Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

September 14, 2022, 10:00 a.m. – 12:00 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Aaron Miri	**Baptist Health**	**Co-Chair**
Denise Webb	**Individual**	**Co-Chair**
Medell Briggs-Malonson	UCLA Health	Member
Hans Buitendijk	Oracle Cerner	Member
Steven Eichner	Texas Department of State Health Services	Member
Cynthia A. Fisher	PatientRightsAdvocate.org	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Valerie Grey	New York eHealth Collaborative	Member
Steven Hester	Norton Healthcare	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
Arien Malec	Change Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Aaron Neinstein	UCSF Health	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Brett Oliver	Baptist Health	Member
James Pantelas	Individual	Member
Raj Ratwani	MedStar Health	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Carelon Digital Platforms (an Elevance Health company)	Member
Thomas Cantilina	Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative

Name	Organization	Role
Ram Iyer	Food and Drug Administration	Federal Representative
Jonathan Nebeker	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Elisabeth Myers	Office of the National Coordinator for Health Information Technology	Deputy Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Seth Pazinski	Office of the National Coordinator for Health Information Technology	Director, Strategic Planning and Coordination Division
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Gillian Haney	Council of State and Territorial Epidemiologists (CSTE)	Presenter

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

Michael Berry
And good morning, everyone, and welcome to the September 2022 HITAC meeting. I am Mike Berry with ONC, and I would like to thank everyone for joining us today. As a reminder, your feedback is always 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. So, let's get started with our meeting. First, I would like to welcome ONC's executive leadership team to the meeting, and with us today is Elise Sweeney Anthony, the Executive Director of the Office of Policy, and Avinash Shanbhag, the Executive Director of the Office of Technology. I will now begin roll call of our HITAC members along with our federal agency representatives of the HITAC, so when I call your name, please indicate that you are here, and I will start with our cochairs. Aaron Miri?

Aaron Miri
Good morning.

Michael Berry
Denise Webb?

Denise Webb
Good morning.

Michael Berry
Medell Briggs-Malonson?

Medell Briggs-Malonson
Good morning.

Michael Berry
Hans Buitendijk?

Hans Buitendijk
Good morning.

Michael Berry
Thomas Cantilina? Steven Eichner? Cynthia Fisher? Lisa Frey?

Lisa Frey
Good morning.

Michael Berry
Raj Godavarthi? Valerie Grey? Adi Gundlapalli?

Adi Gundlapalli
Good morning.

Michael Berry
Steven Hester?

Steven Hester
Good morning.

Michael Berry
Ram Iyer? Jim Jirjis? Meredith Joseph? John Kansky?

John Kansky
Good morning.

Michael Berry
Ken Kawamoto?

Ken Kawamoto
Good morning.

Michael Berry
Steven Lane?

Steven Lane
Good morning.

Michael Berry
Leslie Lenert? Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
Arien Malec?

Arien Malec
Good morning.

Michael Berry
Clem McDonald? Jonathan Nebeker? Aaron Neinstein?

Aaron Neinstein
Good morning.

Michael Berry
Eliel Oliveira?

Eliel Oliveira
Good morning.

Michael Berry
Brett Oliver?

Brett Oliver
Good morning.

Michael Berry
James Pantelas? Raj Ratwani? Alexandra Mugge?

Alexandra Mugge
Good morning.

Michael Berry
Abby Sears? Alexis Snyder?

Alexis Snyder
Good morning.

Michael Berry
Fil Southerland?

Fillipe Southerland
Good morning.

Michael Berry
Ram Sriram? And Sheryl Turney?

Sheryl Turney
Good morning.

Michael Berry
Good morning, everyone, and thank you so much, and now, I would like to introduce Dr. Steven Lane, who has a brief announcement. Steven?

Steven Lane
Thank you, Mike. I hope you can hear me well. I am announcing a change in my representation, which will become effective next month. In addition to my clinical practice at Sutter Health, which is contracting into a smaller program of telemedicine, I am going to be taking on next month the role of chief medical officer for Health Gorilla, which is a health data company which is applying to be one of the first QHINs under the new TEFCA, so, clearly a different role in relationship to ONC, and I wanted to announce that to everyone here before that change happens next month.

Michael Berry
Great. Thank you, Steven, and now, please join me in welcoming Elise Sweeney Anthony for her opening remarks. Elise?

Welcome Remarks (00:03:46)

Elise Sweeney Anthony
Hi, everyone. Thanks so much, Mike. Thank you so much, everyone, for joining today's HITAC. Thank you to the members and everyone who has joined to listen in as well. I wanted to give a couple of updates on behalf of Micky Tripathi, who is speaking at a conference this morning. He will plan to join the meeting later today, but I wanted to make sure we shared some of the exciting things that ONC is engaged in. So, first, I wanted to note the ONC tech forum. So, hopefully you joined last week for the kickoff. It was an amazing, amazing afternoon, and the focus of last week was health IT standards driving modernization and healthcare in public health, and we had an excellent lineup of speakers and great participation from our stakeholders, and we are looking forward to the next two meetings as well, so September is going to be a busy month for the tech team.

So, next Friday, the theme is going to be guiding innovation through data standards and real-world implications, and then, the third and final meeting will be on the 23rd, and the theme is how health IT certification is modernizing healthcare and public health. So, you are welcome to participate in any of these scheduled sessions, and that is for anyone on the line. You can register online. If you would like to review the agenda as well, you can do that online at HealthIT.gov, and just search "tech forum" and it will come up. There is also the tech showcase, which is really cool as well, and it is a tab on the website that has videos and demos from health IT innovators highlighting some new and exciting work being done to advance digital health and improve care, so I encourage folks to check that out.

The next announcement that I wanted to make is to announce that the Sequoia Project, which many on this call are familiar with as the recognized coordinating entity for ONC in regards to supporting the implementation of the Trusted Exchange Framework and Common Agreement, or TEFCA, recently announced new standard operating procedures and the QHIN application, so all of that is available on their website, and they expect to open the application portal to prospective QHINs on Monday, October 3rd. The RCE has held multiple feedback sessions and modified and update the SOPs and application based on the tremendous input from stakeholders, which has been invaluable, and as you all know, throughout this process, we have engaged with the public, we have engaged with you as the HITAC to share your thoughts and feedback regarding the different stages as we move towards implementation of TEFCA.

So, I am really excited for this next stage and all the work that the RCE has been doing. The release of these documents is a major milestone and moves the RCE further into the operational phase of TEFCA, which is exciting in and of itself. The RCE has been invited to present to the HITAC at the October 13th meeting, so stay tuned for that as well. We are looking forward to that presentation, and if you have any questions regarding where RCE is in their implementation or some of the materials that I mentioned today, check out RCE.sequoiaproject.org. Of course, my dog is going to bark when I am presenting. It would not be a presentation without it. Sorry, I apologize.

I also wanted to give an update on ONC's notice of proposed rulemaking, and we discussed this at the January HITAC meeting. It is entitled, and it is a long title: ONC Health IT Certification Program Updates,

Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancement to Support Information Sharing Rule, and it is listed in the unified agenda. So, I wanted to note that the NPRM was accepted by OMB for review, and it was accepted on September 1st. Once it is released to the public, we will ask the HITAC to convene a Task Force to review the NPRM and provide recommendations during the public comment period, so stay tuned for that. The unified agenda has a release date anticipated for October 22, 2022; however, note that the date may change. It is subject to change.

ONC will also be hosting two events that I want to highlight. So, as you know, in the past, we have done information sharing webinars and presentations, we have done a series with providers as well, and we have done office hours, and we want to continue doing those office hours as well. So, the next series of office hours, the information-sharing virtual office hours, are on our website, and it is going to be focused on questions around the information-blocking regulations, any question you may have. The sessions are going to be held on September 22nd, October 6th, and October 27th, so I wanted to highlight those.

We encourage folks to just call in. The platform is really easy to use and gives you a chance to ask the regulatory team any question that may be on your mind regarding the information-blocking regulations, and my team does a phenomenal job, absolutely phenomenal job setting those up, and as many of you who have joined the calls know, we definitely try to listen and understand what you are seeing on the ground and provide answers or direct you to the rule where we are able to do so, so please do check those out. Again, September 22nd, October 6th, and October 27th.

The second thing I wanted to note is something that is happening today and tomorrow. So, with the Security Risk Assessment Tool, ONC and OCR are hosting two webinars, today and tomorrow, for you to receive a basic overview of the tool and to hear highlights of the enhancements made in Version 3.3. There will also be an opportunity for participants to ask questions and give feedback during the session. You can still register for the information-sharing office hours and the security risk assessment webinars on the Events tab at HealthIT.gov.

I also wanted to note as a reminder that ONC recently opened the submission period for the new data classes and elements for USCDI Version 4, and we are really interested in receiving your comments on existing data elements as well, so, again, if you search “USCDI” at HealthIT.gov, information will come up regarding the submission process. Do note that submission period ends on September 30th, 2022. It is hard to believe we are already in September, talking about fall, but the submission period will end on September 30th, 2022. There is also an annual comment period for the Interoperability Standards Advisory, or ISA, and that opened on July 28th. The comments, suggestions, or proposed additions also have to be in by September 30th, 2022, so that is a really important date, so please do take a look at that. You can also find it on our website, and we really encourage feedback.

You always hear me say the importance of hearing what implementation looks like, what is important to you, what is important to anybody in the world of healthcare regarding health IT, and that includes as it relates to standards, as it relates to what would be in the USCDI, and really all of our work at ONC, so this opportunity is to provide comment. As folks know, we read every single comment, we review every single comment, so it is really helpful to get your feedback, whether it is short or long, two sentences or two pages. Whatever is helpful for you to share, we really encourage you to let us know what you are thinking.

So, with that, I want to thank all of the members of the HITAC for all of the work that they have been doing, and I also want to thank the Adopted Standards Task Force for their efforts to develop recommendations that the HITAC is going to discuss and vote on today. I know it has been a lot of work, and we really do appreciate it, and special thanks to Hans and Steve for serving as cochairs on this Task Force. It has been really helpful, and we are looking forward to hearing the discussion later today. With that and all of those updates, I want to turn it over to Aaron and Denise.

Opening Remarks, Review of Agenda and Approval of August 17, 2022, Meeting Minutes (00:11:39)

Aaron Miri
Awesome. Thank you, Elise, and I do want to echo what you said. Your team is awesome at those updates, so please reach out to the ONC. We say it every year, but Elise, your team rocks. Thank you for all the work you are doing. It is not easy explaining to hundreds, thousands, and millions of people what is going on, but thank you for that work. It is very well appreciated.

So, with that, welcome to this month's HITAC, everybody. I am joined, obviously, by my illustrious cochair Denise, so today we are going to walk you through a number of items on a very packed agenda. Before I get started, though, before I turn it over to Denise, I do want to say congratulations, Dr. Lane. We are proud of you. You are going to rock it in your new role and continue to serve the HITAC well, so, congrats, sir. I appreciate you staying on and being part of our family still. Denise, over to you.

Denise Webb
All right. Congratulations, Steven. So, I have a bad cold, so I am going to limp through this meeting, so I am going to keep my remarks short, but Elise, thank you for the great update. Wow, there is a lot going on, and we are all going to be really busy this fall with all of these activities and events. So, we have a great meeting ahead of us, not too long, a couple hours, and welcome, everyone, and hopefully, we will get a lot of good input today and have our recommendations from the Adopted Standards Task Force fly through with no issues, hopefully. So, I am going to turn it over to Aaron and let him review the agenda with you and call for approval of the minutes.

Aaron Miri
Absolutely, thank you, Denise, and I hope you feel better. Okay, so, today's agenda. Obviously we have our opening remarks right now. Next will be the Adopted Standards Task Force, some great work that Steve and Hans have been leading there, very technical, and I could not think of two more qualified, wonderful individuals to lead that effort and explain to us in plain English what all that means, so, congrats to them. We will do the HITAC Annual Report Workgroup, which is near and dear to my heart, and then we will go to the Public Health Data Systems Task Force update, public comment around 11:50, and then adjourn right about lunchtime, Eastern Standard Time. So, with that, hopefully you all got the prior meeting minutes from last month's meeting. It was a robust discussion. So, I would like to call for a motion to approve, please.

Arien Malec
So moved.

Aaron Miri

All right, and a second?

Hans Buitendijk
Second, Hans.

Aaron Miri
All right. All those in favor, please signify by saying aye.

Several Speakers
Aye.

Aaron Miri
Any opposed, please say nay. And any abstentions? All righty, the meeting minutes are approved from last month. So, with that, I am going to transition now over to Steven and Hans.

Adopted Standards Task Force 2022 Recommendations – HITAC Vote (00:14:27)

Hans Buitendijk
All right, good morning, everybody. I think Steve is going to kick us off. Is Steve on?

Aaron Miri
He is on. He may be on mute. I just saw him.

Steven Eichner
I got unmuted. Let's go to the next slide, please. We had a great Task Force that did work over about 15 or so weeks to look at all the standards that ONC is responsible for administering through federal regulations. Under the 21st Century CURES Act, there is a requirement for ONC to review all the standards in regulation and determine whether they should be maintained or retired, and the Task Force was charged with making recommendations in that space. **[Inaudible] [00:15:31]** we are going to then go through the approach we used. We broke down the standards into different groups for discussion, and then we have a set of recommendations to make. Let's go to the next slide, please.

As I mentioned, there is a review of the adopted standards required five years after the passage of the 21st Century CURES Act, and every three years after the first one, looking at determining whether the standards should be maintained or phased out. Again, it comes out of the 21st Century CURES Act. Let's go to the next slide, please. So, the charge of the Task Force was to review these standards. The standards are maintained on the ONC standards hub, which is a semipermanent URL. The charge does not include making recommendations about new standards or implementation specifications for ONC to adopt. In other words, it is not looking at expansion of the regulatory role. Next slide, please.

We had a very diverse Task Force, with healthcare providers, vendors in public health, and other communities, all involved and all making valuable contributions to the Task Force's work. Next slide. We also had a variety of subject matter experts not on the Task Force who provided their insights. So, we went through 55 standards for review. We developed several different standards blocks to facilitate that review. We developed a grid and collected input from Task Force members to identify where we needed to get additional information and do more in-depth research. Through a series of Task Force meetings, we included community-based experts to expand our knowledge and develop recommendations, and then

drafted **[inaudible] [00:17:50]** and rationales for each standard, and have drafted a report for submission to the HITAC for HITAC's approval. Next slide, please.

This is the list of presenters. As you can see, we had a wide range of experts from organizations like the CDC, the Association of Public Health Labs, ONC, public health departments, and standards development organizations. Next slide. For each standard, we developed a disposition framework looking at either recommending that the standard be maintained, looking at maintained or phased out with replacement, and by replacement, we were looking at a version change of the standard. For example, currently, in regulations, there might be a reference to a 2015 standard, while there might be a new standard currently available or an updated version of that standard available, so the Task Force may have made a recommendation for a standard to be replaced, again, looking at a phase-out with replacement, similar in nature, or the option of phasing out entirely, and I do not believe we had any standards that we recommended phasing out entirely. Next slide.

As I mentioned earlier, we broke out the standards into a number of different logical groups to facilitate the review, including data scopes and vocabulary standards, several data access standards, care coordination standards, public health exchange standards, benchmark quality measurement standards, privacy and security standards, accessibility standards, looking at things like WC3 and the accessibility of resources for individuals with disabilities, and standards about the certification process. Go to the next slide, please.

This slide presents summary information about the disposition of each standard. As you can see, in the majority of the standards, the Task Force found that there might be a suitable replacement currently available, including in SVAP, and there were several that we suggested maintaining with phasing out and replacement, and 14 standards where there is not currently a central replacement standard. And again, as I mentioned earlier, there were no standards that we suggested that could be phased out. Next slide, please.

This is a summary slide representing the disposition of each standard by group to give a sense of what changes might need to be made, again, looking at the data scope and vocabulary standards, having a suggested number of standards that might be phased out with replacement, and the standards are just by number. We did not do a proportional graphic. Next slide, please. This is the first slide that represents a breakdown of the specific standards, so we will turn the floor to Hans and let him walk us through the first standard, and we will alternate going through. Hans?

Hans Buitendijk
All right, thank you, Steven. Now we are diving into a little bit more of the details. We are not planning to look specifically and address each individual standard with the specific recommendation because there is a lot of similarity among them, so we are going to be highlighting some of the key areas where it is, and then, in the next couple of slides within this section, we are going to look at the general disposition as well, but we are not going to review each specific recommendation at this point. However, if you have any questions about the specific standards, then certainly put it in the chat, and then we can bring it up, or just at the end that we can go back to that.

So, in this group, we had a variety of standards that are around vocabulary, the SNOMED, LOINC, etc. type of code systems, as well as USCDI, which sets the scope for the data that is mostly being addressed in other standards. So, that was the area. We had 21 standards in that. You will see that most of them are

on phase out with replacement, and the rationale behind that generally is that there are more current versions out there, and particularly with the vocabulary advancement generally is that even with what is in regulation, there is already the opportunity to use a more current version in certification or otherwise, so, from that perspective, that was an anticipated large number there.

A couple things jump out. USCDI Version 1 is in the regulation, but we already know that there is a Version 2 in SVAP, there is a Version 3 out there that is being worked on further, and we are starting to look at a Version 4, so that is clearly one that can be looked at and should be considered in a next regulatory update to look at a more current version, and therefore, it is a phase out with replacement. Generally, the notion of phase out and replace, which really bears repeating, is that we are not phasing out now. It is important to have a replacement so that there is an orderly transition from one to the next.

There are some dependencies with USCDI that one has to be careful not to advance USCDI too far. For example, if USCDI Version 3 were to literally be chosen today, the underlying and supporting standards FHIR US CORE and C-CDA are not ready yet to support that, so you have to be careful about the dependencies, but in general, Version 1 can be phased out and replaced by a more current version. The specific version is outside of the scope of this Task Force to nail down exactly.

With LOINC and SNOMED, we had a number of different standards that are referencing SNOMED and LOINC, different versions. Here, the theme is that yes, clearly, they can advance. There are more current versions, and going back to the statement that it is already permissible to use more current versions based on the guidance in the regulations, but also, there are a couple different versions specifically referenced among the references, and therefore, it should be looked at if we can reference just one, the most current one, and then apply that process accordingly, so there is an opportunity to consolidate both references to SNOMED and references to LOINC respectively into fewer, if not one, reference.

Then, there is a small one, but still notable. There was a reference to OMB race and ethnicity, and based on how the value set and code set is being referenced, there is ambiguity as to exactly which revision is being considered, so that is something just to look at to make sure that that is clear to the reader and the implementer. The last statement, vocabulary advancement, is very valuable. That opportunity to have, certify, and use the most current version available in LOINC or SNOMED, whichever one, is very valuable to ensure that we do not have to go through a regulatory update in order to use them, we do not even have to go through SVAP to already use them, we can already take advantage of them as well, so it is effectively, for most of these, a matter of raising the lowest version at that point in time while we continue the progress.

If you go to the next slide, we are generally not going to go into detail, but here, you will have a quick look at which ones are specifically phased out with replacement. If you go to the next slide, that continues. All the links are here to go out. There is an interesting one on tags for identifying languages because it depends on what is available whether it should be maintained or not, so you will start to see that, but that is in the details, and the last slide in this section is where you see the three that are being noted as maintain because we do not have awareness of a more current version that would be better suited, potentially, or as an alternative, so maintaining was the recommendation.

So, that is the first section, and then we are going to go onto the next section, which is on Slide 22. In this section, we are looking at general data access. We grouped in there a number of the FHIR standards that

enable APIs and bulk data and relate to SMART framework, so those are the ones that are in there. Generally, what we are seeing there is that we had phase out with replacement because for a number of those already, there are new published versions out there, and perhaps already in SVAP as well. So, the combination of those two really led us to indicate that phasing out with replacement is appropriate.

The one notable on maintain is related to the base FHIR standard. There is actually a more current version out there, which is FHIR R.4B, and today, there is actually the opening of the ballot for FHIR R.5. We do not believe at this point in time that it is appropriate to recommend going to a new version. There is a substantial amount of effort that would be required, both on the adoption of the standard and all the implementation guides that are built on FHIR R.4, but we did note to indicate that the recommendation is to maintain. However, it is appropriate to start to explore when advancement is appropriate. What are the criteria? What are the considerations to do that? Because this particular one would require a reasonably long runway to ensure that everybody in the industry is lined up and ready to make that kind of switch, so today, if you will, if somebody were to say, "Okay, let's move to FHIR R.4B," that would be quite a challenge. If we say we are building towards a couple of years from now and starting to consider that, then we can get everything lined up that needs to be ready to make that happen, given all the dependencies.

So, that is the main theme here, and if you look at the individual standards on the next page, you will see that that is on the first one, but for FHIR US CORE, there are more current ones that are already starting to be referenced in SVAP, so the progression makes a lot of sense, and the same with bulk data access and the SMART launch framework as well. So, that is in this space, but the key one is to provide an appropriate runway, and in the absence of that, maintaining is the appropriate recommendation for now.

Then, let's move on to the next one, and then we are going to play musical chairs again. Care coordination is where there are a number of standards that have been specifically used in the coordination of care, not that others could not be used, but it seemed like a reasonable way to group them without having to enlarge the group. That is where C-CDA standards and implementation guidance are listed, and a couple other ones as well. Here, you see that the primary C-CDA document, Version 1, is a maintain because that is what the guidance for C-CDA is built on, and there is not a new one out there, other than some errata, that we are aware of. All the work is being done for guidance in the companion guides and associated work, so those are the ones that would be appropriate to progress, and therefore, there are already some references, publications, and work in flight there, so that is a reasonable one to indicate to phase out the companion guides with replacement, but the C-CDA, unless something comes out that I am not aware of, would be a maintain.

There is another one that is being referenced here, C-CDA IHE Health Story. That is providing guidance on the older versions of C-CDA, and there are effectively two types of standards to be looked at. One is for what we use to generate documents moving forward and what we need to support to always be able to view and, as appropriate, to incorporate data from earlier versions of C-CDA. So, here, the statement is around ensuring that capability of viewing and being able to use an existing, older version of C-CDA is to be preserved, hence the maintain in that space, but we make it very clear that it is for viewing, reconciling, or incorporating purposes, not for generating. As we have started to see, the idea would be that the most current version is where we would like to see generation occur, and the other ones should be able to continue taking advantage of the content of that data. There are a couple of variations that could be used, and that would be up for discussion once that topic comes around in rulemaking.

So, those are the main things that jump out. If you go to the next slide, we look at the specific details. We probably should have made a little bit more note on the prior side of NCPDP as well, that No. 32. There is a proposal out. We noted there is a more current version in play beyond 2017, and therefore, it is marked as phase out with replacement. There is a conversation going on on which is the right one, 2022.011 or 071, but it clearly is indicative that there is an appropriate and suitable replacement in play that additionally has some capabilities that are of quite a bit of interest. So, that is the picture that you see here with the recommendations that we are making, and with that, I am going to switch it back to Steve.

Steven Eichner
Thank you. Can we go to the next slide? So, we are going to talk a little bit about public health exchange standards, and this was a collection of standards that support exchange of data between healthcare providers and public health. One of the things that is a little bit different about many of these exchange standards is that currently, public health data systems are not certified and most public health agencies are not using certified systems as EHRs to receive data from providers, so that is important as we are looking at considering standards modification or standards progression in this space, that there is active conversation between CDC, ONC, public health, and healthcare providers to ensure that there are appropriate resources to support any standards qualification or standards evolution, and that the data exchange to those two standards or anything standard continues to meet or better meet public health needs for data.

That being said, let's go back for a second. Thank you. So, looking at things like the immunization registry, cancer registry, and laboratory reporting, there are several specific opportunities for looking at laboratory reporting, one being looking at a newer version of ELR, electronic laboratory reporting, as well as potentially looking at the use of laboratory reporting interfacing, which incorporate ELR as one of its categories so that there are some different tasks that ONC can choose to pursue in looking at adopting a replacement standard. And again, this is the distribution between maintaining and looking at replacing, with nothing looking at being phased out entirely. With that, let's go to the next slide, please.

Like the other group, this provides a little more detail and the disposition recommendation for each slide. The full report does include not only the disposition recommendations, but the rationales that the Task Force developed to explain its recommendations, providing additional detail. Let's go to the next slide, please. So, looking at clinical quality measure reporting standards, these standards are used to report information from healthcare providers to CMS for quality measures, and we noted that there is an updated QRDA standard to support any changes in CMS quality implementation guides, so there is a majority of the standards of this group looking at phasing out with replacement as CMS modifies its quality reporting standards. Next slide, please. And again, this is a list of the standards that were included in the group and their disposition recommendations. Next slide, please.

Looking at privacy and security standards, these are standards that are used to define privacy and security requirements. They are well established and have been in place for a number of years. There is currently a public comment period looking at the Secure Hash standard as a catalog of standards. If the standard is maintained as is, there should be a notation in the standards that SHA-1 is disallowed. There were problems in using SHA-1, which is a security risk, and it is not currently used in practice. It should actually probably be noted that it is not used or should not be used in future efforts. And again, most of these standards are

looking at being maintained, with a couple looking at potentially being replaced as a new, updated version becomes available. Next slide, please.

And this is the detail for the privacy and security standards. Again, the Task Force grouped these for convenience of administration and review, but it is not recommending that there be a reorganization of federal regulations in that space. This is just an administrative action for convenience. Next slide, please.

And finally, in my catalog, looking at accessibility standards, and these standards are technical standards relating to the access of information electronically. The Task Force consulted with **[inaudible] [00:40:14]** at the Health and Human Services Department to identify if there were any changes that OCR affected going forward in accessibility, with the idea of if there were, looking at alignment of the standards for EHRs, aligning with any other work OCR is engaging in to create a more uniform perspective not only within electronic health records, but across the domain of electronic access, and OCR was very helpful in providing guidance. They are not looking at any other changes, so, again, looking at phasing out with replacement at such time as a replacement standard becomes available. Next slide, please. Again, there were only two standards in this catalog, looking at web catalog accessibility. Let's go to the next slide, please. Hans, do you want to take this one?

Hans Buitendijk
Sure. So, in this set, this is a fairly straightforward one. When you look at the group highlights, there are currently two standards in this space that focus on the process that certification agencies use, and we are not aware of any newer versions that are in play. That does not mean there might not be something in the future that might occur, that some updates might become available, but at this point in time, we are not aware of that, so in that context, the recommendation that we made was to maintain the current ones, but obviously, in the future, that would be something we could reconsider. These are, in that regard, temporal recommendations based on what we know today and not what we necessarily will find out next year.

So, this one was that everything was marked as maintain, so the next slide is going to be very straightforward for the two standards in play, a maintain. With that, we are at the end of the detailed 55 list. Clearly, each one in the report has a full description of the disposition, as well as a rationale, and the rationale provides that additional clarity that we provided in the highlights during this presentation. When considering a phase out and replacement in particular, what was the rationale for doing that, and the main reasons that you will see is because there is awareness of a new published version, there is already a reference in SVAP of a more current version, and therefore, it is a reasonable consideration to move forward. Whether that is the exact version to move forward with is out of the scope of the Task Force.

These dispositions were the main focus, but we felt that without providing a rationale, it is hard to understand why we recommend to maintain or phase out, but it is up to the next cycle of rulemaking otherwise, and it sounds like, from updates from Elise Anthony, that we have something to look forward to pretty soon where a number of these standards could come back and we see that there are these updates being made. That is really the time where consideration of the exact version and the exact approach would be addressed. So, that is where we stopped, but we do have a couple of takeaways that Steve is going to walk us through where we had some learnings, this being the first time this was done after five years of the enactment, that could be considered for future iterations as well, and that probably is going to be a good point to then solicit for input as well from the HITAC committee overall. So, Steve, back to you.

Steven Eichner

[Audio cuts out] [00:44:44] defined, as we talked about throughout the presentation, is that we did not find that any of the reference standards could really be phased out entirely or retired, that there is ongoing need for regulatory guidance to facilitate information exchange across all the standards areas. It is important for ONC to consider as it updates regulations and replaces references to standards that there be a suitable replacement available and a good transition plan to move from one standard to the next. It is important that regular reviews and updates occur to continue to advance capabilities in these regulated areas. It seems like three years may be an appropriate approach from a time perspective.

Looking at recommending only to maintain or phase out fully without looking at identifying a potential replacement might be insufficient in looking at developing useful information for ONC, so the Task Force developed a rationale to help explain or identify what potential standards might be considered in a future rulemaking effort, again, looking at identifying where there is a viable or potentially viable alternative, and we suggest that something similar occur looking to the future because it is really difficult without considering what is on the horizon to determine whether an existing standard could be maintained or phased out. Next slide, please.

One of the challenges of that space is that the CURES Act review process does create potentially duplicative processes, looking first at the review to determine if a standard should be maintained or replaced, and then, at the tie of opening a rule or developing potential replacement regulations to again revisit, identify, and specify, perhaps in greater detail, what specific standards might be used as replacement, and it might be more efficient to determine a way or figure out a way to do it as a more unified process.

The Task Force also understands that the SVAP process enables voluntary adoption of standards by HIT developers outside the normal regulatory updating process, and that does create a new floor, but one of the challenges of SVAP is it may inadvertently create some interoperability challenges, especially when a standard adopted through SVAP is not backward compatible with other systems and/or if other trading partners do not make similar updates to their systems. That is something that we need to be cognizant of going forward. And, as a last takeaway, a couple of reference standards and viable alternatives were not available at no cost to Task Force members, which limited the ability for a thorough review of the standard by all members. However, presentations by subject matter experts did enable us to understand what the focus and **[inaudible] [00:49:11]** areas of those standards were, but that was just a limitation that we wanted to acknowledge in our presentation and our report, and I believe that is the last takeaway. Let's go to the next slide. So, I would now like to open the floor for discussion and questions.

Denise Webb

Thank you, Steven and Hans. That was an excellent presentation, and I wanted to say that you did an exceptional job as cochairs and your entire team on the Task Force in putting together the report. Super report, so thank you.

Hans Buitendijk

You are welcome.

Denise Webb
Questions? I do not see any hands up yet.

Steven Eichner
We do get that there is a lot of technical information in the report, in the material.

Denise Webb
Yeah, it is definitely not a report for the meek.

Steven Eichner
There was one notation about a potential mismark on a legend in one of the earlier slides, looking at something that I think might have been blue that should have been green, and we will make the appropriate change.

Denise Webb
And I also took a note of three different pages that had some typos, but they are not substantive, they are just grammatical corrections, so I will send that via email. I do not think it affects the vote at all.

Steven Eichner
Thank you. Actually, Dr. Lane has his hand up. Dr. Lane?

Denise Webb
Yes, he does. Go ahead, Steven.

Steven Lane
Thank you so much, and thanks for a wonderful presentation, really quite thorough and understandable. I put a question in the chat which really has to do with how is ONC planning on taking these recommendations and turning them into a glide path for the industry to see these advanced standards implemented, how can we move from recommendation to anticipation and subsequent change, and then, I will also just highlight a comment from the public. Chantel Warszla did ask a question about whether there was consideration given to how such changes would be operationalized, and I think those are related but different questions, and I would love to hear the response.

Denise Webb
So, Mike, is there someone from ONC that could respond to that question?

Avinash Shanbhag
Hey Denise, this is Avinash. Can you hear me?

Denise Webb
Hi, Avinash.

Avinash Shanbhag
Thank you. I was about to jump in with my raised hand feature on the Zoom. So, thanks, Steven, and first of all, congratulations again on your upcoming role. I think Hans did a good job. The scope of this effort

was to look at adopted standards in the regulations. Really, the process for ONC, the next crank of regulations that would occur, is that then, we look into updating of all the adopted standards, and certainly, that would be one step. Now, obviously, these adopted standards get referenced in multiple ways. For example, I think the team here referenced the Standards Version Advancement Process, which, again, is a regulatory framework that has updated standards that allowed two of our processes and are also, again, a place where we will consider some of these items.

And finally, I would mention and say that the Interoperability Standards Advisory, which, again, is not a regulatory requirement, but also a place where we are able to highlight updated standards and/or things where we look into the recommendations from HITAC and be able to provide insights to industries that do use standards, but I am not part of our selection program, which can certainly elaborate. So, there are a lot of places, all the way from regulations which happen at a periodic rate, and as Elise mentioned, there is an NPRM that is at OMB up for proposed rulemaking in that coming cycle, and that is one of the primary places. Thank you. Does that help, Steven?

Steven Lane
Yes, absolutely.

Hans Buitendijk
And maybe some additional comments based on some of the chat. You will see in the report and where you have already read it, where you will see that Ike already highlighted it as well as an example, there are some areas, like in public health as a specific example, where there is a more current version out there. In some cases, there are three or four more current versions out there that could be chosen. It then really depends on the stakeholders and the parties that need to make the respective changes, updates, or otherwise what is the right timing for that.

In FHIR, we mentioned that as well. There is a consideration that if you want to go from FHIR R.4 to anything after that, whether you go to R.4B, or R.5 once it is ready, or R.6 if you want to sip all that, whatever the outcome is going to be, there is going to be a need for strong involvement and what it means to adopt that can range from yes, there is the standard that is already out there, like in public health, but it takes work to get there, what is the impact, or, in the case of FHIR R.4 to a later version, all the implementation guides that are currently R.4-based would have to go through an update as well, and not necessarily everything is done the same way in a more current version of FHIR.

This is a little bit of a part of the key takeaway. It was a little bit of an interesting challenge to be asked what can we maintain and what we can replace, but not go too far into discussion of what it should be replaced by and when, because that was not part of the charter. So, it was a little bit of a balancing act, and we hope that with the rationales that we provided, there is some clear indication of the direction which one should consider, and surely with work in progress that already has been considered or is being considered, but that was actually not part of the Task Force's charter.

Steven Eichner
This is Steve Eichner. Just to add onto that piece, where the Task Force did look at the landscape… We were not charged with identifying a timeframe **[inaudible] [00:56:17]** adopting or identifying any or all possible standards. So, we did look on what is currently in place with what we knew about that was coming

up within the next couple of months. Those were kind of our time borders in looking at creating some awareness about what is in place in the landscape today. From a timeframe perspective, we did suggest or identify the next relevant regulatory update, without creating a specific timeframe, but again, tying it back to awareness of what is available today or what would be available. We did not set a hard date, but really, looking within the next month or so about what might be available as an available standard.

Denise Webb
So, I know ONC cannot comment at all what is in the proposed rule that is coming up, but from my perspective, it seems like the work of the Task Force was almost out of sequence with the work on that rule, but obviously, I think that ONC is well aware of some of the nuances in your recommendations, and probably had already considered some of them, but I guess we will see when the rule comes out.

Hans Buitendijk
We had a little bit of a discussion about that as well, the sequencing of these events, given where we are at, what we are starting to think might happen in October, so it is a question of as we do this work, are we looking a couple months ahead, weeks, perhaps, or are we looking a year or two out because we formally do not know when some of these are going to be a part of an update? As it goes through every three-year cycle, according to the act, alignment of that and proximity would help to better understand as a lesson learned moving forward, as well as how can they be better combined, because the moment that you start to talk about maintaining or replacing, you really have to go through the discussion of what you would replace it with, and if you cannot go too far in that discussion, some of that will have to be repeated, in a way, by the time that the actual rulemaking relative to it occurs, so it is a little bit of the way that the act requires what we need to do and how the regulatory sequence plays out that hopefully, we can fine-tune that a little bit more.

Denise Webb
Exactly, Hans. That is generally what I was thinking. So, do we have any other questions or concerns before we go to a vote? I do not see any hands. Is there anybody that is just on the phone? All right. Well, I think we are ready to go forward with the vote, then. So, if I could get a motion for approval?

Jim Jirjis
Jim Jirjis moves.

Aaron Miri
Second.

Denise Webb
Okay, Jim proposed the motion and Aaron Miri seconded it. So, all those in favor of adopting the recommendations from the Adopted Standards Task Force, please indicate so by saying aye.

Several Speakers
Aye.

Denise Webb

And anyone who is not in favor, no. Any abstentions? All right, so, that order of business is complete, and thank you again, Hans and Steven and your entire Task Force. All right, so, now I am going to turn this over to Aaron and Medell to talk about the Annual Report Workgroup.

HITAC Annual Report Workgroup Update (01:00:27)

Aaron Miri
Yes, thank you very much, Denise. I appreciate that, and I want to give a lot of kudos to my illustrious cochair here, Medell. She has done phenomenal jumping into the copilot's seat, helping to really run through this and really bringing some fantastic perspective, so I am very excited to give this update today, and as we continue to build towards our annual report, I think it is important that we get to the goal. So, the way this will work today is I will take us through our schedule and some upcoming events, Medell will bring you through the crosswalk, and then, of course, we will facilitate any Q&A. Medell, anything you want to say up front?

Medell Briggs-Malonson
No. Thank you for the kind words, Aaron, but you summarized this wonderfully. I am looking forward to this discussion.

Denise Webb
Perfect, all righty, let's rock and roll. Next slide, please. This is our membership, a really great, diverse group of folks, some really good voices around the table, and we really worked through your comments, HITAC, so as you feed in your feedback, items that you have brought to the table, that brings a lot of good discussion. We have excellent perspectives on this, so we hope to share that with you as we go further through the crosswalk today, but again, I really appreciate everybody on this list, and of course, thank you to the ONC staff, and especially Michelle Murray and team. They are rockstars, and I could not do this without them. I keep saying that, but it really is true. Next slide.

All right, so we are here. We already did the September 7th meeting, so the October 6th meeting is next, and of course, we will meet all through the year to transmit in the springtime. Next slide. For us right now, we are talking, obviously, at the September 14th meeting, today, what is going on right now, the status in flight of the crosswalk. It is great. The crosswalk is a good representation of the past several years. For those of you who were here in the early days of the HITAC, there was no crosswalk. We had to develop all that, and it was a really interesting matrix and confluence of all these topics, and how do we make it synthesized and digestible, and even this year's representation on this group has continued to work and refine that crosswalk to make sure that it is very understandable, digestible, and there is a lot of content. We try to present it in a way that even with the most basic of understandings of health IT, you can actually read into it and say, "Okay, I know what that is about." Next slide.

All right. So, we are going to continue to develop the crosswalk of topics I was mentioning here. We are going to provide you feedback, and of course, we are going to present the draft report for your approval, HITAC, in early '23 for transmittal to Dr. Tripathi. Next slide. All right, let's go into the crosswalk. Medell?

Medell Briggs-Malonson
Great. Thank you so much, Aaron. So, as Aaron mentioned, one of the things that we want to do today is present the crosswalk, and this actually includes all of the various different topics organized by all of our

key target areas, and what we would appreciate from HITAC is juts any additional comments on this crosswalk as we present it to you. Now, one thing that you will realize when we do go into the crosswalk is that we have three various different columns, and we have opportunities, but not the recommendations yet, so please continue to think about any other recommended activities that you feel will be necessary for each one of these topics.

So, the primary topics that you will see that this crosswalk is organized is underneath five main areas: 1). Design and use of technologies that advance health equity, 2). Use of technologies that support public health, and then interoperability, privacy, and security, and patient access to information, and of course, all of these areas are defined in the CURES Act. Next slide. So, just to orient everyone to how this report looks right now, we have the topic to the far left, the gap, which was really the reason why this topic is even being explored, and then all the various different opportunities that we have, and then, the next time that we come and present to HITAC, we will have some of those recommendations as well, which we have already started, but we are fleshing out some additional items.

So, starting off with the target area design and use of technologies that advance health equity, this is a brand-new target area, and many of you all may notice we have a new name for it as well, and we wanted to make sure this target area directly aligned with ONC's health equity by design initiative and focus, where health equity by design is really being thoughtful and intentional in ensuring that we are promoting and advancing equity in every single part of our policies, our initiatives, and standards.

So, the very first topic of health equity by design is once again thinking about all of those various different areas where we can intricately intertwine equity, and to the core of all we do when it comes to health IT in this country, and the various different opportunities that we have is continuing to help move everyone along to think about how important health equity by design is. It is not something that you think about after the fact, but something that you strategize from the very beginning, but then, also thinking about how we clearly define all of the various different nuances and differences between overall health equity, healthcare equity, and then, also health data equity and justice, which there are significant differences with just equity and justice, even when it comes to data.

But in order to actually get to the point where we are thinking about health equity by design, we also have to take at a look at our data collection, so that is the second topic under this target area, and so, many, many of us, both in the healthcare systems as well as overall public health, have been really trying to figure out the best ways in order to standardize our data collection to promote greater health equity-related initiatives and ensure that we are doing it in a way that is not incorporating biases. So, the opportunity for really diving into our inequities when it comes to data collection is to continue to advance industry standards on how we collect not only various different items that we will get into, such as demographic features, but all of the other factors that play into health equity, as well as thinking about the additional data that can be utilized and increased in order to support items such as missing race or missing social determinants or social drivers of health data. So, a lot of various different opportunities there to start to really structure our standards even more in terms of collecting data that promotes health equity.

And the next topic, when it comes to electronic exchange of health equity and social determinants or social drivers of health, what we have was the gap of how do we appropriately exchange all of this information, especially between our provider systems, our public health systems, and even our social service systems,

and how can we do that electronically where we do not have a lot of redundancy or fragmentation? So, the opportunity in this topic is really for us to promote some of those best practices that are there, or either really spur some additional innovation for the electronic exchange of data that is going to adequately and intentionally promote health equity as well as the various different social driver data, and that will be moving us even more towards having those standards, not only for race, ethnicity, and language, but also for sexual orientation, gender identity, and so many of the other sociodemographic features that we know are so important to our individual patients, our populations, and for us to provide the best care and public health initiatives. Next slide.

Now, the next portion in this target area is bias. And so, we have had many different conversations about all of our brand-new algorithms, and our clinical decision-making tools, and even how AI has so many great potential efforts or impacts that it can make, but if we are not careful, what can occur is that various different algorithms and AI tools can actually perpetuate things such as racism, sexism, and other forms of bias directly through our systems. So, an opportunity that we have here is actually to start setting up the structures to screen both healthcare and public health data systems in order to identify algorithms or clinical decision support tools that may be rooted in things such as racialized medicine, and making sure that we are eliminating those or replacing them with more appropriate algorithms in order not to perpetuate bias.

And, in addition to that, one of the areas that are there for opportunity is really also making sure that we are supporting our overall clinicians, healthcare, and public health providers and professionals of how to conduct and gather data from patients in an unbiased way during their screenings. So, part of the opportunity is also to encourage additional digital tools that actually allow us to do the appropriate patient interviews and screenings without bringing it into our systems or actually relaying this information in a biased manner. Next slide.

Now, that was all of the summary of the key topics of our brand-new target area, which is the design and use of technologies to advance health equity, and this topic area is the use of technologies that support public health, and so, the very first topic is public health data systems. Again, health equity, public health: We were so diving into this even more due to the amplification of so many of the challenges that we have had during the pandemic and now, of course, as we continue into the endemic.

And so, when looking at the public health data systems infrastructure, one area for opportunity that was identified is the need to continue to coordinate as well as to standardize some of the various different gaps that prevent appropriate and efficient sharing of data information, especially when it comes to supporting public health efforts. So, an opportunity, especially for this report, is to continue to promote all of the various different recommendations to improve the bidirectional change of information between public health and healthcare providers and other entities that need to have this information in a very timely manner in order to support public health as well as clinical care.

And that flows directly into the second topic, which comes along with public health data reporting, and especially when it comes to our electronic case reporting, and this also can include our initial electronic case reporting as well. And so, once again, we went through several trials by fire during the pandemic, and now even with some of our additional emerging conditions, such as monkeypox, and we are seeing even other items emerging, that oftentimes, we need to make sure that we can rapidly implement appropriate electronic case reporting in order for us to have a unified public health response, so we need to make sure

that we have that enhanced communication between the overall clinicians and health systems, clinicians, and public health organizations.

And so, an opportunity that we have here for this report is once again to continue to reinforce the adoption and support of ECR by public health organizations, healthcare providers, as well as overall health IT developers and innovators so that we do have those clear standards so that we are prepared as a country to rapidly respond to any type of public health emerging disease or threat that we may actually see.

Public health data reporting still, when looking at electronic laboratory reporting, has the same exact type of underlying concepts and some of the same challenges that we have with electronic case reporting, so really, as we have expanded ELR, we also need to make sure that we have clear standardization across our reporting systems, and so, we can do this even more by aligning the standards, once again, used by public health organizations, labs, as well as healthcare providers so that we do have that appropriate transmission of laboratory data.

And the syndromic surveillance, again, we tend to have it very focused in the acute care setting. I am an emergency physician, so we report out a large amount of public health data directly from our EDs, and of course, we do that directly from our acute care settings, but we have a gap. We do not have the same level of syndromic surveillance in many of our ambulatory settings, or in our long-term facilities, or others, such as rehabilitation facilities, so we need to think about this a bit more and prepare for more large-scale data needs in order to appropriately respond to outbreaks and pandemics by expanding these surveillance systems beyond the acute care settings so that we are not missing one of the largest chunks of our patient populations that we need to focus on to keep them safe.

And then, last but definitely not least, our public health informatics workforce. Wee cannot do any of this work without wonderful people on the ground that are helping us collect data, analyze data, and help to push forward various different initiatives, but we are still experiencing challenges with maintaining a very well-equipped public health workforce, not only in terms of just numbers and their expertise as they are doing this day-to-day work, but also when it comes to the various different forms of technology, so an opportunity here is to continue to think of great various different programs as well as other types of investment to improve the IT capabilities and the capacity of our overall public health workforce. Next slide.

Now, moving into interoperability, and this is an area that has really been discussed in some of the previous years, and they are still very important topics for us to continue to discuss and streamline, and the first topic is streamlining of our health information exchange data, and so, in all of our various different organizations and institutions, we are all expanding electronic data exchange, but as we expand, we can also start to become more fragmented, more siloed, so one of the opportunities that we do have to keep centered is how we can leverage TEFCA in particular in order to advance interoperability with all of these new systems that are emerging in order to reduce the overall number of methods or the overall number of avenues that we have for appropriate electronic health information exchange, and so, that is a really important piece for us to do. If not, we are going to put out information in various different areas and we will not have the overall succinctness that we need to be impactful.

Now, closed-loop referrals is another important piece of this. One item that it came to when coming to interoperability standards and priority uses was that there has been a lack of cross-organizational support

for closed-loop referrals, and especially when it comes in directly for social services. So, oftentimes, information is sent out, but it does not come back to complete that referral, so what can we do about it? One of the things that we can do is continue to explore the opportunities to advance these standards in order to ensure that these referral processes do close and that we can sum them up in more ways than one, but then, also thinking about how we can increase the adoption of various different systems with integration with our social service agencies. Again, coming out of the pandemic and transitioning into this new time, we know now when it comes to overall health and overall public health that we have to be as united as possible with our social service agencies, and this is definitely one of those clear areas that we can dive into and enhance even more.

Now, e-prior authorization also brings up various different opportunities and challenges for us because there has been a lack of common standards to support prior authorizations across payers. I can tell you even from my own clinical practice and also my administrative work, I think all of us have been impacted by e-prior authorization in more ways than one, so if we do want to make sure that we are being as patient-centered as possible and we are making sure that we are getting our patients to the appropriate level of care in the most efficient and effective way possible, we still need to take a look at these standards on how we can improve systems across the country in order to expedite these prior authorizations.

And then, lastly, in the area of interoperability, one thing that the workgroup was also discussing, and of course, other input from HITAC as a whole, was looking at our directory standards and management, and so, there are numerous healthcare stakeholders that we have, and we need to have appropriate communication between all of the various different healthcare providers, but sometimes, being able to identify all of the digital codes for each one of our various different healthcare providers can be challenging, and so, therefore, if we are really promoting interoperability and appropriate health information exchange, we need to improve the accessibility of those electronic endpoints and that electronic directory of all of our various different healthcare stakeholders. Next slide.

And then, the next continuation of interoperability is standards for patient matching, and so, this is, by far, a priority, and especially when it comes to assessing the level of care that we are providing to our patients, but then, also just making sure that we are meeting the individual needs of our patients and our populations. And so, the gap that we have identified and have explored as overall HITAC is that when it comes to patient matching, we still have significant room for improvement, and also, as we are thinking about how to improve, we really have to center the needs of our most vulnerable and marginalized populations because some of the various different methods for patient matching may be highly acceptable in one population or one area of the country, but may actually be shunned upon for a different population, so we really want to be comprehensive and inclusive when we are thinking about the various different ways for us to appropriately match patient information.

And so, what is before us? One of the things that is before us is that we really need to dive a little bit deeper into addressing the alignment of various different incentives and certification programs across the various different domains in order to create a much larger approach to improving patient matching, but also, thinking about, again, those various different tools that are needed that will be adopted by various different patient populations as well as various different provider organizations. And then, continuing to develop those standards that enable the appropriate and efficient linking of deidentified data. And moving along in terms of thinking about how we are inclusive and making sure that we are providing the most equitable care

possible through our various different health information technologies, of course, telehealth is right there in the center of that.

And so, one topic that was also really discussed within our workgroup was the use of telehealth as well as how do we use telehealth appropriately in order not to increase the digital divide, but in order to truly provide equitable accessibility and equitable use of all of this technology, so one of the things that has been discussed from HITAC, and also especially within the Annual Report Workgroup, is improving that bidirectional exchange of information through our telehealth providers, which may or may not be affiliated with an overall healthcare clinic or system and ensuring that information from those telehealth providers is able to also be transmitted directly to that patient's care team and vice versa, but then, also being very intentional and thoughtful about the development of our technologies and ensuring that the telehealth platforms that we are implementing are equitable in all ways when it comes to overall ability status, when it comes to language alignment, and then, also when it comes to the overall technology in more ways than one. So, lots of different areas for us to explore in the use of telehealth when it comes to providing recommendations. Next slide.

Privacy and security. So, the first topic underneath the privacy and security target area was looking at the alignment of innovation and regulation, and you will see that there are two primary areas here. One is just general, and the other one is focused on the consent directives. So, one of the recommendations from HITAC when thinking about the alignment of innovation and regulation is that we now have a large number of providers and overall health systems that are adopting various different applications and adopting various different APIs, and so, we want to make sure that all of that data is secured and not adding any additional liability to both privacy as well as security.

And so, one opportunity that we have is to make sure that we are enforcing the importance of yes, we are accelerating innovation, but let's make sure that all this innovation that we are seeing and growing and encouraging also has some guardrails around it in terms of regulation so that we are not like the wild, wild west, but we are making sure that all these various different apps and APIs are created in the most appropriate way in order to protect overall privacy and security. And the same type of alignment between innovation and regulation is very important for the consent directives, and so, as we continue to see the rise of innovation even when it comes to consent directives, really making sure that we are adopting some of those various different common standards to capture and exchange all the various different forms of electronic consent in an appropriate way that aligns with our regulations.

Appropriate exchange and use data is the next topic underneath privacy and security. And so, as we have all been thinking about the HIPAA minimum necessary standards and all the various different data that we are exchanging with one another, there are definitely still some opportunities for improving some of the various different segmentations of that data, not only for ease of use so that we do not have various different sets of data that are being transmitted that have a large amount of unimportant or nonessential information, but also the opportunities are there in which we can promote greater development and adoption of implementation guidelines that actually do improve the overall segmentation capabilities, and we always want to think about reducing the burden on our healthcare providers, so how can we actually also continue to help to recommend structures in order to track the evolving privacy landscape across the country in order to decrease that burden for our healthcare providers?

Cybersecurity events across healthcare infrastructure: There has been a large amount of work that has been working on this, as we know. And so, one of the things that the workgroup offered was that it is our time to actually hear and see what is going on also in the cybersecurity space, and maybe what we can actually do is bring in some of the best practices from outside of the healthcare sector on ways that we can improve our cybersecurity preparedness within the healthcare sector. So really, having a listening tour and trying to identify those best practices in alignment with all of the other wonderful groups that are working on this in order to continue to encourage and amplify all of this important work.

And then, the last topic underneath privacy and security was privacy of sensitive data, and this sends a little bit of a change from when we previously discussed it with HITAC. Initially, it was thought about women's health, but we know that this should really be focused on overall sensitive health data, really focused on that data for both women and gender-diverse populations. And so, one of the aspects that we have been discussing and we have the opportunity to go deeper into is to make sure that we are improving the awareness of all of our stakeholders about sensitive health data, specifically for women and gender-diverse populations, and how various different aspects of our technology can support that form of privacy as well as clinical care. And then also, creating and thinking about those additional opportunities to improve the technical and operational approaches to protect sensitive health data because we want to protect it, but we also want to use it in a way that, again, we are providing the best prevention, treatment, and overall outcomes for all of our gender-diverse as well as women populations and others. Next slide.

Now, the last topic is patient access to information, and there are three main topics underneath this target area. So, the first topic was looking at safety and impact of mobile health applications. This is very similar to what we were discussing with the innovation and regulation alignment. We are starting to have a large number of mobile applications that are coming out and definitely being marketed to the general public, but we are not really quite sure and there may not have been as much research and insight into the overall effectiveness of a lot f the various different mobile health apps, and so, it is really important that we think about the guidance, and especially when it comes to data security in these mobile apps. So, the opportunity that has been identified is to continue to support the awareness and education for providers and patients regarding not only the validity of some of these various different apps, but then also making sure that we are supporting the data security of the apps as well through some additional recommendations and standards.

And cost transparency has been a very hot topic, as we know, over the past couple of years, and especially coming down from some of our other regulatory bodies, and what we have seen, though, is that overall, there has been a lower-than-expected compliance rate among hospitals with some of the price transparency rules, and one important aspect of HITAC is always to think about and center patients' experiences and voices, and so, one area that we think that we can provide in this annual report is to try to gather information to understand patients' experiences with trying to access all of the various different cost transparency data and also getting their feedback on what we can do to try to overcome such barriers as well.

And then, the last topic is consolidation of health information. Once again, with all of these new systems, all of these new mobile health apps, our patients actually can have their information stored in various different platforms, and that does sometimes present a challenge because we want to make sure that all of our patients have the ability to not only access all of their protected health information, but also consolidate

it and share it across multiple platforms, multiple portals, and also be able to consolidate it into one review for themselves to review or to review directly with their providers. So, one thing that we think is also very important is to recommend to continue to push a streamlined form of access and consolidated viewing of all the various different health information that a patient may have stored in different portals, in different platforms, but then also continue to support the development of apps that address the needs of our most under-resourced and marginalized communities as well because this is an important aspect also of the exchange of health information.

Various different apps may work for some and may not work for others, and so, as we are thinking about the unique experiences and the unique abilities of various different and diverse patient populations, all the way from those that may be vision impaired to those that may not have the economic means in order to have certain type of mobile devices, we really do want to think about and continue to encourage the industry to develop more inclusive applications so that there are no inequities in terms of having access to patients' own information. Next slide. So, that was a little bit of a whirlwind, going through some of the various different topics in each one of our five target areas, and so, I will actually ask my cochair Aaron to join me, and we will see if there are any questions directly from HITAC.

Aaron Miri
Absolutely. So, real quick off the bat, while folks raise their hand and whatnot, I did want to address that I got a few HITAC members reach out to me that are new to the committee saying, "Hey, how can we incorporate our feedback?" There are a couple ways. No. 1, obviously, you should have all received the most recent document here in the summary that was sent out to all HITAC members of all of our documents and topics. Please review it. If you did not, reach out to me, reach out to the ONC team, who will make sure we get you a draft of the crosswalk. You can get your comments back to me and Medell if you want to email us, or Michelle Murray, of course. All of your comments and feedback items are incorporated into our discussions, and of course, then, if we need further clarity or follow-up, we invite the respective member to come to an Annual Report Workgroup meeting and just talk about it so we can understand and seek first to understand. So, I just wanted to throw that out there for the new members, that your feedback is absolutely heard, and we want you to take the time and to listen. So, first up, we have Ike with his hand raised.

Steven Eichner
Thank you so much for this, and thank you so much for all your work on developing the framework. I do notice, looking at discussion of public health resources and public health components, that there is certainly other work going on in other places about data standards and electronic case reporting, and I want to make sure we are aligning efforts in that space and really targeting the right issues, not necessarily looking at adding additional standards, but looking at complying with existing standards and making sure that we are getting high-quality data across the system, so it may not necessarily be that we need a new standard, it may be that we need some different changes.

We are also looking at not just staffing, but looking at ongoing support for infrastructure is a necessary thing. It is one thing to build a system; it is another thing to maintain it, as we all well know, so there has to be a good forward path so that we can not only operationalize one, but maintain that infrastructure.

Aaron Miri

Good points.

Medell Briggs-Malonson
All really, really good points, and we do want to emphasize for all these various different topics, opportunities, and recommendations that this is all directly in coordination with all of the other workgroups, as well as all of the other work that is being done, even outside of HITAC, with the various different efforts, so, absolutely, it is not about adding more, but coordinating and making sure that we are filling in any gaps, so thank you so much for that.

Aaron Miri
Great comments, Ike. Dr. Lane, you are up, sir.

Steven Lane
Thank you. I just really wanted to thank the cochairs and the members of this workgroup. I have been participating in the group and have been thoroughly impressed with how useful and deep the conversations have been. I also want to encourage other HITAC members to appreciate the critical importance of this workgroup. It is really an opportunity for HITAC members to provide direct and specific input to the ONC. Even though it kind of may seem sort of boring to work on an annual report, we really do not have a lot of other opportunities to work at this level of detail to provide that input, and I think others who want to participate may choose to step forward and jump into the fray. In particular, Dr. Briggs-Malonson, who is a new HITAC member and stepped into this role as a workgroup cochair, which is not a small task, has just done a tremendous job helping to both lead and organize the discussion, and I just wanted to thank you publicly for that.

Medell Briggs-Malonson
Thank you so much. I really appreciate it, and it has all been a group effort. This workgroup is amazing, and I must say it is not boring work, so, for any new HITAC members, it is really not boring. I have been learning so much, even from all my co-workgroup members, so I appreciate you all.

Aaron Miri
All right. Any other comments from the HITAC? Again, take your time, look at the documents that were sent out, marinate on it, think about it. We have some time still, but your comments do matter, and if anything pops into your head at a random hour or whatever, send us an email. We are happy to look at that and take care of it, or just shoot me, Medell, or Michelle a note directly, and if you feel comfortable that way, we got you. We want to make sure your comments are heard and your voice is heard, particularly in some of the new areas around health equity and others. Those are very, very critically important, and the workgroup feels very passionately about that topic, that we have to incorporate that appropriately and dynamically, so your feedback matters. Okay. I do not see any other hands raised, so, with that, I think I am going to go to the next Task Force, then. Medell, thank you very much. Great job. I appreciate you, always. Again, this is just rockstar stuff, so, again, I am so grateful that you are on this committee with me. All right, next up, we have Gillian and Arien. You are up.

Public Health Data Systems Task Force 2022 Update (01:35:06)

Arien Malec

Good morning. How are you all doing? So, we recently convened the Public Health Data Systems Task Force. In usual HITAC fashion, this Task Force was announced at the last meeting, and we have already had three meetings, so we got off the ground and running extraordinarily quickly. Go to the next slide. So, we are going to briefly review charge, which Micky covered in the last meeting, give you the usual one-page membership, and then Gillian will cover timeline, approach, and how we are going about carving up the work. So, go on to the next slide.

Our charge, as Micky noted in the last meeting, is to really follow on, first of all, the great work of the standards update Task Force, and then the continued work, particularly of the last Public Health Data Systems Task Force, to look at certification criteria and the associated standards and implementation criteria. And so, in particular, this charge is divided into three groups. One is looking at gaps, functionality, and standards in existing F criteria for the EHR side of this, so I think as Micky mentioned in the last meeting, if we think about this as pitchers and catchers, Subcharge 1 is all about making sure that we have the right standards updates for, in most cases, the pitchers, the data transmitters for public health, although in the case of immunization, there is a query-retrieve portion to this.

The second is looking at public health data systems themselves. As was previously mentioned, we have historically not had certification criteria for public health data systems, and so, we are looking at the F criteria and associated standards and implementation guidance associated with public health to look at opportunities to further standardize and potentially certify public health data systems. And then, Subpart 3 is looking at the end-to-end data flows, and so, in most cases, we have simple pitchers and catchers with respect to the public health data, and then, in other cases, we have some intermediaries, some other systems along the way. The most complicated of these workflows, probably, is ELR, where we have a provider ordering a test, a lab doing the test and analysis, and then, secondary data flows to public health, and so, it is really important for us to contemplate the end-to-end data flows that are associated with certification criteria. So, that is our charge. I will turn it over to Gillian.

Gillian Haney
Next slide, please.

Arien Malec
Oh, sorry. I have this boring slide. It is not a boring slide, it is our fantastic Task Force and roster, but everybody can read the illustrious folks that we have here. We are lucky enough to have great participation from the full ecosystem really thinking through the provider side, EHR vendor side, as well as the public health/STLT side and national federal providers, including CDC and CMS, so we are well covered in terms of expertise on this Task Force. Sorry, now over to you, Gillian.

Gillian Haney
Thank you. So, as Arien mentioned, we have a very tight timeline, and we have been off and running and have had several meetings. We hope to wrap up our recommendations by mid-November, and we will be coming back to this group to present along the way. So, next slide, please. So, our approach has been and is to review the various different F criteria, which I believe are going to be mentioned on each of the slides, and really discuss what are the key components, the key questions that are arising, the key challenges/areas for each of those criteria, and are having subject matter experts representing both the provider/public health and state/federal level, and subject matter experts from various different vendor

organizations presenting to kickstart each of the discussions that we are having on the call. Next slide, please.

These here are the list of the F criteria, which we are reviewing. We began with immunization registries, and we have worked through electronic case reporting and will be moving on to electronic laboratory reporting, cancer registries, and microbials and healthcare surveys, as well as syndromic surveillance. I think it is really important to note that each of these criteria are at various stages of implementation and different standards and requirements in play, different problems, and different data uses for public health. And so, as we are walking through each of these criteria, we are documenting those differences and discussing what might be meaningful for measured improvement. Next slide, please.

I think it is important for us as we ask each of the subject matter experts to look at really what are those gaps, what recommendations can we do to advance in tightening up criteria, and to acknowledge that there is the importance of standards and the need to reduce variability, but there is also recognition of the critical need for data quality to result in public health action. These are a set of the questions that we are having each of the presenters address when they come on the calls, and I think that they have provided extremely good grounding in terms of all of the issues that are at play. Next slide, please.

So, in terms of where we are to date, as I mentioned, we began with immunizations, and we did so because they have done a lot in recent years to encourage voluntary engagement with their measurement and improvement initiative to improve alignment and functional standards in data quality, so we had Mary Beth Kurilo from AIRA, Hans Buitendijk representing the provider experience, and then, Aaron Bieringer from Minnesota representing state, and I think that they have done an enormous amount that we can learn from to tighten up those standards and improve data quality.

The challenge before us is really finding that balance and recognizing that we exist in a federated public health system, and that there are often laws and regulations that require variability within the standards, but we also really need to develop consensus within the public health community and tighten those existing standards in order to reduce that variation. One of our meetings was then focused on the electronic case reporting criteria, and I think that that also was a good measure to bring up initially because the public health community really came together to determine the data requirements for the initial case report and used a centralized approach via the AIMS platform to develop a superset of trigger codes that has been managed by the Association of Public Health Laboratories, and so, we had Laura Conn from CDC, Steve Lane representing the provider community, and then Ann Kayser from Minnesota representing the state perspective, and we have had very lively discussion about how to move forward with recommendations and what would make sense.

To document all of this, we have initiated the use of a topics tracker worksheet that really enables members to provide discrete technical recommendations within each of the criteria to recommend further developing standards that ONC has already published, as well as to create a written forum to discuss and create frameworks for public health information certification. So, we are moving rapidly, and next up will be electronic laboratory reporting, and we will come back to update you as this moves forward. Thank you. I believe that is our last slide.

Arien Malec

Aaron, over to you.

Aaron Miri
All right, I did not know if there was a further continuation or not. All right, so, with that, then, any questions or comments from anybody in the HITAC? That was a great update, lots of stuff going on, as they both stated, and at warp speed, as to what Arien was alluding to, which is par for the course, I think, as we turn these things around. Any questions from the HITAC? Okay, Dr. Lane?

Steven Lane
Just another comment of thanks to the workgroup members and cochairs. Here again, we have a relatively new cochair joining to help to lead this committee, doing a fabulous job. To those of you who have not had the pleasure of cochairing workgroups or Task Forces, I highly encourage you to do it. It is a tremendous opportunity to impact the direction of discussion, and here again, I think we are really seeing great work going forward, and I am very excited to be a part of this.

Gillian Haney
Thank you very much for that. I have to say, I am the newbie here, and Arien has been very helpful in providing a framework for how these meetings are being run, so I am very grateful for that, and to everybody's participation and engagement. It is very lively.

Clem McDonald
This is Clem, but I cannot find my hand. Can I speak?

Aaron Miri
Yes, you may. Go ahead.

Clem McDonald
Okay. So, we talk about quality, and that might contain what I am worried about, but what we see is we have a standard, and then, it is not very well adhered to, or if it is adhered to, for example, there are some studies we and others have done that suggest that the mappings are wrong from laboratories, maybe five percent, maybe 20% of the mappings from local codes to LOINC are wrong. No one is looking at that. So, the standards are there, but there is sort of a non-attention, in some cases, to them, and that might be part of data quality, but I think we ought to specifically focus on really doing the standard, not just saying it is there.

Gillian Haney
I think a lot of the data quality issues are being addressed by individual jurisdictions, and so, there is potentially an opportunity to come together to have a more centralized approach for that, but I worked in Massachusetts for over 20 years and oversaw the electronic laboratory reporting efforts there, and there was an enormous amount of work around initial onboarding, data quality, and ensuring those mappings were correct, and then, of course, the ongoing work to ensure data quality as information changed.

Arien Malec
Yeah, and Clem, your feedback is very consistent with feedback that we received. In the Task Force updates, for example, for ECR, the most significant issues with ECR adoption were not actually the standard

and implementation guidance itself, it was the applicability of trigger conditions to the data that was being received, and in particular to nonstandard lab data that is being received, or to EHRs that, although they are certified, do not have the ability, for example, to do discrimination based on SNOMED codes because they only have proprietary terminology internal to the systems. They receive the trigger codes, but cannot actually fire them.

And so, that is why I took some pains to underline Subpart 3 of our charter, which really looks at data intermediaries that Clem totally endorsed, that interoperability in practice and certification in practice has been a theme that has come out of the testimony to date, and the need to make sure that not only do we get certified to the standards implementation guidance, but that data transmission and data use in practice is consistent with the standards implementation guidance that, as you know, has been one of the major limitations that we have heard nationwide. Thank you.

Clem McDonald
Can I just add one more thing? So, we have been doing some work in the space, and you can actually automate correction of a lot of the errors because there are certain patterns. People mix up substance and mass concentrations, but units shout out which one it really is, and we have developed a tool, but we have not published it yet, that can help to correct up to 95% of the errors that you would see in mappings, at least for quantitative results.

Arien Malec
Thank you.

Aaron Miri
Clem, as always, you and your group are blazing the new trails, as you have been always doing. Love it.

Clem McDonald
Thank you.

Aaron Miri
Other comments or questions from the HITAC? This is good work. All right, I do not see any. Well, great job, the two of you. Thank you very much for the update. Well done on the leadership of this Task Force and getting us closer, at least across the line.

Arien Malec
Work to be done, thank you.

Aaron Miri
So, well done, and we really, really thank you for that. Denise, over to you. Any comments?

Denise Webb
Thank you, Arien and Gillian. No, I had no other comments. I think we are at the point where we can transition to Mike for public comment.

Aaron Miri

I agree.

Public Comment (01:50:27)

Michael Berry
All right, thank you, Denise and Aaron. We are now going to open up our meeting 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 and unmute your line. So, let's pause for a moment to see if anyone raises their hand. In the meantime, I just want to remind everyone that the next HITAC meeting will be held on October 13th, and if you are ever looking for HITAC meeting materials, whether for this meeting or our Task Forces, that can be found on the HITAC pages on HealthIT.gov, and I am still not seeing any hands raised, but if anyone wants to raise their hand, please feel free to do so. Otherwise, I will turn it back to Aaron and Denise to close us out.

Final Remarks and Adjourn (01:51:17)

Aaron Miri
Absolutely. Denise, do you want to start?

Denise Webb
Sure. Well, thank you to all the presenters today. There is definitely a lot of great work going on, and I appreciate all the cochairs' leadership and all of the Task Force members, and I wish you all a good rest of your month until we see you all in October, and thank you very much.

Aaron Miri
Absolutely, and I want to echo those thanks. First off the bat, Denise, I hope you get to feeling better. Thank you for being a trooper and being here in the copilot's seat, helping to run this, as you always are, just a champion, so I appreciate that, and thank all of you for your efforts today. I do want to remind you about the October date for the full EHI definition. It is right around the corner. Please, please, please, do not forget about that. That is all the data, all comprehensive as part of the information-blocking under 21st Century CURES, and that October date is critical from a mandate perspective, so if you are not thinking about it, please be thinking about it, and there are a number of sites out there, including on the ONC website, that really give some good specificity and detail if you are still wondering how you go about identifying a designated record set and all the data elements as part of the full EHI definition. So, please, please, please, do not forget October. Other than that, have a great rest of the month. We will see you on various committee meetings, and we will see you next month at the next HITAC.

Denise Webb
Thank you, Aaron, for your help.

Aaron Miri
Absolutely. Bye, all. Have a good one.

Denise Webb
Bye, everyone.