Eichner
One thing that you said just in passing a moment ago was "current." I think we also want to say we should aim at what is the latest up-to-date, whether it…

Arien Malec
Yes, SVAP, current and inclusive of SVAP.

Steven Eichner
And maintain in the future, so it is not just SVAP.

Arien Malec
That is right.

Steven Lane
The way I phrased that is "and evolving coordination with now other health IT certification programs."

Hans Buitendijk

In the sentence that is highlighted with an isolated aspect of criterion or criteria, I could see part of the problem/challenge is that an isolated aspect of criteria, plural, is where it could be split across multiple HITs, so they are related, but they can be done across different IT. Not all the HIT needs to support all of them, but in combination, they need to be there. That is the complicated part.

Gillian Haney
Erin?

Erin Holt Coyne
As we have been having this discussion, I want to make sure that whether it is on the public health side or another side in sending the data, there is the ability to use more than one technology solution in meeting that certification criteria, not a singular technology solution.

Hans Buitendijk
Yes, and on the EHR certification side, you have two responsibilities, in a way. The developer develops the capability, and where it is split across multiple HITs, it is on the provider to make sure that all the different HIT, whether it is one or more that can satisfy it, but that the combination of HIT can support the combination of criteria that are relevant to them. So, it is a two-part responsibility, and they need to fit.

Erin Holt Coyne
When I am saying "multiple technologies," I am not necessarily making a distinction between types of surveillance systems or vendor-supplied surveillance systems, but in the additional tools that we might use above and beyond those surveillance systems to be able to meet those criteria, like an EDI engine, for example.

Steven Eichner
And not a single EDI engine. There may be multiple vendors supplying, and ideally…

Arien Malec
Again, I remind everybody that in our overarching, we make recommendations that the certification programs should provide paths for certification of technology inclusive of self-certification…

Erin Holt Coyne
Would the word "solution" be a better option, rather than "product"?

Arien Malec
"Technology."

Bryant Thomas Karras
Yes, or a parens-S behind product. "Product or products."

Arien Malec
No, we have consistently used "public health technology."

Steven Eichner

Arien, all the way up at the top, do we want to include "from multiple vendors" or "supporting multiple vendors" all the way at the top? In other words, the program should be available to multiple vendors, not just a singular…

Arien Malec
Where?

Steven Eichner
All the way up at the top, when we are talking about the definition of certified technologies in the first place, but looking at it with the idea that public health can pick how it wants to implement it, but it can also potentially pick from multiple vendors. In other words, it is a certification program like the…

Arien Malec
Yes, it should be "modular (independent of vendor)."

Steven Eichner
"Modular and encourage participation for multiple vendors" or "support participation for multiple vendors" so that, again, it is not looking at "Oh…"

Arien Malec
I think we are good.

Hans Buitendijk
Arien, for the final paragraph, where the term "modular certification" is, I made a couple tweaks to that in the chat.

Steven Lane
I would still request that we include the concept…

Arien Malec
We have five minutes, we have to go to public comment, and…

Steven Lane
I just do not want to lose the alignment with existing health IT certification programs. I think it is really important that we capture that.

Hans Buitendijk
Yes. We also need to recognize that "current certification program" is challenged at times to have the right granularity of criteria.

Arien Malec
So, here is what I propose. We will take the chat, we will draft some language, we will send it up via email today, we will either get agreement on that language or not, and proceed with the edit, but we have to close it out today so we can finalize and publish to the full HITAC. The world will not end if this language is not

perfectly precise. Our wordsmithing here is very unlikely to radically change and reconfigure ONC policy, but it would be good to get the language right. Okay, let's go to public comment.

Public Comment (01:52:12)

Michael Berry
All right, everyone. We are going to open up our call for any public comments. If you are Zoom and would like to make a comment, please use the hand raise function 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 pause for just a moment to see if anyone raises their hand. I am not seeing any hands raised, so I will turn it back to Arien and Gillian.

Next Steps (01:52:38)

Arien Malec
All right. This has been a journey. I just want to remind everybody that I know that ONC in particular, and also CDC, I believe, is anxiously awaiting the approval of these recommendations through the full HITAC, that the work that we did is going to radically improve the nation's ability to respond to future public health crises, and we all can remember our time on this task force as being foundational for an improved and more resilient public health system informed by interoperable data.

As I said, we will make sure that the final draft that we are proposing is sent out to the full task Hforce. I think we can go back and forth with the email, as long as we can get to some level of consensus for fine-scale edits. Please tune in for the HITAC meeting, where we will present the net effect of all this work to the HITAC and overwhelm them with the brilliance and sophistication of our recommendations, so please feel free to attend and cheer us on. I thank everybody for their effort and active engagement. This was a highly engaged task force, and I know it was frustrating at times as we were trying to steer toward the home stretch, but I do feel like we got to highly impactful recommendations.H

Gillian Haney
I would just like to thank everybody as well, and just add that one of my main goals coming into this task force was to really develop some sensible recommendations that would ultimately reduce burden and to improve data quality and interoperability, and I think our recommendations would do so, so I just want to thank everybody for their very engaging participation and patience, and my apologies again for finishing off with not so much of a bang, but COVID. That is one of the reasons we are here.

Arien Malec
It is all very on brand that our two cochairs were both affected by COVID, and one presumed affected by RSV, so, very on brand for this workgroup.

Gillian Haney
[Dog barks] My dog would like to second that.

Arien Malec
Exactly. All right, thank you, everybody, and again, thanks for all of our panelists as well in the past, and feel free to eagerly await in your email the proposed final, final draft. Thanks, everybody.

Gillian Haney
Thank you, everyone. Bye-bye.

Adjourn (01:55:53)