Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) ADOPTED STANDARDS TASK FORCE 2022 MEETING

July 26, 2022, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Hans Buitendijk	**Oracle Cerner**	**Co-Chair**
Steven (Ike) Eichner	**Texas Department of State Health Services**	**Co-Chair**
Jeffrey Danford	Altera Digital Health	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Jim Jirjis	HCA Healthcare	Member
John Kilbourne	Department of Veterans Health Affair	Member
Hung S. Luu	Children's Health	Member
Clem McDonald	National Library of Medicine	Member
Deven McGraw	Invitae	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Vassil Peytchev	Epic	Member
Samantha Pitts	Johns Hopkins University School of Medicine	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Ram Sriram	National Institute of Standards and Technology	Member
Raymonde Uy	National Association of Community Health Centers (NACHC)	Member
Debi Willis	PatientLink Enterprises	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Josianne Charles	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Liz Turi	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Scott Bohon	Office of the National Coordinator for Health Information Technology	ONC Staff Lead

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

Michael Berry
And, good morning, everyone. I am Mike Berry with ONC, and I would like to thank you for joining the Adopted Standards Task Force. As a reminder, your feedback is welcomed, which can be typed in the chat feature throughout the meeting, or can be made verbally during the public comment period that is scheduled at about 11:50 Eastern Time this morning. We have a number of guest speakers with us today that joined the Task Force to help answer questions that we may have, and I would like to welcome them as well. I am going to begin roll call of our Task Force members, so when I call your name, please indicate that you are here. And, I will start with our cochairs. Steven Eichner?

Steven Eichner
Good morning.

Michael Berry
Hans Buitendijk is off today, but he will be joining us in the future. Jeff Danford? Raj Godavarthi? Jim Jirjis? John Kilbourne?

John Kilbourne
Good morning.

Michael Berry
Hung Luu is also absent today, but should be back next week. Clem McDonald?

Clem McDonald
Here.

Michael Berry
Deven McGraw?

Deven McGraw
Here.

Michael Berry
Eliel Oliveira? Vassil Peytchev? Samantha Pitts?

Vassil Peytchev
Vassil is here, sorry. Couldn't find mute.

Michael Berry
Thanks, Vassil. Samantha Pitts?

Samantha Pitts
Good morning.

Michael Berry
Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Ram Sriram?

Ram Sriram
Good morning.

Michael Berry
Raymonde Uy?

Raymonde Uy
Good morning.

Michael Berry
And, Debi Willis? All right, thank you, everyone. Now, please join me in welcoming Steve for his opening remarks. Steve?

Steven Eichner
Thank you, and good morning, all. Thank you for joining us. Today, we are going to continue the work that we have been doing, looking at reviewing standards listed in regulation and continuing to make or develop recommendations whether those standards should be retired, or maintained, or, in some cases, replaced by a newer, updated standard. Today, we are going to focus mostly on public health-related standards, looking at standards that are used for exchanging data between providers and public health agencies, but before we do that, we want to clean up one outstanding discussion looking at the standards hash and security, so we will jump to Line 41 in the template, if ONC wants to advance us to the…

Michael Berry
Liz will be sharing her screen.

ONC Standards Review – Groups 3, 4, & 6 (00:03:40)

Steven Eichner
Thank you, Liz, and I believe it is Line 41. Last week, we were discussing whether this particular hash standard had a more modern release, and thanks to Ram, we have learned from NIST that there is not a more current release of the standard. There is another hash standard that could apply. There would be the

potential for inserting language that said you could use either 180 or the other standard, but there are no significant advantages in listing the other standard. It seems to make sense to have a more limited set that is in a single reference for continued use rather than pointing people to the entirety of the NIST website or FIPS website and using any potential hashmark, so my recommendation would be to continue to maintain. I will open it up to the floor for some conversation on that. Do any Task Force members…?

Deven McGraw
If I understood you correctly, Steven, you are suggesting maintaining the standard, but also allowing folks to adopt some of the more recent ones?

Steven Eichner
No, no, no. Maintain the existing standard. There is not a more current standard released; there is another potential group of standards that do the same thing. It does not seem practical to say to use anything on the website. We want to point people to a more consolidated list.

Deven McGraw
Yeah, I would agree with that. Also, there is no indication that this standard is not as robust as it was when it was initially adopted, at least to my knowledge, so there is not any reason to move.

Steven Eichner
Correct.

Ram Sriram
This is Ram here. There is the FIPS 202 that is a SHA-3 standard, so I do not know whether you want to… It is supposed to be better then SHA-2. That is the one which I might prefer to **[inaudible] [00:06:12]**, but it all depends on what people are using it for. But, given that, I think we can just leave it as is.

Steven Eichner
Okay. Do we want to include language of "ONC should…"?

Ram Sriram
You can just put a pointer to the FIPS 202/SHA-3, but the question is whether… The thing is, who is using this? Is anybody using SHA-2 anymore?

Steven Eichner
I am unsure how it is being used for encrypting data.

Ram Sriram
Yeah, because we need to find out if there are any vendors who are using this because we are not vendors.

Liz Turi
Vassil has his hand up, Steven.

Vassil Peytchev

I think the context is really important because if we are talking about web services and securing web services with certificates and we point to this, which includes SHA-1, which is considered as a weak and insecure certificate-signing method, are we doing disservice here? In general, FIPS standards are required, obviously, for government compliance, but also, for a long time, FIPS referenced DES and Triple DES as adequate encryption even after it was known that they are not adequate anymore. So, can we keep the reference and forbid SHA-1?

Steven Eichner
I do not think there was any intention of removing the standard.

Vassil Peytchev
Right, but can we add that this FIPS specification, which specifies SHA-1 as a valid use, needs to be restricted in regulatory language to exclude SHA-1 that is specified in this specification, but SHA-2 and others, like SHA-256, are fine, except for SHA-1? Because if we keep that for another three years, again, I do not have a good suggestion, except to bring up the point that keeping SHA-1 is not a good thing.

Steven Eichner
Mike, would it be possible for next week or two weeks out to get a better understanding of where the regulation is applied, to what systems the regulation is applied, or to what usage the regulation applies to? In other words, yes, we understand what the standard is, but in what situation is the standard being used?

Vassil Peytchev
And, in particular, I would contrast two usages. One is for certificate signing, and the other use is for checksum against existing entities. For checksum, SHA-1 is fine, this whole thing would be fine. For certificate signing, it is not.

Steven Eichner
Okay. And, is that the application of the regulation?

Vassil Peytchev
Right, that is the question.

Clem McDonald
Is SHA-2 the appropriate replacement?

Vassil Peytchev
All the others listed in this specification are appropriate. SHA-2, SHA-256, 384, whatever.

Ram Sriram
SHA-3.

Vassil Peytchev
SHA-3. They are all appropriate replacements for the particular use of verifying certificates.

Steven Eichner

Clem, this is Steve. I think the question on the table is still what is the usage of that particular regulation? In other words, to what application does the regulation apply? Does it apply to certificate validation, or does it apply to something else? Fillipe?

Fillipe Southerland
Hi, good morning. I just wanted to point out to the committee that NIST does have this FIPS 180-4 out for public comment, due by September 9th, and it appears they are requesting comment on disallowing SHA-1, so we could potentially just note that this is out for public comment, and SHA-1 is under consideration to be disallowed.

Ram Sriram
Yeah, I think there is an announcement. If you go to their website, you can look at what exactly they want.

Steven Eichner
That would make sense if we are looking at a recommendation or a comment that says, "This particular standard is currently open for public comment. Task Force and the HITAC recommend that the situation be monitored and the standard updated as appropriate based on the final rule resulting from the comment period," or something of that ilk.

Ram Sriram
That is right. You got it.

Steven Eichner
I think we will make notes and update the worksheet to reflect that, and we will revisit quickly next week as we review potential comments. Now, shifting gears to public health, the first public health standard we are going to talk about is electronic laboratory reporting, and to help us understand and dig into public health reporting and ELR, we have a couple speakers to help us understand what is going on, including Riki and Rachel Abbey and company, so will you please introduce yourselves?

Riki Merrick
Sure. I am Riki Merrick, the Lead Terminologist for the Association of Public Health Laboratories. I am also the Orders and Observations Cochair, and have been involved in ELR specification writing since the first one, Part 1.

Steven Eichner
And, Rachel, do you want to introduce yourself quickly? Then, Riki has a wonderful little presentation to help bring us all up to speed.

Rachel Abbey
Sure, absolutely. Thanks, Steve. My name is Rachel Abbey with ONC's Office of Policy, and I specifically work on issues related to public health, and have been involved in this space with Steve and Riki for many years. Thank you.

Steven Eichner
Actually, Laura, do you want to introduce yourself?

Laura Conn
Sure, good morning. My name is Laura Conn. I am the Electronic Case Reporting Program Lead at the CDC, and I am just here to support the conversation between ELR and ECR if there are questions that arise.

Steven Eichner
Thank you so much for that. If I missed anybody, please introduce yourself. Riki, do you want to go ahead and do your presentation, please?

Riki Merrick
Sure. Can you pull up my slides for me, please? Okay, so, next slide. I was asked to talk a little bit about lab standards. I do not know much about this first one, so I just provided links that I got from the food safety program at APHL. I do not know what to say to these. It is just background. Next slide. So, this is more of what I can talk about. So, "ELR" stands for electronic lab reporting, and it is reporting results of lab tests for reportable conditions to public health at any level, mostly local and state.

So, initially, there was no national standard established, but various states had ELR implementation guides in 2.3, 2.3.1, and some in 2.2, maybe, and some of these are still in use. But, in 2009, we used several of those state-specific 2.3.1 guides and created the first national electronic laboratory reporting guide using Version 2.2.5.1, and that is referred to as ELR R1. It is named in promoting interoperability regulation, and it is widely implemented and used in labs in at least all the states' state public health agencies, but probably also a quite a few of the local public health agencies, and because it is so widely implemented, we worked on creating some adaptations to it to support HHS-supporting elements for SARS-CoV-2 during the pandemic.

When the ELR IG was named for promoting interoperability regulation, NIST created tooling to help with the certification of electronic health records, and so, while we were building those toolings, we had to create a clarification document because some of the rules were… The table was saying one thing, and the notes were saying another thing, so really, when you are implementing ELR R1, you should implement both the IG and the clarification document because that really helps. And, over here on the right, I have the supported workflows of lab to public health. Next slide.

So then, we went on to look at… The laboratory creates results not with a main focus to report to public health, but really with a main focus to report to the clinician, and so, in 2012, we started on this with the SNI framework. We were trying to make it easier for the labs to create the standard that could do double duty, basically, reporting the results to the provider and supporting CLIA, as well as reporting results to public health. So, we created this lab reporting interface, or LRI, guide that has multiple profile components, so depending on which use case you are supporting, you can take the base LRI profile and then add on additional data elements.

And so, for the reporting for public health, that is the public health component, that you add on the base LRI component, and that took all the ELR R1 data elements, and it was initially published as ELR Release 2 as a separate standing document because people were used to having an ELR IG guide, but it made it more confusing because we had two separate documents, but they were both using LRI as a component.

So, going forward in 2015, and then again in 2018, we published only LRI, but the public health component within that still represents the latest version of the original ELR. I am not sure how easy that is to understand.

But, what is important about LRI is that in the base, LRI supports the CLIA elements, so, everything the laboratory needs to report under CLIA to the ordering providers. It also has support for AOEs, and sometimes, public health uses AOEs to get some of the public health information across to the labs, to public health, because that is currently the main way of public health automatically getting clinical information, for example, like pregnancy status or other things that public health might be needing.

And, the other thing that is interesting is that that first LRI R2 has a functional requirements document for each RS certification, so when HL7 puts out an implementation guide, that is really just a specification of how the data goes across the wire. It does not necessarily talk about what the receiver must do with the data, but for a certification process, of course, that is an important piece, and so, HL7 workgroup did work through and created this ERH functional requirement that says, "If you are an EHR and you are getting an LRI R2, this is what you are going to have to do with each of these data elements," which is important for certification. That document has not been updated to the later versions because LRI was not included in promoting interoperability regulation. Next slide.

It should say '22, sorry. I must be a year behind. And so, this year, in August, we are going to publish a new LRI, which includes the HHS requirements, and it also still supports all the other use cases. So, for example, one of the use cases in the earlier LRI R3 is newborn screening, which uses orders and results reporting to the provider, and so, those use cases are still supported by this LRI guide. But, it does relax some of the OID requirements for the public health component profile, so in the initial ELR R1, you needed to identify your assigning authority, so, those systems that create identifiers like the patient identifier, the specimen identifier, and the order identifier. They had to be identified using an OID, which is an object identifier.

And, we do not have a national OID registry, so for some of your partners, it would be really hard to use an OID to identify them as the assigning authority for identifiers, and most public health agencies had already relaxed that rule, so, basically, they were not really compliant with the ELR R1, but it is something that you have to do to make it work, and so, this new version will support that and allow, for example, the use of CLIA or NPI as a means to identify the assigning authority.

So, in general, I would say ELR R1 is widely implemented for public health reporting, and no changes would have to be made. However, from a broader perspective of supporting standards implementation in the laboratory space, moving to this latest version of LRI would probably be beneficial because it actually describes what is current practice for public health agencies, like not requiring OIDs, but also allowing CLIA and NPI. It supports the HHS-required elements for SARS-CoV-2 reporting, it allows guidance around AUEs, and it includes all the CLIA elements so that when the lab implements the LRI base component, it can use that to also report to providers. So, new implementations certainly should be considered. We should find out from the public health agencies how easy that is to support, and then, for existing implementations, just for the public health reporting side, it would be interesting to find out what the ROI is. I think that is it.

Steven Eichner
Thank you so much for that. Rachel, do you have anything to add?

Rachel Abbey
No. Thanks, Steve. Thanks, Riki.

Steven Eichner
Laura, do you have anything as initial observations, and can you talk for a moment about the intersection of ELR and ECR?

Laura Conn
Nothing more to add on the ELR standards. I just want to clarify for folks that both electronic lab reporting and case reporting are required by law in all U.S. states and territories. The electronic component varies across jurisdictions. Some actually have laws that say it needs to be submitted electronically; some do not. Both of these programs are working towards making electronic feeds to support those regulations in states, so they are complementary data feeds to public health agencies, ELR obviously focused on lab reporting and electronic case reporting focused on the provider mandated reported. There is some laboratory information in an electronic case report, but not to the degree and detail that comes in an electronic lab report.

At a public health agency, jurisdictions marry the two reports to get a full picture of a clinical person with a condition of interest to public health from the clinical perspective and from the laboratory results perspective. I think there have been discussions at times, especially during COVID, where the use of ask on order entry questions was…this might be strong, but seeking to force some clinical information into a lab result report that could potentially be found in an electronic case report, and electronic case reporting was just getting off the ground as COVID response was also ramping up, and so, it is definitely not in place nationwide, but looking towards the future, we really want to be parsimonious around what data should be shared in what type of documents or reports, and through a lab report if it is laboratory-associated information or information that a laboratory needs in order to run that test, but if it is really clearly clinical data, those should be looked to as being shared through an electronic case report.

Riki Merrick
Yeah. If you are looking at this image still, I have the two arrows from the lab to public health and to the provider, and for what Laura is talking about, the case report would go from the provider, the EHRS, over to public health, so it is an additional arrow.

Steven Eichner
This is Steve. To add onto the discussion a little bit, there are really three channels of information exchange related to laboratory services and public health, one for electronic lab reporting, which is sending information about notifiable or reportable conditions to public health from a laboratory perspective, second, looking at the electronic case report, and thirdly, laboratory services that may be provided by the public health lab. For example, the Texas Department of State Health Services Public Health Lab does newborn screening testing and does use the LRI message to exchange data with submitting providers for a significant percentage of the 800,000-ish lab tests performed on an annual basis, so there is that differentiation. Riki, I am taking cochair's prerogative for a moment. Can you distinguish a little bit the difference between R1, what is in place right now, and what is being balloted or prepared for August '22?

Is it an extension, but pretty much everything that is in R1 with the exception that the OID modifiers are supported in the LRI with the PH components?

Riki Merrick
Yeah. So, LRI as the base makes you choose whether you are identifying your assigning authorities using OIDs or if you allow other means. So, the base LRI makes you make that choice, and the ELR originally was constrained to only use the OIDs. The only thing we have done in this release is we are relaxing the requirement that the public health component has of using OIDs. You can still use OIDs, but if you do not have an OID, you can also use a CLIA or an NPI to identify your assigning authority, but yes, there is no change in terms of the data elements that are supported in ELR R1 versus the public health component in LRI R5.

Steven Eichner
Okay, wonderful. Clem, you had your hand up a moment ago. Do you still have a question? Are there questions or observations from the Task Force? Is there any CLIA realignment with HL7?

Riki Merrick
I am not sure I understood that question, sorry.

Steven Eichner
Sorry. There is a comment or question from chat whether there is any need to do further modifications to messaging to support any of the CLIA changes that may be in the works.

Riki Merrick
If there are new CLIA requirements that were not around when we initially worked on LRI, then we have not been made aware of them, but the idea behind LRI was that we wanted to ensure that it supports all the CLIA elements. So, one of the carrots to getting labs to implement LRI was to say if you are implementing LRI, then some of your CLIA requirements around recertifying interfaces whenever there is a change made after the initial instantiation or implementation of an interface currently have to go through pretty rigorous retesting and reverifying of the view that the provider has of the report, and it needs to get compared to the view that the laboratorian had when they made the report, and that takes a lot of time and resources. And so, one of the carrots was LRI supports all those elements, and so, once that is verified that you are actually doing LRI correctly and supporting all those CLIA elements, then some of those changes that invariably happen over time to an interface do not have to be that rigorously verified every single time.

Steven Eichner
Okay, thank you for that. So, as we look at the worksheet for Task Force members, Lines 23 and 24 are the core ELR reporting measure or reporting content, and then, the supplementary material that Riki mentioned. Do we want to make a recommendation that ONC consider moving to the 2022 release, but work on a plan involving public health authorities and entities and stakeholders to ensure that there are appropriate resources available for any necessary transition? Is the Task Force comfortable with that type of recommendation, or is there another approach that would be preferable?

Deven McGraw
Steven, that sounds reasonable to me. This is Deven.

Fillipe Southerland
Me as well. This is Fil.

Steven Eichner
Thank you for that. Has Craig been able to join us yet, Mike?

Craig Newman
This is Craig Newman. I am here, yes.

Steven Eichner
Wonderful. So, we are now going to shift over to a discussion of immunization reporting, and Craig, could you talk a little bit about immunization registry reporting?

Craig Newman
Sure. So, immunization registry reporting has been happening electronically for a good number of years. Historically, it has been using standards developed and published jointly by the American Immunization Registry Association, AIRA, and the CDC. And so, what you have got on your screen there is the most recent version, which is Release 1.5.

Steven Eichner
Craig, I am going to interrupt you. Please introduce yourself.

Craig Newman
Oh, sorry. I will actually put some light on as well. My name is Craig Newman. I work with Altarum, and I am a cochair of the HL7 Public Health Workgroup. I have previously worked as a contractor with the CDC in the area of immunization standards, and so, I have a history of contributing to, writing, and implementing some of these V.2 implementation guides, including those related to immunization.

Steven Eichner
Thanks so much. Please continue.

Craig Newman
Sorry about that.

Steven Eichner
No, do not be sorry. I want to make sure you are well recognized because you have great information, a great history, and great insights.

Craig Newman
Great, thank you. So, Release 1.5 was the most recent release of CDC-AIRA document. It was published in November of 2014, and then, what you actually see here is, shortly after that, about seven months after that, an additional addendum was published. I contributed to the original 1.5 guide as a commenter, but ultimately, as that contractor to the CDC, I wrote the addendum, and so, I am familiar with that, and that really just did some clarification because we knew going into EHR certification for 2015 that there were

some holes in the implementation guide. There always are. So, we tried to clarify as best we could with the addendum. I was also involved in creating the test cases for the 2015 EHR certification process, and so, those reflected what is in the Release 1.5 guide.

As we were doing that work and afterwards, we sort of read between the lines or heard whispers. There was never anything official, but our understanding was that when new versions of certification came out, it would be preferred if they pointed to an SDO-balloted document. So, while the AIRA-CDC documents were always available for public comment and input, they were not officially balloted through HL7, so part of the work that we did was to create this Version 2.8.2 implementation guide, which is an official HL7-balloted document, and the idea there was to have that official process behind it. It largely was based off of Release 1.5, but it did make some relatively significant changes.

Just the practical matter of things is that the community has settled on Release 1.5, and AIRA, together with CDC, has done a tremendous job helping remove some of the variation in the implementation of Release 1.5 between jurisdictions, but that Version 2.8.2 implementation guide never really got any practical traction in the community and, to my knowledge, has not been implemented by anyone at this point. That is sort of the background. Steve, I do not know if there is anything else you want that I can provide before we have whatever discussion you are planning on.

Steven Eichner
That was great background. I think looking to the future a little bit and talking a little bit about the HELIOS work, and what might be coming next, and how that impacts standards might be worth mentioning.

Craig Newman
Sure. So, the immunization community has been looking at FHIR for a few years. I cannot speak officially for anybody, but my personal impression was that it took some time to educate the community on FHIR. I think there is excitement about what it can do. I think the HELIOS FHIR accelerator is new. It started up just towards the end of last year. We are about seven or eight months into that. One of the goals of the FHIR accelerator is not to rip and replace what is happening. So, the goal, at least in the short and middle term, is not to replace the V.2 messaging that is happening today that is well established and successful and replace it with FHIR, but to augment in the immunization community with FHIR to do things that Release 1.5 just is not equipped to do and was never designed to do. We have already seen work in getting COVID immunization status into the hands of consumers. Things we have talked about are clinical decision support for forecasting and inventory management.

And so, I would say that the goals of the community are not to replace V.2 messaging with FHIR, at least at this point, and I would say that HELIOS is behind that. There is a HELIOS priority area related to accessing immunization data in bulk from IIS so that authorized users like providers can access data on a population level to provide clinical care and better population support, but it is not expected to be a replacement for the V.2 messaging that is implemented and has been successful.

Steven Eichner
Thank you for that. And again, as Craig mentioned, I think there is significant interest in FHIR in the immunization community, and so, as Craig mentioned, there is work going on looking at bulk FHIR, as well as more limited work going on looking at individual messaging and individual data access, but to our

knowledge, there is not yet an implementation guide in development that is working on those specific aspects. There is not a Version 2.9 or a Version 3.1 waiting in the wings for near-term adoption.

Craig Newman
Yeah. I would say in terms of V.2 messaging, AIRA and CDC are working on projects that are looking at gaps between Release 1.5 and the real world to try and clarify. Beyond the addendum, there have been a number of guidance documents published, and so, they are working to make sure that the standards represent what is happening out there in the world, and again, I cannot speak for them, but to my knowledge, they are not planning on coming out with a whole new implementation guide, but they are still very much in the planning process, as I understand it.

Steven Eichner
Okay, wonderful. We have a few questions. Vassil, would you like to ask your question? Is your hand raised?

Vassil Peytchev
Yeah. It was partially answered by the last comment about additional guidance documents for ongoing clarification. Is it possible to add them to an updated regulation? Because from what I understand, there is a lot of work that has been required that has happened from July 2015 to today, and it would be great if we can keep that standard to incorporate those additional guidance documents as well.

Craig Newman
Yeah, and that is my understanding, that they are looking at producing sort of a composite document, but again, I do not have all the details on that, but I believe that is what they are hoping to do long-term, or sort of short- to medium-term, but yeah.

Steven Eichner
Thank you. Vassil, that was an excellent point. Do we have other questions from Task Force, or any other observations, or a recommendation as to a path forward?

Craig Newman
I will mention one last thing, that Version 2.8.2, as with any HL7 standard for trial use, has a limited lifetime. Off the top of my head, I forget when the current STU expires. It can always be extended if we want to go that route, but I do not know that the CDC sponsors of that have intent to extend that, so again, you would need to talk with them and the IISSB, Immunization Information System Support Branch, at CDC to know what their expectations are. But, that Version 2.8.2 may be retired if it is not actively extended. Again, it will still be available to people, but it will not be an active standard.

Steven Eichner
I would concur with your observation that there has certainly been focus on the 1.5 standard, and like yourself, I am not aware of any implementation in the field of 2.8.2, though 1.5 is currently supported in the Promoting Interoperability Program requirements so that Medicare providers that were not complying with the 1.5 IG might run into some issues looking at seeking Medicare payments and might be impacted negatively on reimbursement rates if they were not complying with the 1.5 guide, assuming that the public health authority was also using the 1.5. So, it may make sense to look at a recommendation that says,

"Maintain the 1.5 IG, but look to the compiled addendum. We are replacing it; we are updating it as the evolution continues and as the guidance documents might be incorporated into a more updated or a more current version," but not yet necessarily a 2.0 version, something like a 1.7, a 1.8, or whatever the numbering works out to be.

Craig Newman
Yeah. My personal opinion is that is a very realistic and reasonable approach.

Steven Eichner
Task Force, is that a recommendation that we should draft for review and potential forwarding to HITAC?

Fillipe Southerland
That seems reasonable to me.

Deven McGraw
Yeah, I agree.

Steven Eichner
Okay. Well, we will make notes in the worksheet and send those out for review.

Craig Newman
If I may make a suggestion, once there is a draft of that, if it could be shared with the folks at AIRA for their feedback just to make sure it aligns with their understanding, I think that could be a good thing to do. I am happy to also comment if that is at all helpful, but I think getting AIRA's input will be critical.

Steven Eichner
Thank you very much for that. Yes, there is a comment period or comment review process for Task Force recommendations and for HITAC recommendations to ONC.

Craig Newman
Excellent, thank you.

Steven Eichner
We will now shift to syndromic surveillance, which is Line 22 in the worksheet, and I believe we have some folks here. Rosa, are you here to talk about syndromic?

Rosa Ergas
I am here to participate in the discussion, but I do not have anything to present.

Steven Eichner
Well, as a resource. So, looking at syndromic surveillance, syndromic surveillance has been included as a public health reporting measure for some time as part of the Promoting Interoperability Program requirements. In the current iteration of proposed final rules and expected future final rules, syndromic surveillance reporting is required by hospitals participating in the Medicare Promoting Interoperability Program. If they do not submit data and the public health authority has the capability to receive the data, it

may impact the hospital's ability to receive maximum Medicare reimbursements. The current standard in regulation is Release 2.0, which was released in 2015. There is an updated version of syndromic surveillance Release 1 U.S. Realm from 2019. Rosa, can you share any information you would like to share about syndromic?

Rosa Ergas
No.

Steven Eichner
Okay. Are there any questions or observations from the Task Force regarding what we should do with syndromic surveillance standards?

Deven McGraw
Steven, is there documentation of what the updates are that are included in the 2019 version?

Steven Eichner
I do not have them as a short list. I believe some of the modifications included additional support for patient identifiers, among other things. Do we need to revisit this when we have more information and a tighter comparison between the different versions?

Deven McGraw
I personally would love to see that. It is not something that I am aware of. I have not been engaged in this discussion for very long.

Steven Eichner
Okay, wonderful. Let's move to Line 25, which is cancer registries. The current regulatory framework includes HL7 implementation guide Release 2 and Release 1, dated from 2015, as a draft standard for trial use. There has not been a lot of work done in updating the HL7 standard for cancer reporting to public health. Public health agencies support the HL7 standard to be consistent with federal regulations and promoting interoperability programs.

Many public health agencies also support a different standard simultaneously produced by NAACCR, the National Association of Cancer Registries, and support information using that standard as well. We do not have information at hand about what percentage of data is being received by public health using the different standards. It might be a good suggestion to suggest maintaining that standard but, at the same time, doing an evaluation of standard utility to understand how much that standard is actually being used in the field and potentially make an adjustment at the next cycle. I would like to open up the floor for comments or suggestions in that space. Is that a recommendation that we want to make?

Fillipe Southerland
That seems like a good approach to me, Steven.

Steven Eichner
If there is someone who has got additional insight on cancer reporting, it would be wonderful if there is an interest in sharing. So, I will draft some text that includes that in the worksheet as a potential

recommendation for the Task Force to consider it and push forward. The next standard is Line 26, HL7 implementation guide for CDA Release 2, Level 3 for healthcare-associated infection reports, and there is a new release inserted in SVAP, which is coming to be available at the end of August. Is there a suggested approach or suggested recommendation of the Task Force? Is this another instance where we recommend that ONC consider utilizing the data or the standards in the SVAP and continue that support? I am looking at moving in that direction.

Deven McGraw
Steven, is that relevant to Hans's comment in the document, "misalignment"? I was not sure what he meant by an HSN. He says there is a misalignment. Is that what you are referring to?

Steven Eichner
Yeah. One of the challenges as we are looking at the SVAP progression is looking at dependencies, and there is the potential to get a standard in place like a new version of CDA. If you have not adopted the new version of a CDA, then it is difficult to utilize a standard that is dependent upon that CDA or USCDI for operationalizing that standard. So, how do we approach it to ensure that there is alignment between a standard that we would like and a standard required to support that implementation? Because we have run into that in several places.

Fillipe Southerland
So, the proposal here would be to maintain the standard as is, but also support the SVAP?

Steven Eichner
To make the recommendation to ONC that there is a standard included in SVAP so that healthcare vendors can utilize the SVAP list of tools for early implementation, but looking at monitoring its utilization for future adoption as the formal standard. How does that sequence occur, and at what time period, so that you look at an orderly transition? And, that is kind of an ongoing challenge, that it is being released or available at the end of next month. How long does a standard have to be published for to be considered for adoption or utilization? Do we want to make a recommendation that there should be a time period involved in looking at something being listed in SVAP before it be considered for modification of standard as a full utilization, or do we leave it alone? The same issue would apply in several different places.

Deven McGraw
I suspect, Steven, that that is going to depend on the context. There may be situations where there is insufficient voluntary uptake of the newest standard under SVAP, and so, there is a need to retire the old one to push people to get to the latter one, but in another context, it may be premature, and I am not sure there is a time standard that would necessarily apply across all the context, and it is something that ONC, as the ultimate rulemaker here, is going to need to consider. I think the best that we can do is in the context of a particular standard to provide a recommendation when there is a need to a retire a standard. I think it is partly our job to provide that recommendation, but where there is not clear evidence about retiring or maintaining, I am not sure it makes sense for us to say it takes X amount of time for a standard on SVAP to reach the level where it should be elevated. I think it will be **[inaudible – crosstalk] [01:00:01]**.

Steven Eichner

Okay, so we can either stay silent or maybe make a more generalized statement that says to consider adoption rates or whatever is moving something from SVAP into the formally adopted standard without attaching a number, time period, etc., but just as a yardstick to be considered. In other words, a yardstick, a furlong measure, or whatever may be something that ONC needs to decide that may be, again, measure-specific. Okay, wonderful. Moving on to Line 27, looking at national healthcare surveys, the draft standard for trial use is what is currently in regulation. It was adopted in 2014. There is a new iteration in SVAP looking at Release 3. It is the same type of issue, looking at replacement rates and how to cycle through. So, do we treat it the same? The national healthcare survey data is reported directly to CDC as the consumer of that data. So, do we want to make the same type of recommendation?

Fillipe Southerland
It appears Hans is saying his opinion is that we leave the newest version as SVAP and maintain. That is how I am reading that.

Steven Eichner
Yeah. Looking at Line 28, standard code set CVX, vaccines administered, updates through August 17, 2015. This code set is a subset of CVX codes that are used for certification purposes. It is not the entire library of CVX codes. There is not a more currently published version. As long as the CVX file layout is consistent, again, it is a subset that they are using for testing purposes, so do we have a recommendation in that space? Is this something we should leave? Do we need to get additional data or additional information from a testing end? Ram, from a testing/certification end of it, without looking specifically at this particular code set, can you offer some guidance or suggestions as to whether there may be utility in updating a code set with a more modern data set, even if the file layout is the same and you are really testing about file layout more than the content? Can someone offer some insights in that space? Craig?

Craig Newman
From a testing point of view, the older value set is probably sufficient. The expectation has always been set with implementers that the most recent set of CVX codes published by the CDC should be supported. That is one of the changes we made from the 2.8.2 guide, actually, is to specifically label the CVX value set as being dynamic. You are correct, it is not the full CVX, but as critical new CVX codes, such as for the COVID vaccines, have been added, the expectation has been that they be utilized. I do not know how that impacts your approach to testing, whether it is important to be able to test the most recent codes. From a practical point of view, as long as a CVX code can be used to populate a V.2 message, it is typically not quite so important as to what that code is. So, from a testing perspective, it is probably sufficient. From a real-world utility point of view, it will be very important that newer codes are populated. I do not know if that helps or not.

Steven Eichner
I very much appreciate that, and the Task Force's position is really looking at suggesting a particular standard be maintained or retired, and that there is not a more current code set. The limitation, if you will, of the code set listed is it is just a subset of codes that was established in 2015. That is just the descriptor. And again, from a testing perspective that is outside the Task Force's purview, is there a need for having more current codes available for use and testing? Even if the Task Force cannot determine that, is that something that we should recommend, acknowledge, or note in a recommendation about maintaining, just looking at a description of that code set that says something along the lines of "This code set represents

CVX codes that were available through 2015 and may not include more current vaccines, so if testing scenarios are intended to be more specific or utilize more recent vaccines, you may need to modernize"? Is that a recommendation that the Task Force cares to make? Or, do we just say to maintain as is or to retire?

Fillipe Southerland
Steven, it seems we may want to include… So, I am trying to understand if August 17th, 2015 is an arbitrary date, or is there a newer date that we could recommend?

Steven Eichner
There is no more current code set published, so this is the standard, if you will, and its last published date.

Craig Newman
My recollection from that process is in order to be able to point the testing tools to a defined subset of CVX codes, there had to be an official publication or however you want to think of it, and so, that was the origin of this list. It was mostly just a technical requirement, as I recall. The codes still on it should certainly still be viable and appropriate for use. It just might be incomplete relative to what is expected to be exchanged in the field.

Steven Eichner
Right. There are certainly vaccines that are available today that are not in the code set because they are newer vaccines. The same thing can also be true if there are vaccines in the code set that have been retired subsequent to 2015. But, that list is not used for clinical care. It is used strictly for testing purposes. In a recommendation, some list probably needs to be maintained or made available, so I think the question for the Task Force is whether we make a recommendation to maintain and potentially modernize if you need to test against vaccines that were released after August 17th, 2015.

Fillipe Southerland
That makes sense to me.

Steven Eichner
And just calling attention to that limitation of the code set. So, we can make that happen. Looking at Line 29, public health data systems, consortium to source a payment topology code set, Version 5.0, October 2011, there is a new version available, Version 9.2. This list is a catalog of different payment types, and Version 9.2 expands on categories that were established in Version 5.0. I have not done a line-by-line comparison. I am unsure where this topology is used specifically. Do we make a recommendation that it be replaced or that further research may be needed to ensure that the new code set is inclusive of previous codes so that a migration to a new code set adds flexibility, but does not require a recode or a reanalysis because codes are lost? Do we have a recommendation?

Most of the comments in the existing worksheet are "phase out," "replace," or "update," so if there is no concern with that as a recommendation, we will draft some text for the Task Force to review that elaborates on that idea, again, calling attention to ensuring that based upon the concept that the new code set does not eliminate codes that were established in the previous version, that it is backwards compatible, that an update should be advanced or considered.

Looking at Line 30, national drug code directory, vaccine, NDC linker, updates through August 17th, 2015. The current worksheet has comments that range from “working maintain” to “retire.” Do we need to get additional information and revisit it? I am not aware of a replacement code set. Again, I believe that this code set is used primarily for testing purposes, and not as a live data set for clinical care. Is the Task Force interested in getting additional information and revisiting it next week? Would that be helpful? I think we will revisit it. Mike, do we want to go to public comment?

Public Comment (01:15:08)

Michael Berry
Sure, we can do that. I will put up the public comment slide. We are going to put up our call for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute or unmute your line. So, let’s pause to see if anyone raises their hand. I am not seeing any hands raised, Steve, so I will turn it back to you, but we will continue to monitor.

Next Steps (01:15:42)

Steven Eichner
Okay, thank you. I would like to open the floor for any comments or questions from our Task Force members today looking at the standards we have reviewed or upcoming questions regarding standards for next meeting, where we will be looking at additional standards. We are making good progress, but we do need to report out on our progress to HITAC at the upcoming HITAC meeting in mid-August, but I think we are making good progress, again. If there are any comments from Task Force members, we would love to hear from you. Is this process working for you? Is there additional information that needs to be provided to better evaluate standards? Are there changes in process that we can use to make it more effective? Do you have the information that you need?

Fillipe Southerland
I cannot think of any at this point, Steven.

Deven McGraw
Me neither, Steven. Sorry for the silence. I think you and Hans are doing an amazing job at taking us through all these items, and it is not always easy to keep up when you have expertise in some and not in others. I do wish we were getting a little more public comment, but we cannot make people come to these meetings, so I think we are doing the best with what we have, and I thought having the speakers today was really helpful to add a little bit more information. Thank you.

Steven Eichner
John has his hand raised.

John Kilbourne
Thank you. This is John Kilbourne. Yes, I share that. Thank you very much for holding this together despite our silences. For these cases like the NDC codes and the CVX codes, what are we supposed to do? I

guess I had a naïve idea that SVAP would make it all better, but if the organization that makes a standard does not update the standard, it is like we are stuck. Anyway, I guess I am just voicing my complaint. I do not have a suggestion. I just do not see an obvious thing to do in cases like that with the CVX, for instance. If CDC does not update their CVX list, what can anybody do?

Steven Eichner
That is an excellent question. Looking at that particular code set, it is actually what that standard was established to do, which makes a difference. It is not that CDC has not updated the CVX code set, it is that that particular standard is used exclusively for testing EHR technology, and there has not been a request made by ONC to update the list of CVX codes, or if there has been, the responsible entity has not yet updated that code set.

So, my personal expectation is that if you are testing something related to CVX codes in EHRs, you need a set of CVX codes to test against. Without understanding or knowing the testing methodology and what is actually being tested for, it may be that you could use a CVX code from 1976, if CVX codes existed in '76, and it would be perfectly valid for that testing purpose, for example, if you were just populating a particular field with a CVX code. But, if you are looking at decision-based or computer decision support testing that is reliant on a particular vaccine being applied or being administered, and that vaccine is not in the code set, then you cannot test the EHR functionality around that particular code. So, in the narrow sense of having a CVX code to test against, the existing standard might be sufficient for that purpose, but if you are looking at changing testing criterion for other purposes, you might need to modernize that particular standard. Does that make sense?

John Kilbourne
Yes, very much. Thank you for clarifying that. So, the standard that we are looking at is not the actual list of CVX codes that are the actual list, but the sort of derived or…not pretend, but selective list for testing, which will tell you that you have the right numeric fields and your API call will not crash, but it will not actually help you with the current content of the vaccines because it does not have more current vaccines than 2017 or whatever the year was. Anyway, thank you. I was misunderstanding that we were talking about the actual CVX code list itself, and that is not what we were talking about.

Steven Eichner
Right. So, for this particular standard, do we make the recommendation to maintain but observe that the standard has not been updated since 2017? If you are looking at testing functionality based on what the actual vaccine is, you may be out of date.

John Kilbourne
Yeah, that will not work.

Steven Eichner
If you are only testing for a CVX code, you may be fine, but note that some CVX codes may have been retired since that date.

John Kilbourne

Yeah, that makes a lot of sense. And, who owns that? Who is responsible for updating that document, artifact, or standard? Sorry if I am asking a really dumb question.

Steven Eichner
No. That particular standard is maintained by NAHDO.

John Kilbourne
Ah, okay. Again, it is not the actual official CVX list maintained, I think, by CDC. Maybe just adding that disclaimer or that added comment would be helpful for now because I do not know how much influence there is to actually get the standard changed. It might be another period of time before the standard actually gets changed.

Steven Eichner
In this particular case, it would be ultimately up to ONC or HHS as to whether there is a necessary change in testing protocol that would benefit from a different list of CVX info, right?

John Kilbourne
Yes, yes.

Steven Eichner
If they are not changing the testing methodology, and the methodology is only "Hey, can you populate a message with a CVX code and send it on?", then there is no need to change.

John Kilbourne
Then we are good, yeah.

Steven Eichner
But, if you are looking at things like AIRA checking if it is a valid CVX code, if you are checking one of the subsets against the real CVX code and the CVX code was retired in the real world, then you are going to pop an error.

John Kilbourne
And, maybe testing for validity is not really a useful kind of test for this content that changes, like drugs, which changes so frequently, so you can test for some other kind of valid code. I was going to say gender code, but that is changing a lot too now, but how many volts there are in your power line probably is not going to change. But, for content that changes with some velocity, is it worth saying that that is a different kind of test and needs to be treated differently?

Steven Eichner
We do not know what the testing protocol is, so from a Task Force recommendation, if we said something along the lines of "Hey, be cognizant of the limitations of the code set and how it may impact your testing. If you are testing against more current codes, you may have an issue, but if all you are testing is populating with a CVX code, there is no need to change," right?

John Kilbourne

I like that. I like what you are saying. That makes a lot of sense to me personally.

Steven Eichner
We have a question in chat. "Where does RxNorm, for example, fall into CVX/NDC/vaccine cross works?" "Never mind, disregard my question." So, we can certainly include text like that in a recommendation, and we can put something together for the Task Force to review. I am happy to do so. Are there any other questions or observations before we close our meeting?

Fillipe Southerland
Just an observation from my side, Steven. So, when I click on this link on Line 30, I cannot find a reference to that August 17th, 2015 date, so I am wondering if that was a date chosen when this standard was originally adopted, or if that is something where we could go in there, update that, and say, "Updates through this updated date," which would incorporate some of the newer codes.

Steven Eichner
Sure. We can look at updating that information and make sure it is current and complete. Well, I would like to thank our speakers and our guests for joining us on this meeting, I would like to thank the Task Force members for their input, I would also like to thank the ONC and other staff for supporting us, and I would most certainly like to thank our guests and viewers for observing and participating in this Task Force meeting. Our next meeting is scheduled for next Tuesday at 10:30 Eastern Time, again, virtually, and ONC will send you a link for the meeting. Meanwhile, if there are any questions, please feel free to contact us by email. I will turn the floor over to Mike to close us out and take care of any remaining business. Mike?

Michael Berry
Oh, thank you, Steve, for holding down the fort while Hans is out. I know it is a lot to manage the entire meeting just by yourself, so thank you so much, and we will look forward to seeing everyone next week. Meeting is adjourned.

Adjourn (01:28:28)