



Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

July 14, 2021, 10:00 a.m. – 2:30 p.m. ET

VIRTUAL



Speakers

Name	Organization	Role
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin	Co-Chair
Denise Webb	Indiana Hemophilia and Thrombosis Center	Co-Chair
Michael Adcock	Magnolia Health	Member
Cynthia Fisher	PatientRightsAdvocate.org	Member
Lisa Frey	St. Elizabeth Healthcare	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
Arien Malec	Change Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Brett Oliver	Baptist Health	Member
Terrence O'Malley	Individual	Member
James Pantelas	Individual	Member
Carolyn Petersen	Individual	Member
Raj Ratwani	MedStar Health	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Sasha TerMaat	Epic	Member
Andrew Truscott	Accenture	Member
Sheryl Turney	Anthem, Inc.	Member
Robert Wah	Individual	Member
James Ellzy	Defense Health Agency, Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
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
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Acting Executive Director, Office of Technology
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Janet Hamilton	Council of State and Territorial Epidemiologists (CSTE)	Presenter
David McCallie	Individual	Presenter
Michael Wittie	Office of the National Coordinator for Health Information Technology	Presenter
Fred Blavin	Urban Institute	Presenter
Gary Ozanich	Health Tech Solutions	Presenter





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

Operator

All lines are now bridged.

Mike Berry

Great. Thank you very much and good morning, everyone. And thank you for joining the July 2021 HITAC meeting. I'm Mike Berry. I'm with ONC and we're excited to have you with us today. As a reminder, we welcome public comments, which can be typed in the chat feature throughout the meeting or being made verbally during the public comment period that is scheduled for around 2:15 this afternoon. You can also send written comments to me or to ONC-HITAC@accelsolutionsllc.com. So, let's get started with our meeting today. First, I'd like to welcome ONC's executive leadership team to the meeting. And with us today is our national coordinator, Micky Tripathi, Steve Posnack, our deputy national coordinator, Elise Sweeney-Anthony, the executive director of the Office of Policy, and Avinash Shanbhag, the acting executive director of the Office of Technology. I'll now call the meeting to order and begin roll call of our HITAC members and our federal representatives of the HITAC starting with our co-chairs. Aaron Miri.

Aaron Miri

Good morning.

Mike Berry

Denise Webb.

Denise Webb

Good morning.

Mike Berry

Michael Adcock.

Michael Adcock

Good morning.

Mike Berry

James Ellzy. Cynthia Fisher. Lisa Frey.

Lisa Frey

Good morning.

Mike Berry

Valerie Grey.

Valerie Grey

Good morning.

Mike Berry

Adi Gundlapalli.

Adi Gundlapalli

Yes, good morning.

Mike Berry

Steven Hester.

Steven Hester





Good morning, everyone.

Mike Berry

Ram Iyer. Jim Jirjis. John Kansky.

John Kansky

I'm here.

Mike Berry

Ken Kawamoto is on PTO today so he won't be with us. Steven Lane. I believe Steven Lane is on PTO today as well. Leslie Lenert.

Leslie Lenert

Here.

Mike Berry

Arien Malec.

Arien Malec

Good morning.

Mike Berry

Clem McDonald. Jonathan Nebeker.

Jonathan Nebeker

Good morning.

Mike Berry

Brett Oliver.

Brett Oliver

Good morning.

Mike Berry

Terry O'Malley.

Terry O'Malley

Here.

Mike Berry

James Pantelas.

James Pantelas

I'm here.

Mike Berry

Carolyn Petersen.

Carolyn Petersen

Good morning.

Mike Berry

Raj Ratwani.





Raj Ratwani

Good morning.

Mike Berry

Michelle Schreiber. Abby Sears.

Abby Sears

Good morning.

Mike Berry

Alexis Snyder.

Alexis Snyder

Good morning.

Mike Berry

Ram Sriram. Sasha TerMaat.

Sasha TerMaat

Good morning.

Mike Berry

Andrew Truscott.

Andy Truscott

Good morning.

Mike Berry

Sheryl Turney.

Sheryl Turney

Good morning.

Mike Berry

And Robert Wah.

Robert Wah

Present. Good morning, everyone.

Mike Berry

Great. Thank you so much, everyone. And now, please join me in welcoming our national coordinator, Micky Tripathi, for his opening remarks. Micky?

Welcome Remarks (00:03:09)

Micky Tripathi

Great. Thank you, Mike. And good morning, everyone. Aaron and Denise, I don't know what kind of show you're running here allowing people to take PTO on the day of a HITAC meeting. Isn't there an approval process for that? Good morning, everyone. I'm really delighted to be here. And I just wanted to give a few opening remarks. There are more than a few and there are so many opening remarks that I need to update the HITAC on. I'm, actually, going to have to refer to Notes, which I don't normally do. But first off, I'm going to do it now. I will do it in the middle. And I'll do it at the end of my opening remarks here as well, which is to just thank all of you and to thank you for all of the guidance and advice that you provide to us. ONC has been very busy. The HITAC, I know, is very busy. And we so value all of the input and all of the guidance





you give to us. And we really couldn't do our work without your partnership and without your guidance and advice. So, I just want to thank you. As I said, I'm going to thank you now. I'm going to thank you in the middle. I'm going to thank you at the end.

So, a few things that I wanted to update everyone on. First off, I just wanted to thank all of you who participated in those Advancing Social Determinants of Health Data Use and Interoperability for Achieving Health Equity Workshop that we had yesterday. As many of you may recall, we did reschedule it. It was originally scheduled on the date that turned out to be the federal observance of Juneteenth, which we were delighted about. And so, we rescheduled it and we had it yesterday and it was a great event. It was great engagement, great turnout. And for those who participated, thank you so much. We discussed existing and emerging data standards, tools, approaches, policies, models, interventions. It was a ton of really great engagement and experience and expertise offered throughout the day. Again, I just want to thank everyone on the HITAC who was involved, everyone who was listening who was involved, and, certainly, all of the participants of that workshop and the ONC team for putting it together because it's a tremendous amount of work in the background just getting something like that going and up and running.

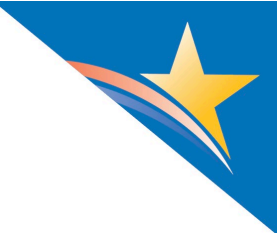
Last Friday, we released the USCDI Version 2 as no doubt all of you saw, which laid the foundation for the provider community to start systematizing and capturing use of social determinants of health and sexual orientation and gender identity in the clinical setting. We got a ton of feedback from the HITAC task force. And we, certainly, heard a lot of general input from the industry as well about how the USCDI needs to reflect America's diversity and include data elements like social orientation, gender identity, and social determinants while helping to address disparities and health outcomes for minoritized, marginalized, and under represented individuals and communities. We got a tremendous amount of feedback. Almost all of it universally positive since the release of that. And we really look forward to working with the community on now making it a reality. So, thank you, again, for all of the HITAC's input and engagement in this important effort going forward.

I've got two new announcements to highlight. One is the TEFCA updates. Many of you may have seen the blog that we published yesterday about TEFCA and the release of drop developer measures for the EHR reporting program. So, first on TEFCA, I'm really excited to announce the timeline for TEFCA where the Cures Act calls on ONC to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally." Our goal is to complete the common agreement and the qualified health information network technical framework, the QTF, so the network can participate in that in the first quarter of calendar year 2022. So, the target now is that, in the first quarter of 2022, we will be able to make available the common agreement and the QTF's that accompany that for any network that chooses to participate in the TEFCA framework going forward. So, we're really delighted. We've done a ton of work working with the RCE, the Sequoia Project to get us to this position.

And we believe that it's really important for the market to know the timeline so that everyone in the market can start to adjust and think about how they want to participate and be able to make their investments and get their decision making started appropriately. So, we're really, really grateful to be able to do that with all of the feedback and participation of the stakeholders who allowed us to get to this position to be able to convey this timeline now for the industry. The RCE is managing the public feedback process. So, please stay up to date on their website, RCE.SequoiaProject.org. The RCE will also be reconvening the common agreement work group comprising prospective QHIN's and their participants. Many of you may have participated in that or may be familiar with that. That was a really important forum for us to be able to get industry feedback from those who were anticipating being participants in the TEFCA framework. So, it was particularly focused and engaged, which was fantastic for those who are, actually, interested in implementing and moving forward on this.

So, that will be reconvened to be able to allow that to be a very useful vehicle for us to be able to get more feedback. In addition, we recognize that the timeframe is really tight to complete the common agreement by the beginning of 2022. And we believe it's really important for us to do that in the beginning of 2022. But it's also really critical for us to get feedback from the HITAC members. So, in lieu of a task force, which I





think, as all of you know, has a certain amount of overhead and has a certain amount of time associated with it, we just don't see how we can do that in these timeframes. So, what we're proposing to do is we're going to add a special HITAC meeting in October on October 13 to focus on the key elements of the common agreement and the QTF to be able to get the HITAC engagement on that and be able to have a full meeting where we can all spend time devoted to the issues related to the TEFCA framework, the common agreement, and the QTF's and to get HITAC engagement and HITAC advice engagement and HITAC advice and guidance on that. So, we very much look forward to that.

The RCE will be presenting topics where the HITAC's expertise is most needed at that meeting. It will be, as I said, on October 13. So, please mark your calendars for that and we'll have more to come on that as well. And, certainly, HITAC members are also most welcome to participate in the RCE led stakeholder engagement activities and to provide additional feedback to the RCE individually and for those that qualify to be a part of the common agreement working group. That's another vehicle as well for any HITAC members who are in that position as well. So, more to come on that. We're really excited about moving forward and really excited about getting the HITAC's engagement and input on that as well. The next announcement is regarding the draft developer measures for the EHR reporting program, which we'll be hearing about a little bit later today. As many of you may know that was a 21st Century Cures requirement to have some type of reporting of EHR functionality in a public way.

And so, this is the presentation of those initial reporting measures for the HITAC's input. The ONC and the Urban Institute have been working with stakeholders to develop a draft set of initial measures for developer reporting that initial set of measures that targets key interoperability areas, which the program team will review later today. Yesterday, the Urban Institute began a public feedback period to obtain input on draft measures as well. And everyone is invited to provide feedback during that public comment period. Today, I'd like to ask the HITAC to kick off a task force to review the draft measures and provide recommendations by the September 9 HITAC meeting. So, we'll have more to come on that. But I very much welcome the participation of HITAC members and that task force to be able to provide advice and guidance to ONC and the Urban Institute as we move forward with that reporting requirement from the 21st Century Cures Act. The rest of today's meeting, if that's not enough, is also action packed.

We have two HITAC task forces ready to present their recommendations, the interoperability standards priorities task force led by Arien Malec and David McCallie. They'll be presenting their final recommendations on vocabulary standards, which we very much look forward to. And also, Carolyn Petersen and Janet Hamilton on the important work they've been doing with respect to the public health data system task force, which is important input to the executive order work group that ONC and the CDC are co-leading with respect to data driven response to high consequence public health threats. So, we very much look forward to that as well. Again, the opportunity for me to thank everyone in the middle for all of the fantastic and tremendous and valuable work that you do with the task forces and all of the guidance and advice and engagement you provide to us. So, very much appreciate that. And I know it's a tremendous amount of work to be able to do that.

Finally, just for your awareness and I promise I'll get off the stage and turn it over to Aaron and Denise for the rest of the agenda. There is a workforce notice of funding opportunity. Many of you may be aware of it. ONC received \$80 million in funding for the Public Health Informatics and Technology Workforce Development Program to implement and expand training certification and degree programs in public health informatics and data science at minority serving institutions. So, and that's to address some of the health and social inequities that became widely apparent, I think, as we know during the pandemic. Applications are due by August 11. And we expect to fund up to 30 cooperative agreement awards for a four year period of performance based on availability of funds. And we anticipate the program starting on September 14, 2021. So, the notice on funding opportunity can be found on our website. Please take a look at it if you're a tall interested and we welcome your engagement.

It's a very important thing, I think, for all of us to be able to do that, important capacity building in two communities that have been untapped to date. And we want to be able to have that full engagement in the





way we think about public health and public health capacity going forward. The ONC tech forum is coming up on September 16 and 17. There will be more details provided soon but we're looking forward to virtually seeing all of you there. And that's the opportunity for us to be able to host meeting for the more technically oriented with regard to some of the use cases that we all work on but more from a technical perspective and to have sharing of lessons learned and visibility of the different activities that are going on in the industry. And then, finally, I don't want to leave the stage without mentioning our health interoperability outcomes 2030. We're receiving a ton of good ideas and we welcome those. We're also getting video clips if you haven't seen those from HITAC members and the public and our former national coordinator. That was a great watch and to formulate our interoperability outcome statements, which we'll publish later this year.

If you haven't already done so, please submit your ideas and videos. We really look forward to those. Finally, on member updates, for your awareness, the GAO has informed us that they will be publishing a federal register notice around mid-July for five new HITAC members whose term expires at the end of this year. So, we'll provide that link to the federal register notice when it's available. And please think about anyone who you think might be interested in serving as a HITAC member and point them to that federal register notice. Let me close by thanking, again, all of you for all of the work that you do and the dedication that you bring to the table here in this very important work that all of us do. Your input and recommendations on ONC's priority topic areas is just extremely valuable to me and to the entire ONC team. So, we're really grateful to offer that. So, finally, let me turn it back to Aaron and Denise and thank you for your patience and I look forward to the rest of the meeting. Thank you.

Remarks, Review of Agenda and Approval of June 9, 2021, Meeting Minutes (00:15:48)

Aaron Miri

Thank you very much, Micky. And good morning to you and good morning to the folks listening. Welcome to our July HITAC. First, let me just open up real quick and just say congratulations to the entire ONC team, Micky, you and your leadership and the wonderful work that's been done from a community perspective. You've seen it on social media. You can follow along with hashtag HITAC and look at all of the comments of how excited folks were, particularly with the most recent update to the standards. I think it's just tremendous, tremendous work. It's a credit to everybody and the hard work going on there. Today, we do have an action packed agenda, some really good stuff as Micky was alluding to that just continues to push the ball forward and share with the industry that we are listening and that we are galvanizing together and moving forward in one voice. So, let me turn this over to my co-chair, Denise, who will take us through the agenda and the approval of minutes in the prior meeting. Denise?

Denise Webb

All right. Good morning, everyone. Well, we have an action packed meeting here this morning. And I think Micky, actually, did a great job of previewing our agenda. So, I'll quickly go through it just to let you know the order of events. We are going to start with the recommendations from the public health data systems task force. They were under a very tight timeline and will be presenting, I believe, 52 recommendations. And, hopefully, everybody got to read through the report prior to the meeting. It's pretty extensive. So, Carolyn and Janet will be doing that. And then, the ISP task force will be coming back to us with Recommendation No. 3. If you'll recall, we did not vote on that. It went back to the task force for some more work. And so, they are going to present the resolution on that recommendation. And we will be voting for both the public health data systems task force and the ISP task force recommendations. Then, we're going to take a break.

And after the break, we will start with the annual report work group update from Aaron and Carolyn. And following that, we will have two presentations on the electronic health record reporting program draft developer measures. ONC has contracted the Urban Institute to help with this. So, we'll have a framing presentation from Michael and then, Fred and Gary. And Gary is a subcontractor from Health Tech Solutions. They're subcontracting to the Urban Institute and they'll be giving a presentation on the draft developer measures. And then, we'll conclude our presentations with public comment and final remarks.





And then, we'll adjourn. So, I welcome everybody. We're going to have a busy morning. And if we can start off by getting a motion to approve the minutes from the June meeting.

Robert Wah

Denise, this is Robert Wah. Before you entertain a motion to approve, I just have a very small correction on the meeting notes. I'm sorry. I just want to make sure they're right. On Page 7 of the PDF in the discussion of the international procedural standards and classification, in my comment, it says something like, "Some countries do not have code procedures and others have developed their own code sets." I think the correct wording should be, "Some countries do not have procedural codes," so that would be a couple of word changes. "And others have developed their own code sets."

Denise Webb

Okay.

Robert Wah

So, if that's acceptable to everyone, I would move approval to the rest of the notes.

Denise Webb

All right. So, we will have the minutes modified to say, "Some countries do not have procedural codes and others have developed their own code sets." Is that correct, Robert?

Robert Wah

Yeah. I think that makes more sense than what's written.

Denise Webb

Okay. If there is no objection to that, if we could have a motion to approve the minutes with this minor modification.

Arien Malec

Motion.

Unknown

Second.

Denise Webb

All right. And all of those in favor of approval of our June minutes say aye.

Group

Aye.

Denise Webb

Are there any noes? And any abstentions? All right. Our minutes from June are approved. I'd like to now introduce and turn over the presentation to Carolyn Petersen and Janet Hamilton to cover their 52 recommendations for public health data systems.

Public Health Data Systems (PHDS) Task Force Recommendations – HITAC Vote

(00:20:59)

Carolyn Petersen

Thanks, Aaron and Denise, for this opportunity for Janet and I to present the recommendations of the public health data systems task force to the HITAC today. Next slide, please. What we're going to do today is to review the charges on our membership, to go through the recommendations briefly and then, have some discussion so that the HITAC is prepared to vote on what the public health data systems task force has





prepared for you today. Next slide, please. And this is our charge. It's two parts. First, the task force shall identify and prioritize policy and technical gaps that are associated with the effectiveness, interoperability, and connectivity of information systems relevant to public health. And second, we are to identify characteristics of an optimal future state for information systems relevant to public health and their use. Slide, please.

We have an updated task force scope as well for you. We are focusing, specifically, on bidirectional data exchange between public health data systems and clinical data sources. And this is to include focus on the challenges, gaps, and the ideal future state for data sharing between public health systems and clinical data sources such as but not limited to EHR's, laboratory systems, vaccine management software, and operational and other relevant data sources. Topics that were previously in scope that are now being recommended for future HITAC discussions include research and innovation, social services data, and in depth analyses of specific public health data systems. And this has to do with the fact that we had a very short timeframe and a lot more than we were able to cover in that period. And finally, recommendations and discussions surrounding health equity and patient engagement were addressed in each topic rather than representing unique topic areas for meetings and categories for recommendations.

Although as you see, when we go through the recommendations, we were able to do more work in that area than we had initially anticipated under our updated scope. Slide, please. And this is our roster. Slide, please. So, between the hearing at our May 13 HITAC meeting and the finalization of the recommendations being presented today, the task force had seven weeks. During this time, the task force conducted 10 public working meetings, gathered input via six sets of written homework that members completed between our meetings, and worked on the recommendations in groups for six weeks and then, in an online shared document for three weeks. All together, we estimate that this involved 20 to 25 hours of work per member as well as the additional work on the shared document and recommendations last week after our final meeting. Today, Janet and I will review the task force's 52 recommendations by group and then, engage HITAC members in discussion. Because many of these recommendations are interrelated, we will present all of the sections together first before taking your questions. Next slide, please.

So, as we got into our deliberations, it became clear that some recommendations were broad in nature and addressed the ecosystem as a whole rather than focusing on specific components or systems or ideal future processes. As a group, these six recommendations provide a foundation on which the remaining work rests. These crosscutting recommendations direct ONC to partner with other federal agencies around preparedness planning and data standards for information collection during public health emergencies. Partner with other federal agencies around a data ecosystem that supports public health during responses to high consequence threats in which public health institutions are treated as full partners. Slide, please. Explore and support development of additional data standards and classes for public health purposes. Work with CMS and other HHS agencies to find ways to invest in interoperability among healthcare entities that were not covered by the meaningful use and promoting interoperability programs in support of public health. Slide.

To encourage HHS to continue supporting data modernization efforts and opportunities of public health to share knowledge and experience. And require standardization of address information collection to facilitate interoperability, geolocation, and merging with consensus and other social determinants of health data and to support resource allocation appropriation for these and related efforts. Slide, please. And with that, Janet will take you through the lab and case reporting recommendations.

Janet Hamilton

Great. Thank you so much. Just a quick sound check.

Carolyn Petersen

Go ahead, Janet.

Janet Hamilton





Thank you, Carolyn. So, I want to just start with really saying thank you before I get into going through these next set of recommendations. This is an exciting and challenging time. And I really think it is wonderful that ONC and the HITAC was able to put this group together and take the time and energy to do this work. And there were a number of accomplishments that we were able to achieve in this incredibly short timeframe as Carolyn reviewed for us despite, of course, that we didn't get to everything. I think in the beginning portions when we met as a group, too, there was also just really strong recognition that there was and has been a huge amount that public health has accomplished as a whole despite being in a situation with inadequate resources and support in order to really evolve our public health surveillance activities and data systems in the way that we would like to see them.

I would also just say as some foundational settings that there was also broad recognition that what we do for public health and surveillance activities in public health during day to day times are the same things that we should really be doing during public health emergencies. And that allows us to ensure that we have the infrastructure in place and built and then, it can be moved into scale. So, thank you all so much. And now is the time to really move forward with recognizing that public health is part of our healthcare ecosystem. And it is just wonderful that ONC has taken the opportunity to really be a leader in these efforts. So, moving forward onto the laboratory recommendations, I want to say that, on the lab recommendation section, we do have three overall recommendations. And those recommendations are Recommendations 7 through 9. And they focus on reviewing and adopting the use of standards and end to end data flows.

Laboratory data was recognized as critical to our public health infrastructure and often supporting some of the initial ways in which public health is able to access data and information and really a foundational component of our public health surveillance processes and activities. The other piece to really recognize here is that the lab is a component of a multistage process. And so, to really recognize that it is end to end flows that starts with the provider, the order process, the laboratory testing and then, the provision of those results to the public health agency. The other space where the lab recommendations come into play is sharing across the public health infrastructure as well as the state, local, tribal, territorial, and federal levels and that laboratory testing is completed at multiple levels and the sharing of that information is critical across our infrastructure. Next slide, please.

And finally, the other recommendation is really focused on completeness and timeliness of data and that there are standards that exist but there can be more to be done to ensure that the data that comes to public health is complete and supports a level of demographic information that is able to ensure consistency as well as addressing issues in health disparities. Next slide, please. For case reporting, there were two recommendations, Recommendations 10 and 11. And these recommendations are around advancing adoption of specific standards. So, there are EICR and ECR case reporting standards but really pushing forward the adoption and use of those existing standards, working with CMS to explore incentives and to explore utilization of those standards outside of those that have been included in conditions of participation for hospitals, to expand those to nonhospital based providers and other locations, and also to ensure that certification programs for health IT as well as support of use of EICR standards through exchanges that are done through HIE's. Next slide, please.

This recommendation is really focused then on working across multiple agencies, ONC, CDC, and ASPR as well as HHS and state and local Health Departments to ensure that notification requirements avoid any duplicative requests or failure to meet surveillance goals at different levels. The task force recognized that state, local, tribal, and territorial Health Departments have certain data needs and goals, for example, identifiable data that are different from the federal level. And we need to ensure that there is alignment across those groups and to ensure that TEFCA and also the RCE's are able to support along with working across CDC, CSTE, APHL, and STLT's to support tools to facilitate the development of standards for interjurisdictional routing of case reports and exposure notifications. And with that, I'm going to turn it back over to Carolyn.

Carolyn Petersen





Thanks, Janet. We will now move into the immunization recommendations. Here, our task force members developed six recommendations related to immunizations and processes supporting data collection, use, and sharing. These recommendations address a broad range of technical, regulatory, and legal barriers experienced by both healthcare organizations and public health agencies. Briefly, ONC should work with CDC and STLT's to advance development and adoption of the HL7 implementation guide by healthcare provider systems and public health agencies, including policy and implementation activities. Slide, please. Collaborate with CDC, public health, and vendors to develop standards and implement infrastructure supporting a range of provider initiated and multijurisdictional activities. Slide. Work with the Office of Civil Rights to provide STLT specific guidance enabling parental access to minors' immunization record and consumer access to their data.

Work with CDC, STLT's, and industry to identify a prioritized set of immunization data elements for providers to collect and report to public health and to define a minimum set of IIS functional standards. Slide, please. And to work with CDC and others to identify policies that limit or prevent public health from exchanging immunization data across the healthcare ecosystem and public health. Slide, please. The task force developed one multipart recommendation around syndromic surveillance. Here, the task force recommends that ONC collaborate with CDC and STLT's to explore traditional and nontraditional data sources and surrogate markers for early identification of public health events. These efforts should facilitate real time access to healthcare data, tracking of public health related events, and other activities related to situational awareness data, which Janet will now address.

Janet Hamilton

We grouped, as a task force, the situational awareness recommendations in the report right next to those associated with syndromic surveillance. And there are four recommendations in this situational awareness section. And the grouping was intentional as many times, syndromic surveillance approaches in public health have been tied to the evolution and practice of the public health surveillance work. So, systems used for syndromic surveillance have also been used to support broadly situational awareness activities. These four recommendations, Recommendations 19 through 22, identify and recognize the need for standards development and, specifically, standards development to advance the exchange of situational awareness data. This recommendation is focused on working with multiple stakeholders, including CDC, ASPR, and CSTE as well as other industry groups to identify appropriate elements to include in the USCDI that would further support the reporting of situational awareness data.

Additionally, there was recognition by the group in this recommendation to support the development of other standards outside of the USCDI for situational awareness that could not necessarily be derived out of the EHR system. And these would be things like inventory and staffing management, equipment repair, and other types of systems and data for inclusion. Next slide, please. The next set of recommendations were to support additional activities and situational awareness around patient movement and resource allocation. And, specifically, to develop preparedness plans that would support data needs and reporting requirements during high consequence events. This would include defining metrics and definitions that would be needed as well as transport mechanisms that public health must utilize around these nationally defined metrics. Next slide. The third recommendation in this area is really focusing on collaborating with CDC and the STLT infrastructure to ensure that their identified core public health data systems function and that the infrastructure supports utilization across different sizes of responses in both scope and size, and provide information across the infrastructure that supports both national and local issues.

And the information exchange that is needed at higher levels of government should also be supported throughout the data collection framework and process. And in order to do this, there would need to be some level of flexibility as well as addressing other areas around receiving, cleaning, and de-duplication of data. Next. The final recommendation is really then working with EHR and IT industry experts that would be able to identify core functionalities needed within the EHR to support varying data needs that are necessary during high consequence events. And, specifically, addressing calculation and reporting of core and aggregate metrics such as surge index scores and also supporting identification of core public health data fields. Carolyn?





Carolyn Petersen

Thanks, Janet. We will now into the infrastructure recommendations. Here, the task force identified six recommendations related to infrastructure that is needed to achieve this bidirectional data exchange between public health data systems and a broad spectrum of clinical data sources. To achieve this ideal future state, ONC should define a core standard set of data elements for patient matching across public health and healthcare systems with incentives for STLT's to collect and submit complete data. Encourage the use of health information exchanges, master patient indices, record locator services, and existing data infrastructure to provide public health with more complete information about race and ethnicity, disability status, SOGI, and others. Slide, please. Work with CDC, STLT's, HIE's, the TEFCA, RCE, and clinicians to continue the use and expansion of public health gateways and avoid duplicative reporting by providers. Work with CDC to standardize display of agreed upon measure and aggregate reporting elements so stakeholders can build to that standard. Slide, please.

Encourage CDC and other HHS agencies to support use of the patient unified look up system for emergencies. Slide. And to work with CDC, STLT's, and healthcare organizations to assess the need for and development of certified health IT for public health emergency preparation and response. Slide, please. And with that, Janet will take us through the recommendations around funding mechanisms and policy.

Janet Hamilton

Great. So, there were a total of eight recommendations around funding mechanisms. And these recommendations span Recommendations 29 through 36. And I think while most of the recommendations within the report focus on various types of standards development and work for the systems themselves, there were also really critical needs represented by the group that the infrastructure itself needed support and funding and that there was a broad recognition amongst the task force that public health had not been funded during initial activities associated with the HITAC. And that as a result of it, there had been really an inequity that was set between public health and healthcare for public health to be an active data exchange and partner. And so, the first recommendation is really the recognition of this and the need to provide education as well as support for significant investments so that public health can really be an equal trading partner within the healthcare ecosystem. Next slide, please. Recommendations also supported funding for CDC's current data modernization effort and five key pillars that represent scalability during a response.

And those five key pillars are ECR, the National Notifiable Disease Surveillance System, laboratories, ELR limbs, and ETOR vital records, syndromic surveillance and, of course, the public health workforce. Next slide. The funding activities should be encouraged to support a disease agnostic infrastructure. I think there was broad recognition that many times, there is disease specific funding. And disease specific funding, while important, can also result in the creation of siloed disease surveillance systems and that in order to really achieve the ecosystem that we're looking for, funding should be directed in a disease agnostic way. Next slide, please. Additionally, it would be important for ONC to work across HHS to create better opportunities to leverage the Medicare and Medicaid programs as well as other departmental funding to support public health initiatives. And keeping in mind the framework that cost allocation strategies should be evaluated as both costs to the individuals as well as cost to the society and the recognition that support for appropriate societal investments should be equally balanced.

The next recommendation, Recommendation 33, is focused on the need for dedicated funding to support the public health data workforce and developing a staffing and execution plan and, specifically, that this public health workforce needs funding and training across both the federal as well as the state, local, tribal, and territorial levels and that mechanisms that not only support funding but also support the ability to move in this very dynamic space, such as shortening time periods for hiring, extending noncompetitive offers to ensure that employees can be brought on quickly, as well as looking at other creative activities such as student loan repayment, internships, and fellowships. Next, please.

Finally, funding recommendations included working with HIE's to ensure that as HIE's continue to develop that there are good sustainability models that ensure support for public health capabilities and capacities





and that HIE's and public health work together hand in hand to ensure those public health data needs are met and that we're not simply just moving data feeds from one place to the next but are expanding strategies for HIE's to support those data feeds into public health. And finally, that ONC should collaborate with CDC to encourage the incorporation of equity considerations into funding models. I will say we do have another section that is specific to equity but it was really felt critical by the task force that we recognize that equitable funding structures are critical to be able to build these systems in equitable ways and that we don't pass over the needs of under resourced communities.

And the final recommendation for funding mechanisms is for ONC to collaborate with CDC and CMS to invest in educational campaigns that would enhance the knowledge and use of public health data that resources themselves need to be used to educate the public on how public health uses the data, privacy rights, and also to enhance trust. Carolyn?

Carolyn Petersen

I thought you were going to go through this one.

Janet Hamilton

Oh, sorry. We're at policy recommendations. Thanks. My bad. So, policy recommendations, Recommendations 37 through 44. We have eight policy recommendations. The first is collaboration with CDC and OCR to develop and release best practice guidance for applying the HIPAA minimum necessary standards for sharing information with public health entities and that these should be aligned with TEFCA so that it is clear that the support for public health and allowing of national networks and HIE's that serve as public health intermediaries are not overly constrained and that they uses of data provided for public health purposes is communicated to those whose data are collected. And I think, additionally, this is recognition, of course, that public health surveillance is, typically, HIPAA exempt but there's not necessarily broad recognition of that. And we need to ensure that public health is an authorized purpose and use under TEFCA. Next slide, please.

Also, under policy recommendations are to support policies that facilitate data sharing without the use of any discriminatory purposes and to ensure the appropriate level of access is provided to each of the different levels within our public health infrastructure so that there are appropriate access levels for state, local, tribal, and territorial, as well as the federal level. And those policies should ensure that secondary use of data by other government agencies and partnerships comply with the policies that are associated with the initial data collection. Next slide, please. Additional policy recommendations here include collaboration with CDC to identify a public health task force or work group with adequate authorities to really address additional interoperability, connectivity, and information systems needs relevant to support public health. This recommendation really gets at where we started in some of our opening comments that a lot of work was accomplished but there is still a lot of work that needs to be done.

And there is a location for that work to occur in an ongoing basis. And, of course, there, certainly, are some existing advisory committees and task forces to leverage but really the formation of something that is truly dedicated to the broad scope of public health. Recommendation 42 focuses on the evaluation of policy barriers that prevent or impact public health reporting through HIE's. As HIE's have evolved and become available, there still are instances where certain types of laws do not necessarily recognize these new data sharing activities and can, to some degree, be impediments. Next slide, please. The final set of recommendations under the policy section are listed here. And this is about ONC working with HHS partners to support existing privacy and confidentiality regulations, payer access where appropriate to public health reporting data to facilitate maintenance and complete patient health histories and clinical data sharing.

And finally, ONC should work with CDC to establish a co-led certification body for public health data standard and that there would be adequate funding for that as well as participation, not just from federal groups but also from state, local, tribal, and territorial Health Departments. Now, Carolyn, I will turn it over to you.





Carolyn Petersen

Thanks, Janet. So, we will now take a look at the recommendations around health equity. The task force recognized health equity as an important goal that is really at the heart of the ideal future state and that should underlie all of the recommendations as well as inform the way these recommendations are achieved. Health equity considerations featured in all of the task force's deliberations rather than as one discrete discussion. As a result, the task force's work resulted in two recommendations, one of which contains 10 subsections and three subparts. First, ONC should collaborate with CDC, CSTE, and STLT's to ensure consistent collection of agreed upon standards for health equity data elements, including race, ethnicity, disability condition, and resulting impacts, preferred language, SOGI, and data for SDOH. Standards should be implemented through USCDI or other mechanisms to meet community identification needs and support updating and use of data for prioritizing service provisions. Slide, please.

And second, ONC should support the development of technology for patient use while waiting in treatment rooms or other private areas to review and update SDOH data. Data collected this way should be available to all entities in the health ecosystem serving the individual as permitted by applicable privacy laws. Slide, please. Finally, we come to our last section. This has to do with the recommendations around individual engagement. Although the task force's charge focused on bidirectional data exchange between public health data systems and clinical data sources, the task force recognized that many aspects of the ideal future state will be of interest and concern to individuals outside of the clinical and public health environments. As such, the task force identified six recommendations related to interactions with patients, family members, caregivers, and the public. In summary, ONC should work with appropriate HHS stakeholders, including STLT's to identify ways to provide transparency about the collection and use of personal information for public health. Slide, please.

Explore delivery of public health related information through API's, patient portals, mobile apps, and other digital channels to ensure that patients and consumers can access this information in the same ways that they access their protected health information. Slide, please. ONC should work with other HHS agencies to ensure that patients, family members, and caregivers have access to situational awareness data. Should work with health IT developers to ensure that patient portals support updating of important pieces of information by patients. Slide. Should collaborate with CDC and health IT developers to ensure that public health data systems generate output in formats that can be readily understood and used by governing and other bodies at the federal, state, and local levels. And finally, should support development of tools to screen data systems for bias and algorithms to ensure that decision making for public health related needs is equitable. Here, we're tying back to our concerns about health equity. Slide, please.

So, this concludes our review of the task force's 52 recommendations. And we would now like to take your questions and have a discussion. Thank you.

Denise Webb

Thank you very much, Carolyn and Janet, for your presentation. And I just want to remind our committee that this task force had a very huge charge in a very short timeframe. And so, obviously, they couldn't cover the entire landscape in the period of time that they had to present this report and these recommendations. So, thank you very much to both of you and your task force for all of the work you did in such a short time period. So, let's see. Hands up. We have Alexis Snyder. You're up.

Alexis Snyder

Good morning. Thank you for your presentation and all of the hard work of your task force. It sure is a lot of information. I just had one quick comment around the recommendations towards the end around 48 and 49 about patient and caregiver access to the public health information. And I just think it's important to maybe rewrite the recommendation to add some language, not only around accessing the public health information but in a way that's easy for patients and caregivers to understand so some lay language and lay terminology when accessing information for those who are not in the healthcare field and may have a harder time understanding some of the language in the reporting system.





Carolyn Petersen

You said that was around Recommendation 48 and 49, Alexis?

Alexis Snyder

Yes.

Carolyn Petersen

When we get to a vote, would you consider proposing language for that please?

Alexis Snyder

Sure.

Carolyn Petersen

Thanks.

Denise Webb

Yeah. I should let everybody know that for any of the recommendations that anyone has any particular issues with, if we're not able to resolve it today, there will not be an opportunity to bring them back to the task force because of the deadline they are on to provide these to ONC because they're working within a timeline at the federal level. So, we are going to do a majority vote on this. And I think we have 20 HITAC members present. So, if we are able to come to agreement on some language and you can have that ready, Alexis, to present to all of us that would be great while we continue with our Q&A. Andy, you're next.

Andy Truscott

Thank you. Good morning. This is great output. Thanks ever so much for the work you've done here, guys. Really good to see. A couple of things came to mind and I apologize because the number of the pages on what was presented and the numbers of the pages on the handout were not the same. So, I'm referring to page numbers on what you presented rather than what's in the handout. Just as a general principle, the bidirectionality focus I think is great. Bidirectional [inaudible] [01:01:14] interoperability is awesome. But given that the state of the public health infrastructure right now, I think it might be worth considering that we don't insist upon bidirectionality even though it's desirable to have. Does that make sense? I'm sure you had a discussion on this in your group. There was a comment that was made about syndromic syndrome. I agree completely. I think maybe trying to push HL7 to incorporate and expand their work so it does include it, I think that would make sense as opposed to defaulting to another standard, which is the impression I got from the recommendation you had.

I was slightly surprised not to see any mention of payers more voluminously. There was a mention at the end but the claims integration goes on right now across the country. That's, potentially, actually, quite a rich source of data, which could be taken and used. And it wouldn't require setting up new routes, etc. And then, finally, we said it a couple of times in the recommendation, "develop other standards." Now, standards development is a fairly complex, robust, and slow process. I think maybe my suggestion would be whenever we're talking about in the absence of USCDI doing it, we'll develop another standard. Maybe we should explore using other standards ahead of developing a new one because, for me, the thing is only types of data you were talking about, for example, bed management, etc., and resources availability. There are other standards out there. Just because it's not in USCDI doesn't mean it doesn't exist. That's it. But apart from that, great work. I don't know whether you can get these in in your rephrasing or not but I think, certainly, the bidirectionality one is one that's worth considering.

Janet Hamilton

This is Janet. Excellent comment. In terms of the bidirectionality, do you have a specific recommendation where you wanted to see that incorporated more fully. And I would just say I think, yes, part of these recommendations are about getting to the appropriate future state. And I think there is recognition, of course. But right now, we are definitely in a space where there is more data coming in than there is going





back. And I just wanted to follow up if you had a specific recommendation. As I understand it, we need to come to agreement on the language here today so that we can have things move forward appropriately.

Andy Truscott

Yeah. That's what I just picked up as well. Maybe if we look at the recommendations that talk about bidirectionality.

Denise Webb

Do we want to have them pull up those slides for you, Carolyn and Janet?

Carolyn Petersen

I suspect that bidirectionality is mentioned in a number of recommendations because that was part of what we were asked to do by ONC. So, to say we don't want to address that, at this point, kind of goes against the charge of what we were asked to do. The HITAC, of course, can do with that as it wishes. I would also note that payers are mentioned in the report more frequently than we mentioned them in the slides and the presentation today. That is there in the reading material.

Andy Truscott

So, Carolyn, are we voting on the report or voting on the presentation.

Carolyn Petersen

I'm sorry, Andy?

Andy Truscott

Are we voting on the report or voting on the presentation?

Carolyn Petersen

We're voting on the report.

Andy Truscott

Okay.

Carolyn Petersen

The presentation is a bit of an abstraction of the 25 page report because we had a limited amount of time to present and discuss. And we aren't in a position to rewrite as ISP did from the last meeting.

Andy Truscott

I appreciate that.

Denise Webb

All right. We have Leslie Lenert next in the cue. Leslie, are you on mute?

Leslie Lenert

I just wanted to say how important the bidirectionality is to the spirit of these recommendations and to the idea of setting the future state. Currently, public health data flows are largely unidirectional without a lot of feedback to the providers or to collaboration with population health. And if we're really going to achieve the ends that we need, we absolutely need bidirectional communications between public health and the clinical care system to create a working ecosystem. Anything less would be a huge step into the past where we would be setting aside some of the gains that we've already made. Even though these are aspirational in some areas, it is where we need to go.

Janet Hamilton

Thanks, Les. And I would just say I think there was a lot of consensus around that within the work group and the task force deliberations.





Denise Webb

All right. We have Alexis Snyder next.

Alexis Snyder

I was just going to support what was just said about the bidirectionality speaking as an engagement specialist. You can't really have authentic or true engagement without bidirectional communication and transparency. So, I fully support the bidirectional piece. And then, just back to the comment earlier, I was reading the recommendations offline that were sent in the report over the past couple of days. And it looks like a couple of recommendations earlier around Recommendation 46 or so, maybe 45, I'm sorry, the numbers offline are hard to find, states something about plain language. So, I think that you perhaps could just use that sentence to carry through in Recommendation 48 and 49 with access rather than suggesting rewording. There is a line about supporting the use of plain language in any communication related to access. And I think if you just carry that sentence into Recommendations 48 and 49 about access that that would make it more clear.

Carolyn Petersen

Thanks, Alexis. That's really helpful.

Denise Webb

Andy Truscott, you're up again.

Andy Truscott

Yes. I'm just going to respond back on the bidirectionality. I fundamentally agree with you that bidirectionality is where we want to get to. I absolutely agree. My concern is the timeframe it will take if we're trying to force all interoperability across public health to be bidirectional. That's my concern. I'm not saying we don't care about bidirectionality because we absolutely do and that is where we want to get to. I note that the bidirectionality scope was, actually, a revised charge that was given to the task force. Was that a revision by the task force of its own charge? Or was that something that ONC passed down?

Carolyn Petersen

That was something that the co-chairs negotiated with ONC prior to the beginning of the bulk of the work of the task force because we recognized that it would be impossible to cover everything that was included in the initial work. And we understood from our ONC leads that the bidirectionality was a key piece of what ONC wanted to better understand and visualize about the ideal future state. It really isn't an intention to provide an aspirational look at what the future should be like without trying to constrain ourselves in today's reality or what funding we think might happen sometime depending upon unspecified criteria.

Andy Truscott

Okay. I hear what you're saying, Carolyn. It's an aspirational find. I am trying to think about reality as well. And we don't have billions of dollars available or an infinite amount of time to fix some of this stuff. I've said my piece.

Carolyn Petersen

And, honestly, that is the same constraint that we really felt in the initial weeks of the task force as we debated do we come up with a list of ideas about low hanging fruit that would largely replicate previous task force work and lists of low hanging fruit that could be addressed now versus what is the ideal future state and what does all of that encompass in part so that things like funding and timelines could be assessed together and developed in ways that are realistic and advance the field and the community and the ecosystems.

Denise Webb

Arien Malec, you're up.





Arien Malec

Thank you. It's been a pleasure and an honor working on this task force and I really appreciate the leadership of the co-chairs. One of the a-ha's that I had during this task force has been the extent to which what we're calling for is the integration of public health into the US healthcare sector and building public health interoperability as a key actor and partner of interoperability for the nation for too long. And I think the issue here has been both the US healthcare traditional providing of individual care sector and public health. It has treated public health as a little bit of an island or something special. And we do our best work when we contemplate public health as a portion of a broader healthcare interoperability ecosystem. And my favorite example of this is that, for good reasons, we left the job of orders and results for physicians undone in meaningful use. We were seeing significant adoption of electronic results into physicians' offices.

The burden of pushing in electronic orders and standardizing electronic results seemed like it was too large. And yet, what we discovered over the past 18 months is that that failure to complete the job for the healthcare system led us to have significant gaps in demographic and contact tracing data in our public health and pandemic response. So, really a plea on both sides that A) we finish the job and finish the mission with respect to interoperability as a nation and B) that we contemplate that public health is a part of that mission.

And then, the second a-ha that I had during this task force is the extent to which because of the way we structure public health in this country, and there are very good reasons for structuring public health this way with a substantial amount of state, local, tribal, county level authority for public health, we need to be very conscious about building public health interoperability as a national priority with a preference for national standards and build public health interoperability in the context of a broader national interoperability mission while letting the local folks who know their communities and know their regions do the job well on the backbone of national interoperability. So, that was my big a-ha and sort of my plea for the committee and ONC going forward and also for the nation going forward that we really finish the job with respect to interoperability, and that we treat interoperability as a system, and that we incorporate public health as a key part of that system, and that we not let state and local authority undermine the notion of building national standards and national interoperability.

As I said, it's been truly an honor participating. And I hope the full committee enthusiastically endorses these recommendations to ONC. Thank you.

Carolyn Petersen

Thanks, Arien.

Denise Webb

This is Denise. I want to echo what Arien just said. Having worked in the Division of Public Health in Wisconsin and having 72 counties as well as our tribal and territorial areas, it's very challenging without having that framework or umbrella at the national level driving those national standards for interoperability that include public health. So, I echo and endorse what Arien just said from my personal standpoint. It doesn't look like we have anyone else in the cue presently. So, I'll ask the co-chairs and the committee are we at a point now where we're ready to consider a motion to vote on the full report with the 52 recommendations given 1 adjustment from Alexis to carry forward the plain language text that's in Recommendations 45 and 46 into Recommendations 48 and 49.

Aaron Miri

Carolyn, I just want to make sure we saw Andy's comment. I think he just posted details in the chat about a recommendation he also has, a change.

Carolyn Petersen

Do you want to recognize him for discussion?

Aaron Miri





I believe should. I just he wrote all of that out right before we go to vote.

Denise Webb

Oh, thank you, Aaron. I didn't see that.

Carolyn Petersen

For some of us, the public chat is really not very visible. So, it might be helpful to read what's written there out loud.

Andy Truscott

So, basically, on Recommendation 10A, which currently drafted says, "ONC should require the EICR and ECR specification standards, including bidirectional communications, fee providers, other entities, etc." I've suggested that we insert the words "where possible" in front of bidirectional.

Denise Webb

Is there any discussion on that from anyone on the committee or comments? Alexis Snyder.

Alexis Snyder

I think when you insert language like "where possible", it takes away from the actual recommendation. It's, basically, saying well, take our recommendation or don't. We recommend you do it but only if it's possible for you to do it. So, I think when we add language like that, it gives an out to, actually, trying to follow through or put anything in place.

Andy Truscott

I agree. It's definitely a softening. The danger is that, unfortunately, the recommendation becomes an implied mandate, which would not be helpful either. But I agree with you that it is a softening.

Alexis Snyder

I think recommendations are recommendations, not an implied mandate. So, I'm just saying if you put in "where possible" then, it's just not really a recommendation. You're giving a way out to the thought process of, actually, what the recommendation means. But if we were to take out bidirectionality then, I think you need to change the entire pretext of the recommendations in that area from engagement to involvement because that wouldn't be engagement. It would be involvement if it's not bidirectional.

Andy Truscott

Or you could just drop bidirectional and just say "including communications between providers."

Alexis Snyder

Right. I guess what I was saying and then, we'll move on is that if you take out bidirectional then, that's not engagement. That's involvement.

Denise Webb

We have three more hands probably to comment on this and I'll express, as a committee member, my opinion on this. So, we have John Kansky next.

John Kansky

Thanks. I just wanted to come down in support of Andy's recommended edit in that it's not giving people an out to not take our recommendation. It's a question of what is our recommendation. And as a member of the task force, I would rather recommend something that I thought was realistically achievable and responsible in terms of federal tax dollars, etc. So, if we as an advisory committee think that the words "where practical" or "where achievable" make the recommendation better then, that's what we should approve. And I think it does make it better.

Denise Webb





Sheryl, you're next, Sheryl Turney.

Sheryl Turney

Thank you. I was thinking that perhaps instead of using the words "where possible", we could say something like where it makes the most sense because, at the end of the day what we're saying is bidirectional is the goal that we should achieve. But, of course, bidirectional for all things may not make sense. So, instead of using something that's, basically, where possible saying possible based on the technology that's available, the standards that are currently available. Really, to me, it's where it's desired to be. And that's really what we're talking about here. And if it does take time to implement then, there will be a timeframe. And we're not legislating or recommending a specific timeframe. We're recommending this is the goal that we should be achieving. And it should be applied to all things that make sense.

Denise Webb

Aaron, you're next.

Aaron Miri

So, this conversation reminds me of, for those of us who were part of the standards and policy committee, of the view, download, transmit conversation we had around meaningful use and meaningful use Stage 2 and the threshold that we set. And the same exact conversation around bidirectional. I agree with Andy's point, just like John was saying earlier that we shouldn't mandate but we should encourage. And Sheryl has a good point that there needs to be communication, some sort of transmission communication, even if it's unidirectional. In some cases, we can't even get that going. The state of Texas has a 20 megabyte limit on files uploaded to it from a unidirectional perspective as a provider. So, I had to chop up my vaccine registry into miniature chunks of files to upload. And heaven forbid if you got them out of order. It was just a nightmare. But that's just the way it is. I like the language proposed by Andy. I'm not a wordsmith. I'm an engineer.

But to some degree of a transmittable communication between, obviously, providers and other entities where it's not, basically, mandated every time because it's not going to be possible unless each state adopts similar systems, which that also will be impossible. So, to some degree, I'm supporting Andy and also what John is saying. I just wanted to give some lens to it.

Denise Webb

I was just going to state my opinion as a committee member. While I agree with what Andy is saying that we don't want to specify the recommendations as a mandate, I don't necessarily see it as a mandate. I see it as a direction we're recommending that we need to go and the execution of that and how we get there has to be worked out, those details. I think that there are some opposing views on this. And we may have to just take a vote on that wording change, unless we can select a wording change that everybody can come to agreement on.

Carolyn Petersen

I guess I would just say that this is kind of the fundamental chicken and egg problem. There is very broad understanding today that the system we currently have did not meet all of the needs and allow us to do all of the things that we wanted to do in the recent pandemic situation and also does not adequately support day to day kinds of operations in nonemergency situations. So, we can approach this in two ways. We can say let's figure out how to get all of the funding. And when we have a pile of money then, we can talk about what to do with it. Or we can say what would really work well for all of these needs for pandemic things, for high consequence issues, for public health emergencies, and for all of the day to day stuff. And also, by the way, we've been those providers and clinicians who need access to things like immunization information and maybe can't get that now. And then, when we know what really would work for everyone then, we can start putting numbers around what that would cost and what the timeline would look like.

And then, we can go to our legislative bodies and advocate for that because we can now show them what we want to spend the money on. We've taken that latter approach in doing this work, in large measure,





because ONC asked us to provide the future ideal state. Certainly, one can try to work the other way but in that situation, you have a much higher risk of staying with the status quo. Go ahead, Denise.

Denise Webb

So, I just want to remind everybody that we're voting on the entire package with suggested edits and not to vote down the entire report once we go to a vote.

Andy Truscott

We're trying to wordsmith a couple of comments right now.

Denise Webb

Pardon?

Andy Truscott

We're kind of wordsmithing in the public comments revising to "where appropriate and feasible" as opposed to "where possible".

Denise Webb

Any thoughts on that, Carolyn and Janet?

Janet Hamilton

This is Janet. I would just say I don't think when I was interpreting it that it was a mandate. But this is where we want to go and I think that was how the task force collectively came to this recommendation. However, I also recognize that there are many recommendations in this report. And I think there are a lot of good recommendations. And so, I would like to see this moved forward. I think "appropriate and feasible" is probably better than "where possible". Potentially, even "appropriate" would be the best. I think once we start to add things like "feasible" and "possible", what ends up happening is people say, "Oh, that's a lot of work and so it's not feasible," as opposed to pushing to ourselves towards, actually, getting it done.

Carolyn Petersen

And I would just add that in the transcripts and notes from the public health data systems task force meetings reflect that task force members understood that they were not creating mandates. They, actually, worked hard to frame the language in ways that identified the players who would work together and would suggest and recommend things that contributed to this ideal future state that we did not see them as mandates very clearly.

Andy Truscott

Steve has given us a good reminder that ONC and the agencies can work on this stuff about how feasible it is. Carolyn, Janet, it's up to you guys, you're the chairs, if you want to include it or not.

Carolyn Petersen

Isn't it up to Aaron and Denise to solicit whatever voting?

Arien Malec

And this is Arien. I've got my hand up. If we did have an amendment, I would prefer, to Janet's point, "where appropriate" rather than "where appropriate and feasible". I just don't think it's a good policy for us as a committee to negotiate down the policy goal because public health will never get funded at this level or we can never do this work. I think we should be strong and articulate for a policy goal. And as Steve Posnack says, let the US federal government and congress and, ultimately, us as taxpayers make sure that we do or don't have the funding that matches the policy goal. It's our job to advocate for a policy goal.

Denise Webb

I think because there are differing opinions on this as opposed to the amendment that Alexis requested that was a pretty straight forward carrying forward of some language and some of the recommendations, on this





one since we have some varying views, I would like to suggest that we insert the language “where appropriate” and take a vote on that for this language change and then, proceed with voting on the entire report.

Aaron Miri

Are you calling for a motion?

Denise Webb

Yes, I am, Aaron. So, unless there is some further discussion, I’d like to ask for a motion to amend Recommendation 10A to add where appropriate.

Arien Malec

Seconded.

Denise Webb

All right. All in favor say aye.

Group

Aye.

Denise Webb

And any opposed say no.

James Pantelas

No.

Denise Webb

And that was who said no?

James Pantelas

That was Jim Pantelas.

Denise Webb

Okay. Jim Pantelas. And any abstentions? So, that vote passes. I think we can proceed to vote on the entire report with the amendment to 10A and the amendment to 48 and 49 to carry the language of 45 and 46 related to plain language. Can I have a motion for that?

Arien Malec

So motioned.

Unknown

Second.

Denise Webb

All of those in favor say aye.

Group

Aye.

Denise Webb

Any opposed say no. Any abstentions? So, the report will go forward from to the committee and on to the ONC approved with those amendments. Thank you so much, Carolyn and Janet, for all of your work and your leadership on this task force and all of the task force members for your time and commitment to this work. I will hand it over to Aaron to present the next group.





Aaron Miri

Fantastic. So, great job, again. I want to echo that, Carolyn and folks and Janet. Well done to the committee and good job, HITAC. I agree. I'm sure folks listening are like, "Really? They're arguing about the minutia?" But it's the minutia that matters. Each of those details matters and a conversation around the minutia matters. So, thank you for that and thank you for folks like Andy and others speaking and having the courage to bring those topics up. So, in that same vein, we have an item that is from last meeting that carried over to this meeting. And I want to give a lot of credit to the chairs, Arien and David, for working through the item that was outstanding and really getting to some resolution here. So, as an order of process, I'd like to turn it over to both of them as the co-chairs of the ISP task force to walk through the recommendation that needed some addressing and how they went about that and what the recommendation is going forward.

As a matter of process, once they have finished talking about what that change is and the HITAC gets to discuss any points for the points around that, we will take a motion to vote on that remaining item to close that item out successfully with an up or down vote. If that makes sense then, I will turn it over to Arien and David for their comments.

**Interoperability Standards Priorities (ISP) Task Force Recommendations – HITAC Vote
(01:33:14)**

Arien Malec

Thank you. And it's good to be back. We're here to present on the surprisingly contentious or discussion prone topic of vocabulary standards. After the last meeting, we were asked to go back and get additional testimony on the subject of vocabulary standards, particularly, procedural vocabulary standards. We had a hearing with the AMA and also NCVHS who had made parallel recommendations on vocabulary standards. And the revised recommendations really address the feedback that we heard. I'll do some verbal explanation. In addition, we heard some concerns about the wording of our recommendation on medication vocabulary standards. And after having a brief but very productive meeting with NCPDP, we've made some recommendations for an edit and amendment to the recommendations on those vocabulary standards. They're in line with the task force policy intent but make sure the language is not needlessly confusing. Again, I'll give some verbal explanation there. Go on to the next slide.

We're going to skip over a bunch of the front matter since we've already adequately gone over this a couple of times. Let's go straight to the recommendations. And we've, and by "we" I mean our fantastic ONC staff, have helpfully put together a red line version of the final recommendation so that the full committee can see what we've done. Actually, I guess not in this context. So, here is the broad recommendations. As a reminder, we structured our recommendations with an executive summary and a broad set of recommendations and then, a set of detailed recommendations in particular areas. And at the broad level, we did point to OMB Circular A1-19. And then, we added pointers to NCVHS. And we have footnotes on both of those pointers just to make sure that it's very clear which of the documents we're referring to. So, our previous language talked about open and no cost as a preference for vocabulary standards.

We used the language of the 2019 NCVHS vocabulary recommendations and used the term "free or low cost use" with an editorial strong preference for "free" by providers, researchers, developers, patients, and other stakeholders. We have some additional commentary that's not in the formal recommendations that makes it clear that by calling for free or low cost, we're not intending to suggest that vocabulary development itself is free or low cost but that we, as a nation, as we've done in most of our areas for vocabulary standards and are emergingly doing so for content standards via HL7 FHIR, we're moving to models for standards development sustainment that allow for broad use by the public of the resulting standards. In the case of vocabulary standards, in most cases, we have some level of either national licensure or a public funding model and a grant funding model, for example, for LOINC coding that allows for sustainment of the associated standards designed to address multiple uses and across international standards where available.





And the “where available” here was an insert to allow for multiregional pooled research. The general thrust of our comments is that the interoperability, particularly interoperability for broad uses, will be best done when we define interoperability needs associated with broad uses. We collect once as close to source as possible and reuse multiple times. And so, the thrust of our vocabulary recommendations are really to support the notion that, to the extent possible, we should be source normalizing or normalizing as close to data origination as possible, and should be using federal levers to drive, to the extent that there is regulatory authority or regulatory powers, standards and interoperability as close to source as possible [inaudible] [01:38:41] and can make some comments or lab recommendations or pharmacy recommendations. And we should be contemplating standards that are fit, not just for one purpose but are fit for multiple purposes. And, again, we can make some commentary on, for example, NDC and RX Norm codes when it comes time for those standards. David any comment that you want to provide on the broad recommendations here?

David, if you don't have any comments, we'll just move on.

David McCallie

No, go ahead.

Arien Malec

Okay. Let's go to the next slide. So, we streamlined the recommendations here about how to align federal policy with the policy goals that we articulate. So, basically, making the recommendation that ONC work with key federal stakeholders and we mention a number of them and terminology curators. And we inserted the term terminology curators throughout the document, to transition the nation towards terminology meeting the policy. And then, we list a number of means intending to be illustrative and non-exhaustive. Those means could include licensing, funding, aligning development with policy or making a transition to an alternative terminology standard. As a nation, we have done many and all of these policy choices. For example, our membership in WHO, our sponsorship of [inaudible] [01:40:29], our grant funding for LOINC, etc. Next slide.

So, now we get into the very detailed recommendations for lab. With Clem's help, we put together a very well nuanced set of recommendations relating to laboratory results. And, again, here our notion is that we want to code as close to source as possible and use the appropriate regulatory authority, FDA and CLIA, in this context to make sure that the downstream interoperability is coded appropriately. So, here we make recommendations to use direct levers and work with related agencies of HHS to correctly code as close to source at the [inaudible] [01:41:29] as possible to the identity of the laboratory test or measure. And then, with Clem's help, we made very clear recommendations about where LOINC, UCUM, and SNOMED are used in existing laboratory results with coding. So, David, unless you have any comments, let's go on to the next one.

David McCallie

Just to point out that the LOINC, UCUM, and SNOMED is not a change in any way. It's just to reiterate the best practice currently in use.

Arien Malec

Absolutely. If we go onto the next slide, I don't believe we have any changes on the next recommendations. We have a proposed change for the RX Norm recommendation. We do so I apologize. For D, we streamlined the recommendation here, harmonized procedural coding standards for standards meeting the policy goals listed above and really referenced the policy tools section to do policy alignment here. In the transition to ICD-11, we don't mention SNOMED CT but we encourage harmonization to a lot of single nomenclature for capturing and coding problems and diagnoses for clinical research and administrative workflows. And here, the gloss is that we use ICD-10 in an administrative context and SNOMED in an interoperability context and problemless context. It would be useful, as we contemplate that transition, to





contemplate a transition that allows for a single nomenclature for capturing and coding problems and using them for multiple workflows inclusive of clinical care, administrative workflows, research, and public health.

Recommendation F, there will be a little gloss here and a proposal for an updated recommendation. Here, the policy context is that FDA, through its regulatory oversight for drug licensure and SPL, the structured product label, has oversight for NDC coding and SPL coding. Right now, NDC's are specific to a drug package and manufacturer. So, as an example, Atorvastatin 10mg tablets in 90 tablet bottles manufactured by Sun Pharmaceuticals, that's the level of detail that NDC goes down to. Those codes aren't currently mapped up to RX Norm, which is our national standard for expressing, for example, Atorvastatin calcium as a drug, Atorvastatin calcium 10mg tablets as a concept and then, being able to nuance Atorvastatin calcium is Lipitor manufactured by X and a generic drug formulation.

So, the intent of our recommendations here are to make sure that the FDA and its oversight for drug licensure and SPL takes the work to cross map the label and package specific coding up to RX Norm so we can use a single code set for normalization and use that code universally through the standards that we use for, for example, electronic prescribing, etc., so that we serve the needs of interoperability as a nation. And then, when we talk about the edits to the section, I'll talk about the concerns that NCPDP raised with respect to the way that we worded this recommendation and the language that we came to as an appropriate modification there.

Clem McDonald

Arien, can I make a comment on this? This is Clem.

Arien Malec

It's the chairs' prerogative but go ahead, Clem.

Clem McDonald

Well, the problem is RX Norm doesn't have all of the codes that are in NDC. It's a deep problem. And you don't want to replicate all of that specificity into RX Norm. But RX Norm is missing codes it should probably have. So, you might want to add in the words after FDA and NLM, **[inaudible] [01:46:18]** to encourage them. So, for example, if you get a drug in a powdered form that you mix with fluids, you can't code those in RX Norm now. And it might be important.

Arien Malec

Thank you for that. I think you'll see the edits that we have here. The intent is to, as I said, harmonize between FDA and NLM to make sure that we've got a coding system that goes up and down and don't have split coding systems for the nation. I think the topic that you're raising, Clem is an important one but was maybe something that a future task force should take on making sure that we have the means for addressing all of the pharmacy use cases. Let's go on to the next recommendation.

Aaron Miri

Clem, let's let Arien and David finish and we can definitely follow up once we go to that part of it if you're okay with that, please.

Clem McDonald

Okay.

Aaron Miri

Thank you very much. Go for it, Arien.

Arien Malec

So, let's go on to the next slide. I'm not seeing the next slide. Here we go. So, I believe we have a slide where we proposed the red line. So, as noted, a number of stakeholders in the pharmacy community, including NCPDP, had some concerns about the way we had worded the recommendations here. And in





particular, the concern was that we currently use NDC codes pretty heavily in pharmacy workflows. And it would be inappropriate for us to put a stake through NDC as a coding system when our intent is really to map up NDC's and use the authority that FDA has over NDC's and SPL to cross map into RX Norm. My comment here, and it's not this specific recommendation because we're trying to stay out of the "how", but an ideal form of recommendation would be for FDA to use their regulatory authority over drug manufacturers and labelers to make sure that at time of label registration or label update that the NDC's that are associated with that label are appropriately cross matched to RX Norm in ways that facilitate the NLM mission of creating a single coding system.

So, our proposed revised recommendation, which I will, as a member of the committee, move to adopt is making the following edits. And you can see in red. Recommend that ONC and FDA work with FDA and CMS to continue to harmonize NDC to RX Norm treating RX Norm as a future source terminology inclusive of the semantic levels expressed in current NDC and RX Norm. So, we don't intend to drop the drug labeler and packaging specificity of NDC. We had a little bit of an oops in terms of single source of clinical terminology as opposed to single source of data. And then, striking and replacing NDC for such purposes really focusing on the policy goals. As a committee member, I move to amend the recommendations as noted on this slide. And then, Aaron, I will turn it over to you or to the co-chairs to see if we have a second for that motion.

Aaron Miri

Absolutely. I think that's a good move. First real quick, I just want to make sure are there any other questions related to this before we move on a vote? Let's get the conversation had real quick.

Clem McDonald

When you're talking about NDC with RX Norm, NLM makes RX Norm. And I don't think you can have one hand clapping. And you don't mention NLM in that previous slide.

Arien Malec

That's a good point. Clem, maybe I'll leave it for the chairs to figure out how we organize the voting here. But we could contemplate a single vote that is inclusive of FDA, NLM, and CMS as understood on this slide.

Aaron Miri

I'm okay with that if that's what the committee is good with. Let's have a discussion here.

Denise Webb

Aaron, this is Denise. I just want to clarify. So, are we being asked, Arien, to vote first on this change to F and then, we'll vote on the entire Recommendation 3?

Arien Malec

This is at the HITAC chairs' prerogative but that would be, I think, the appropriate order.

Denise Webb

I wanted to make sure the rest of the committee understands what we're doing here. So, back to you, Aaron.

Aaron Miri

No, you're exactly right. I appreciate the clarification. First, I want to make sure is there any other conversation on this? I want folks to feel heard. It's important that if we have opinions, we speak up, and we talk through it. So, please raise your hands. Robert.

Robert Wah

Thanks. Right now, we're talking about this amendment on the drug code area. And it seems like what I'm hearing is Clem is recommending a second order amendment to what the committee chair just proposed. I think that's to add in the wording about NLM. So, that would be just one comment I'd make about clarifying





where we are. But I also want to say I'm assuming, at some point, you're going to open discussion to the entire recommendation that came back from the task force.

Aaron Miri

That's correct. First we're going to do the red line and then, we come back. You're exactly right.

Robert Wah

And we're going to deal with this specific one we were just talking about with the drug code, potentially, the addition of the second order amendment about NLM. But I want to reserve the opportunity to speak on the broader new Recommendation 3. So, if that's true then, I'll standby for whenever you think it's appropriate to talk about the broader recommendation.

Aaron Miri

I appreciate that. And the nuances matter. So, again, I'm soliciting any feedback specific to this adding the NLM focus on this and the red lines here before we talk about the whole broad recommendation.

Robert Wah

Just to close out, I guess I would support Clem's second order amendment to add NLM in the language that the committee chair just put in the red line.

Arien Malec

I think the motion that I am moving is to proceed with amending the recommendations per this slide and including "comma, NLM, comma" in between FDA and "and" so that the full sentence reads, "That ONC work with FDA, NLM, and CMS," and the rest of the changes suggested on this slide.

Aaron Miri

Okay. Do we have a second for that motion?

Robert Wah

Second.

Aaron Miri

All of those in favor, please signal by saying aye.

Group

Aye.

Aaron Miri

All of those opposed, please say nay. Okay. So, that takes care of, I believe, the red line and inclusion to the "FDA, NLM, and CMS" change there. So, now let's talk about the general recommendation. And Robert, I think that's what you said you had further comments on. And I want to encourage the HITAC to please raise their hand if they have comments related to the entire recommendation. I do not see any right now. Robert, go for it.

Robert Wah

Thank you. And let me just say, I guess, as long as I've got the mic, thanks to the committee chairs for your excellent handling of all of these. I know these are very difficult and challenging issues just as we did with the last task force. And Carolyn and Janet did a fantastic job with all of those recommendations. I want to thank, again, the task force for considering the concerns that Clem and I raised at the last meeting. It's always hard to stop the train when it's moving as fast as it is. But I appreciate that the committee was able to do that. And I hope that we were able to improve the task force recommendations through that process. And I appreciate that the ISP task force then provided an opportunity for procedural terminology experts to present to the overall task force. I also recognize that the addition of the terminology curators as key stakeholders, I think that improves the recommendation as well.





And I think we're all trying to do the same thing. We're trying to look for a way to reduce friction across our data collection and data classification process. And I think as long as we're all seeking that same goal, I think it's good for the overall ecosystem, in general. The other point I'd make is recognition that minimizing workflow disruption needs to be a key process here as well, not just accurate collection of data but we want to make sure that we don't upset the workflow process unnecessarily in the process of getting good data. And so, at this point, I'll just say for transparency I think everybody knows my relationship to the American Medical Association as a past chair of the board of trustees and a past president. I have a lot of familiarity with the overall AMA organization and, in particular, the CPT coding process and how it was developed and all that is involved in that. So, I'll just say that as a caveat or an intro to my remarks about all of this. I do want to say that the AMA, I believe, really does also subscribe to reducing the friction in the collection of this data and the use of the data.

So, I know it is a key goal for the AMA work in this area. I want to say that we're also trying to make sure that the workflow doesn't get screwed up in the process. And as Clem pointed out, a lot of these coding systems are engrained for sure in physician workflow in such a way that we have to be mindful as we consider modifying what that change is going to have and the impact of the workflow. And finally, I'll just say that while I don't think it's a recommended change, there was a letter that the AMA submitted and I think we just all got it as a committee during this call that expresses some interest in making sure that when we reference things like Circular A1-19 and NCVHS 2019 language that we be very careful and specific about what part of those recommendations we are citing and be clear about what language we are referencing in those various other documents. And so, while I don't think it makes a substantial change to the task force recommendations, I think the addition of the recognition of specificity about how we refer to other documents is valuable in this discourse.

And I'm trying to figure out the best way to do it without trying to put forward an amendment to the task force recommendations here. But just to make sure that we are clear about how we're referencing other documents in our current task force and then, HITAC recommendations. But I want to thank the task force and the HITAC chairs for the navigation of these very difficult issues. And I'll leave it here. But I do want to figure out a way to get this reference of the other documents clearly specified as we go forward.

Arien Malec

I appreciate that. I definitely appreciate the overall comments. I do want to make it clear that the Word version, the actual formal transmittal includes footnotes and specific reference to the appropriate documents, the appropriate approved versions of OMB A1-19 and the actual formal recommendations of NCVHS. So, I believe that the actual Word version of the recommendation is pretty clear in terms of the document reference that's noted. Thank you.

Aaron Miri

So, are there any other hands raised? Anybody else?

Clem McDonald

Well, I don't have a hand up because I can't find my hand. But I do have just one additional comment if I may.

Aaron Miri

Go ahead, Clem. Go for it.

Clem McDonald

So, in terms of –

Aaron Miri

Clem, are you there?





Clem McDonald

I'm on mute. I'm sorry. In terms of being open, the problems with ones that have little requirements for payment, it's just mechanically hard to do little things. And along that line, I'd like to highlight the fact that some research survey instruments have a worse problem because there may be 1,000 of them. And how can one really manage the movement of data when that survey instrument has got a very strict licensing agreement that you have to pay per use or something? So, maybe at least get that in the concept so people don't need to change anything. But that's an almost bigger problem for research than other ones that might be. Thanks.

Aaron Miri

Thanks, Clem. Chairs, David or Arien, any response to that?

Arien Malec

No. Definitely an endorsement and this has been consistent with previous incarnations of the policy and standards committee and with this committee that interoperability is best served when some of the foundational pieces are broadly available.

Aaron Miri

Okay. Are there any other HITAC members with questions, please raise your hand? I don't see any others. So, Arien and David, would you like to move to motion to vote on the entire recommendation?

Arien Malec

I so move.

Aaron Miri

Do we have a second?

Robert Wah

Second.

Aaron Miri

All right. With that, all of those in favor please say aye.

Group

Aye.

Aaron Miri

All of those opposed please say nay. Okay. With that, I believe the recommendation now stands as approved and completed. Are there any parting thoughts, David or Arien? Congratulations. Are there any other parting thoughts?

Arien Malec

I do think the remand and revision led to stronger and better worded recommendations with more expansive cross references. So, I thank the committee for the opportunity to take them back, revise them, and bring them back to the fully committee.

Aaron Miri

Perfect. That's the power of discussion here with the HITAC. So, with that, Denise, if you are good with it, I think we go to a short break and return at 12:15. Are you good with that?

Denise Webb

Yes. We're good to go.

Aaron Miri





Awesome. See you guys in nine minutes.

Operator

All lines are now bridged.

Annual Report Workgroup Update (02:12:34)

Mike Berry

Great. Thank you very much. And hello, everyone. I'm Mike Berry with ONC. And I'd just like to welcome everyone back to the second portion of our HITAC meeting. And I'll turn it over to Aaron and Denise to get us started.

Denise Webb

All right. Thank you. So, next we're going to hear from Aaron and Carolyn for an update on our annual report work group.

Aaron Miri

Sounds good. Thank you very much, Denise. So, let me kick it off here with my illustrious co-chair, Carolyn Petersen. So, let's go to the first couple of slides here. Today, what we're going to be doing is, obviously, a quick overview of who is on the work group, talk about meeting schedules and next steps and then, talk about what I really want the HITAC to look at is a discussion on a potential topic list for the HITAC annual report for FY '21 and really starting to think through that given especially all of the wonderful activity that's been going on. Next slide. This is who is on our committee. Again, we are looking for additional volunteers. Carolyn and I and Brett, this is like second nature to us now, I guess, with Michelle and everybody's help getting it done. So, if you're interested, please let us know. Next slide. Let's look at the meeting schedule. Next slide, please. We are at the July 22 meeting, which is coming up next week.

We really need to take some of your feedback from today and in later slides here as we develop our crosswalk of topics that we're looking for FY '21. As a reminder, we're going to keep bringing it back to you guys in subsequent meetings as we further get to goal towards the end of the year for transmission in spring of next year. Next slide. And then, of course, today we're talking, obviously, on the 14th. And we'll be bringing it back to you on September 9, November and then, of course, January and February. And anything in between that, as appropriate, as things come up during the year. Next slide. So, let's talk about next steps with the annual report work group. We're developing that draft crosswalk of topics with the gaps, opportunities, and recommended activities across target areas at, obviously, our work group meetings. And then, we're going to present that draft crosswalk for discussion at the HITAC meeting on September 9. So, that will be a pretty robust discussion, hopefully, with a lot of your feedback incorporated into that. Next slide. So, with this part, I'll turn it over to Carolyn.

Carolyn Petersen

Thanks, Aaron. Can you bring forward the next slide, please? So, we're just going to briefly review our potential topics and then, get into a discussion about what else you think is missing. We have a number here carried over from last year's annual report, things we decided to table at that moment that we may want to take up this year. We have some discussion about ONC activities, including the Cures Act final rule, the TEFCA program. I know we'll have more about that coming up in October as well as the EHR reporting program that we will be hearing about shortly today. There is bidirectional exchange of health data for public health purposes for research and across the care continuum. We have exchange of social determinants of health data and patient matching. That's always a popular topic. Data needs for increased health equity. We, certainly, had some discussion about that in the public health data systems task force and there may be more that this group wants to say about that.

Privacy and security for public health purposes, of course, and transparency around how public health information is used. Beyond HIPAA, some considerations around sharing and patient consent as they relate to the internet of things. As we know with many of these applications, we have a terms of service rather





than an informed consent. And so, there may be something for the HITAC to say about data sharing in that context. There is patient safety related to EHR's and mobile apps. And also, how patients can share and correct incorrect clinical data and the impacts of that on provider organizations and providers. And the use and sharing of patient generated health data, also known as person generated health data. Next slide, please. We have some potential topics that have come out of HITAC members' comments this year to day, particularly, around use of technologies that support public health. And of course, some of this will be familiar from our discussion earlier today.

But just briefly, population health level reporting, particularly, with regard to immunization data, incentives for public health data sharing, alignment of clinical and public health data sets, ELR and ACR, information exchanged for facilitating care and monitoring of patients who have long COVID-19. And then, of course, future needs beyond the COVID-19 response, including the workforce. So, we will be getting into some of the specifics of ONC's initiative around supporting the workforce as well. Next slide, please. And some additional topics based on our comments to date around interoperability. Increasing health equity, getting some definition around that and also, taking up algorithm bias and also around interoperability standards priority uses closed loop referrals. We don't as yet have any particular potential topics related to our privacy and security and patient access to information target areas. And perhaps that's something that you will be bringing forward for us today. Next slide, please.

So, again, we have three kinds of feedback that we're looking for from you today. First, any questions about this list of topics that I've gone through; second, additions to the topic list; and third, anything that should be removed from that list of draft topics. And with that, let's start into the discussion.

Aaron Miri

So, HITAC, will you please raise your hand if you have any items that you would like to add to this list that you just saw?

Denise Webb

I'm not seeing any hands, Aaron.

Aaron Miri

Neither am I. Is there anybody on the phone?

Denise Webb

Would it help to put Slide 9 back up?

Aaron Miri

Sure. Let's do it.

Denise Webb

Those are the topics so everybody can see that on the screen. We'll give everybody a minute to ponder. It looks very comprehensive.

Aaron Miri

These items came from this committee and these folks and carried forward. Well, what we can do, Carolyn, if you're good with this, we can ask the HITAC to think about and solicit via email anything that comes up and let us know. Again, we want to make sure that we are comprehensively listening. The details do matter. Carolyn, what are your thoughts on that?

Carolyn Petersen

That sounds great. Just with HITAC's awareness, we have another work group meeting next week and also in August. So, there is plenty of opportunity to share that with us. And we will reflect it in our update in September at our next full HITAC meeting.





Denise Webb

Yeah. So, there is a total of three slides that have a list of all of the topics. It's, actually, Slides 9, 10, and 11 if you all need to go back to that offline. That sounds good, Aaron and Carolyn. Thank you.

Aaron Miri

Wonderful.

Electronic Health Record Reporting Program Draft Developer Measures (02:21:09)

Denise Webb

So, what we have next, if they're ready, Michael and Fred are on and Gary just joined. Good. So, our next topic is the electronic health record reporting program, the draft developer measures. So, Michael Wittie will start off with a framework discussion about this program. And I'm going to turn that over to him. Michael, are you there? They're just checking on him. He's connected but maybe he doesn't have his audio up yet.

Fred Blavin

Hi. This is Fred Blavin. I just wanted to make sure everyone can hear me.

Denise Webb

Yes.

Fred Blavin

Thank you.

Denise Webb

Well, we definitely need Michael first since he's giving the overview before you present, Fred.

Fred Blavin

And I know Mike Berry just emailed all of us. I assume Michael will be on shortly.

Denise Webb

We may be just slightly ahead of schedule.

Fred Blavin

I think we were all planning on coming on at 12:30.

Seth Pazinski

This is Seth Pazinski from ONC. Can folks here me?

Denise Webb

Yes, we can.

Seth Pazinski

It sounds like Michael is having some issues with his audio. That sounds like him now.

Michael Wittie

I'm here. I apologize. We shall not name the cable monopoly whose connection is not good right now. Hi, everybody. Thanks so much for being here. This is, actually, really exciting. I'll talk in a second about it. It's been a long road getting here but welcome to the EHR reporting program overview. Next slide, please. I'm just going to quickly take you through the background and some of the history and how we went about approaching the developer reported measures for the program and then, the charge for the task force that Micky mentioned earlier, which we are getting ready to hit the ground running very fast and we're also very excited about. Next slide, please. So, as you may recall, the Cures Act created this EHR reporting program that requires that ONC create a condition of maintenance certification for certified health IT developers to





provide data about how their systems work. And also, on the other side, there was a voluntary section of information to be collected from healthcare providers, patients, and other users.

You'll recall last year, we talked about the voluntary user criteria. And now, we're talking about the first round of the developer criteria. And the Cures Act had these categories that you see in front of you that reflect different parts of important health IT functions that we want to now more about. Next slide, please. So, again, it's been a long road. Cures was passed in 2016 and then, in 2018 ONC had the ability to start to kick off the program. So, we issued a request for information in the federal register and lots of folks provided feedback on what they thought could be the realm of possibility. And we also kicked off our contract with the Urban Institute to implement the program. Over the course of the next two years, the Urban team and their subcontractors held a whole bunch of in person and virtual stakeholder engagements where we heard from the field what data were needed in those topic areas and if there were missing topic areas.

And then, in the fall of last year 2020, Urban published, after another public feedback period and we talked to HITAC a year ago, a voluntary user reported measure as a package that is now available for public use for whomever wants them. And we really focused on doing a little bit more research and targeting what would be the best set of criteria to start with for the mandatory developer measures. And now, here we are in 2021 at the end of this slide all the way on the right side looking at getting HITAC and other public feedback on those draft measures, which are posted on the Urban website right now. We'll see the link for that in a minute. Next slide, please. And moving forward in September, we will finish the task force and the public feedback period.

And by December, Urban is going to have worked with us and taken all of that feedback in to deliver an initial set of developer reported measures to ONC, which we're going to then take next calendar year and start the regulatory process and notice and comment process to establish those measures that get finalized as conditions of certain maintenance certification for certified health IT that apply to, obviously, the health IT that are certified to the relevant certification criteria. And then, at some point in the future, that requirement will become live and will be an actual requirement. And developers will corrugate it and we will start publishing data for people to use. Next slide, please. So, a little bit about our approach. The user reported measures are really more about the publicly available comparative information on how users have an experience with using certified health IT products. The initial measure spanned a bunch of the categories, which are laid out.

And the reporting, obviously, is voluntary. And because ONC doesn't have the resources right now, we don't have further plans to implement these voluntary measures. But, again, they are in the public domain and we encourage anybody who is excited about them who thinks they're interesting to take them up and collect data on them and, hopefully, share the data. For the developer reported measures, we really focus on addressing the information gaps in the health IT marketplace and looking for insights on how certified health IT is being used. So, we focused, again, because we want to focus and I need you to see how focus is better. We don't want to just have a laundry list of everything. We focused on what's most important right now, which is interoperability. And within interoperability, again, based on all of the stakeholder conversations and what we know about the market right now and where the gaps are, we focused on four areas: patient access, clinical information exchange, public health information exchange, and standard adoption and conformance.

So, looking at those sometime in the future, reporting on these measures will be mandatory by certified health IT developers through that condition of maintenance and certification under this program. Next slide, please. So, I've alluded to a bit of this before but just to put it all in front of you, we did have a pretty detailed process of developing these draft measures. Of course, there was all of the research and stakeholder engagements that Urban did and we got to participate in, which was really a lot of fun. I always love hearing what people out in the field say. We did some additional research within ONC and we worked with some crack experts here and from outside that were consultants to really dig into the drafts. And everyone was able to talk to some developers about some of those draft measures to just get ballparks in terms of what





they look like in the real world. And, of course, now is the time for everybody else to come in and tell us what you think.

Obviously, the public feedback period is open on Urban's website. Anybody and everybody should please look at that and if you have something to say, say it. It's a great opportunity. Obviously, it's not the last one because it still has to go through rule making but it's a good place to start. And the HITAC task force, which is going to kick off tomorrow, is going to dig in and really do a very deep dive into these draft measures and provide feedback on how to improve them. Next slide. So, again, our approach. We focused on interoperability, key interoperability functions that we know are important to people in the marketplace. Again, this is an incremental start. We don't have the resources to implement everything that Cures envisioned but we wanted to start with the really high priority areas. And we expect, in the future, some years from now no doubt, to iterate on that and to build and refine.

We had these other priorities, which you can all read and see. Basically, we don't want to overburden everybody. We don't want to drive people crazy. We've done the data collection. We want to focus on things that can be measured in a way that meaningfully informs how products are doing rather than just Vendor A versus Vendor B. And we wanted things that we could see movement over time to know if our policies are having the desired effects. Next slide, please. So, as I said before, these are the four targeted areas that we came upon for the initial set of measures. They're, obviously, broad but still targeted within interoperability and within all of these areas. There are two or three measures within each of these areas. And they all track to individual certification criteria so they make sense within the context of the whole program. Next slide. And, again, more considerations that we're just trying to give you the full background on how we thought about all of this.

We want, as I said, not just a comparison tool but something that gives us insights on where the market is and how especially a certification program is playing in that market and is working or not working to advance what we need and what we want. And the big question is how much is developer control versus implementer control. And seeing that variation is going to be informative. As we learn, again, as we iterate on this program and refining these measures moving forward, we'll, hopefully, get better at distinguishing that and finding ways to help both developers and implementers do better as a team. And, of course, a very important point, if a piece of technology is not certified to a given requirement, it won't report on its activities for that requirement. As I said, each of the measures goes back to a certification criteria. If you're not certified on that, it's not going to be relevant. Next slide, please. So, here is the meat. Here is the charge of the task force that's going to kick off tomorrow morning.

Vision is to address gaps and help IT marketplace among all stakeholders, including ONC, and provide insight on how certified health IT is being used. And the overarching charge is to make recommendations to prioritize and improve the draft set of developer reported, interoperability focused measures for the ONC/EHR reporting program. I'll just emphasize it again. The purpose of this task force is to dig into this set of draft measures. We'll think a little bit, as you can see below in the details, about what could come in the future. But we have a very short time. This task force only runs from tomorrow through September 9. So, we have a very short amount of time to do a lot of work. And we want to really focus on getting the best first set of measures that we can out of it so that we can then start regulating on the best thing possible next year. You can read through all of the specifics there. And these slides are going to be posted. I won't tire your ears by reading you something you've read already I'm sure. But this is big. This is really exciting.

As I said, the task force kicks off tomorrow morning at 10:00 a.m. All meetings are open to the public. Folks who want to join in and do more work please send an email to Mike Berry and myself. That's always welcomed. We have a fabulous pair of co-chairs. Next slide, please. We have a fabulous pair of chairs. Raj Ratwani from Med Star who is also on the HITAC, Angela Shoemaker from ADSM who is also wonderful and has joined as a co-chair for this task force. And as you can see, we have a very diverse and esteemed group of folks that I'm super excited to work with on this that will be digging in and tearing up and you'll hear lots of exciting things in the coming couple of months from this group. Next slide, please. So, again, this is when the meetings are. They are open to the public. We encourage participation and feedback both through





this process and through the public feedback process on Urban's website. Next slide. And, again, that's the ONC website where you can learn more about the program, in general, and also find the link to the Urban website to provide feedback.

I think there is a lot of cool stuff here. We have a lot of exciting potential to learn more about the market. And we really do desperately want your feedback and input on how we can make this as good as we can make it. So, with that, I'll stop and I ask for any questions.

Aaron Miri

I think looking at it, we may want to hold questions until right after the Urban discussion.

Michael Wittie

Good point, yes. That's a good point. Thank you. I will then turn it over to Urban team who will really dig into the details of what the draft measures look like. Thanks.

Fred Blavin

Thank you, Michael. I also want to thank everyone on the call today for taking their time to meet with us. I also would like to acknowledge the large team that contributed throughout this project at the Urban Institute, Crystal Ramos, Laura Smith, Emily Johnson and our colleagues at Health Tech Solution, Gary Ozanich who is going to be presenting some of the slides today and Kathy Frey, specifically, and also the large team at ONC who has provided great feedback and assistance throughout the course of this project. Next slide, please. This is just a basic overview of what we'll be going over today. I'll reiterate some information in the timeline that Michael went over. Then, we're going to go over the key domains and the measures that we had developed. We're not going to go into these in specific detail in terms of numerators and denominators. We're going to save a lot of that discussion for the task force meetings. But we will go over a specific example of our public health measures just to give you a sense of how these measures were created and some of the issues and discussion points associated with each of the measures.

We'll also go over some discussion around a lot of cross cutting issues affecting the measure specifications that apply to nearly all of the measures that we have developed. And the appendix slides that everybody has access to include the detailed specifications of all of the measures that we're not going over in detail in this meeting but will be going over during the task force meetings. And as Michael mentioned, the focus here is going to be on improving and optimizing these draft measures while other measures can be considered in future iterations. So, in our appendix slide, we also have lists of other measures that we're considering for the future but are not using right now for various reasons. While I think it's important to share some of these other concepts, we really want to hone in on what are our 10 draft measures that we've developed here. Next slide, please. The timeline, the public comment information is now posted on the Urban Institute website and is open for public comment until September 14, 2021.

The information in there is the same measures and information presented in the slide but in a PDF format. In December, we are going to finalize these measures based on the feedback we received from the public and the task force. In 2022, down the line, these measures will likely be introduced in rule making. And further down in the line in several years, these measures will likely take effect. This will give developers the opportunity to work on these measures and come up with their coding and scheming to be able to report on those measures if they don't already collect some of the [inaudible] [02:41:51]. Next slide, please. Here are the domains that Michael already introduced to everyone. All of our measures have an interoperability focus in areas of patient access, public health information exchange, clinical care information exchange, and centers adoptions and conformance. Within each of these domains, we have two to three measures for a total of 10 measures.

And today, we'll be going over a specific example of those measures in the second group of public health information exchange. And the others are laid out in more detail in the appendix. And now, I'm going to pass it off to my colleague, Gary Ozanich at Health Tech Solutions who is going to provide a little bit more information on the motivation behind why we selected these measures and a big picture overview of what





the measures are and the motivation behind selecting each of the measures and the questions that they aim to address.

Gary Ozanich

Thank you, Fred. Next slide, please. As Michael and Fred mentioned, those four measurement domains in this initial pass all link to interoperability. And for each of these domains, what I'd like to do is present a description of the motivation for their inclusion and then, also the questions addressed by the measures. These questions are explicated into operational definitions and measures, including numerators and denominators that you can see in the appendix. So, the first measurement domain is patient access. And the motivation is really to understand and assess how the 21st Century Cures Act is being implemented regarding whether individuals are electronically accessing the data and whether they're taking advantage of third party apps. Currently, we only have insights into apps that are in public galleries. And they likely represent just a subset of those apps. And we also have no insight into the usage of those apps. There is also little information to guide ONC and OCR regarding privacy policies among patient facing apps.

As Michael mentioned, all of the measurements are linked back to certification criteria. And in the slides, you can see the linkage. So, in the patient access, the draft measures are designed to address the following questions. How are patients accessing their health information electronically? For example, via a portal or third party app. To what extent is usage sustained by each method? A second question linked to measures is to what extent are third party facing apps that are registered being used. How many apps have sustained usage versus a drop off after download? So, after they're downloaded, are they being used? Are they being, basically, renewed? To what extent do register third party patient facing apps include comprehensive publicly available privacy policies? And as mentioned, these are linked to particular measures in the appendix. Next slide, please. The public health information exchange is clearly a very important part of interoperability. And the motivation is to help ONC assess healthcare provider engagement in public health exchange beyond promoting interoperability.

And this, of course, is critical during public health emergencies. These data are not, typically, available to CDC. And there is very limited existing survey data. The linkage to the certification criteria is provided. Two draft questions were established. How frequently are providers using the certified health IT to send immunization and vaccine information to IIS? How frequently are providers using their certified health IT to query IIS for immunization forecasts in history? So, essentially, it captures bidirectionality. Next slide, please. The third domain is the domain of clinical care information exchange. And the motivation is clearly to provide insight as to whether users are using certified health IT to view and use data, receive from external sources, provide insight into availability and use of clinician facing apps. The criteria are linked to the slide in terms of certification. The draft measures address the following questions. The first concerns the use of clinical data received from an external source. The question is is clinical data received using certified health IT being used and viewed?

And of the total number of unique summary of care records received using certified health IT, how many of those were parsed and integrated and then, viewed by an end user and/or clinician? The second area is usage of clinician facing third party apps. This is a parallel to the patient facing third party apps. How many clinical facing apps are registered and to what extent are these apps used? Next slide, please. The fourth domain concerns the area of standards adoptions and conformance. And the focus here is very much on FHIR and API's. So, the motivation is to provide a measure of the use of FHIR profiles, which can help guide updates to US Core and provide insights into volume and types of data used by app users, assess the implementation of health IT provisions of Cures by providing insight into usage of bulk FHIR overall and for different use cases. And the certification criteria is linked there in that slide. The draft measures address the following questions.

What FHIR core and non-core profiles are requested by providers and consumers when using apps? And the second question is how frequently are bulk FHIR transactions occurring overall and by type. Once again, to reiterate what Fred said, the expectation is that these measures would be required in the 2024/2025 timeframe as we move through this process. Next slide, please. There are other draft measures,





which were seriously considered and are listed as concepts for future consideration. And in three of those domains, public health information exchange, one is the extent to which data are being submitted to public health agencies via third party apps or API's. For patient access, the extent to which third party facing app users are using write back functionality or the number of patient apps with users that are using write back functionality at the app level. The earlier measure is at the patient level. So, they're both focused on write back functionality.

And then, a new measurement area really linked to social determinants, which is data quality and completeness, completeness of key sociodemographic and geographic data needed for patient matching and health equity efforts, including race and ethnicity, date of birth, and standard demographic data, including mother's maiden name as examples. So, that really provides some context on the domains and the motivation and also the particular questions that are addressed by the measures in the appendix. And I'll turn it back to Fred.

Fred Blavin

Thank you, Gary. Next slide, please. So, there is a lot of information on this slide here and I'm just going to walk you all through it. These are just a list of the cross cutting issues for discussion that we really want to focus on during the task force meetings and questions that we had proposed in the public comment document to get feedback on. So, most of these issues apply to all of the measures that we are discussing that Gary went over. The first one is how frequently should the reporting on these measures occur. Should they occur annually or potentially more frequently or less frequently than annually? Obviously, a lot of this will depend on a lot of factors, potentially, ONC resources and the potential burden of these measures to developers and the extent to which these measures kind of change significantly over time. The second key issue is how should the results be reported? As we'll go over in these measures, we propose sub groups for the measures and what we want to collect for.

For public health, we propose that all of the measures at least be reported at the state level given a lot of the variation in public health agencies and regulations across states. And within states, we are also proposing to have information by age group and other potential settings. Each of the other measures has their own unique set of demographic characteristics or other sub groups that we would want to collect information on. This also raises the point of what are the implications of including measures that may require data from developers' customers, especially if they're reporting on the characteristics of the customers and how they pull this data, whether it's from the EHR or, potentially, from information that is reported through an app. Does the level of reporting make sense? To the extent that we are collecting measures on certified health IT products, would it make sense to report, obviously, at the developer level but a specific product or grouping of products within certified health IT products for each developer?

And to what extent should reporting consist of distributional estimates versus single value per developer estimates? Obviously, we would want to get a little bit more information to show variation within a developer such as beyond just the mean or the median so looking, potentially, at quintiles or quartile estimates of the consumer base. This is probably less of an issue when we're looking at more detailed sub groups, especially for public health. But this might make sense for some of the measures that we are proposing here. What is the appropriate look back period for the measures in terms of the definitions of the numerators and denominators? For example, would it make sense to look at active patients that have had an encounter within the past 12 months? Or if we want to capture patients who use care less frequently, we can extend that period to the past 24 months. And we've received feedback both ways on how we would, potentially, define these measures. Are there any other aspects of the numerators and denominators that we could get feedback on or are accurately specified?

The next point is how feasible is it for developers to access, analyze, an report data, particularly, for capturing sub groups. In other words, what is the potential burden of this data collection effort to developers? What is feasible today versus what is not feasible today? And if it's not feasible today, what could be feasible by the timeframe for actual data collection in 2024/2025 when the data are, actually, collected? Finally, how do we address potential interpretation challenges for these measures? For example,





these measures could, potentially, reflect characteristics of geographic areas of where developers tend to operate or the characteristics of their clients as opposed to the product themselves. And to what extent are our measures independent of those factors or are they confounded by information that is not, actually, reflective of the product itself? Is there any potential burden on users of certified health IT? Obviously, a priority of the program was not to place any burden on users. We don't anticipate this being an issue but there might be some aspects that could, potentially, be burdensome to users.

And it would be helpful to know if or where that could, potentially, be taking place. Would the reporting unduly disadvantage small or startup developers as well? And finally, what is the value of the measure to provide insights on interoperability, including to multiple stakeholders? So, we only really want to collect measures where the value or the benefit of doing so exceeds the potential costs. So, we don't want to place any additional burden, unless these are high value measures. And thinking about it from a cost benefit perspective, the benefits of collecting this information outweigh the potential costs. Next slide, please. Here is an example of our public health information measures. On the left hand side, we include the definition of the measures along with the numerator and denominator specifications. And on the right hand side, we have information on reporting elements and formats. For public health, we have two separate measures that capture both sending and receiving electronic health information to and from immunization information systems.

So, the first measure is the percentage of vaccinated individuals whose immunization data was sent electronically to immunization information systems. The numerator is the number of individuals whose immunization information was electronically submitted to the registry. And the denominator is the number of individuals with an immunization administered. The second measure captures immunization forecasts. It's the percentage of IIS queries made for individuals with an encounter. So, the numerator for this measure would be the number of immunization forecasts and histories received from IIS into the EHR. And the denominator would be the number of individuals with an encounter. In terms of reporting and formulating issues for each measure, as I mentioned before, we would collect numerator and denominator counts at the state level for each of these measures and also at the state and setting level such as inpatient versus outpatient in the state and age group, which is important for immunizations so collecting it separately for adults, adolescents, and children and infants.

We would require developers to report information on both the numerators and denominators and not just the percentages so that ONC would have some flexibility in terms of reporting out different pieces of information. And we can look at data and different types of data. The developer would need to construct these measures at the client level and then, roll it up into aggregated groups for the reporting purposes. For these measures, we don't think quintile distributions would be of value given that we already have a lot of variation across developers by the state level and the study level. And we have a lot of reported data for various sub groups. Again, as mentioned in the prior slide, the frequency of the reporting and the look back period for the numerators and denominators are to be determined. It could, potentially, be 12, 24, maybe even 18 months depending on a lot of the feedback that we get during the task force meetings. Next slide, please. For these measures, there are some questions that we want to pose to the group.

Specifically, what individual characteristics should we collect these measures by? Would health IT developers have access to data on these patient characteristics such as age? For the second measure on queries, we indicate that it's important to note that queries that would occur if we had portals would be excluded from this measure and we wouldn't be able to collect that data. To what extent is this a limitation? How common is this occurrence within the marketplace? And also for that second measure, there was some discussion on how we should define the denominator whether it be using encounters, ENM visits, or vaccinate individuals. Right now, we are using the number, basically, of patients with encounters for that denominator but there are arguments for, potentially, using vaccination [inaudible] [03:00:27]. Next slide, please.

So, the rest of the slides that you all have access to include similar detailed slides with the measures in the other domains along with key discussion points around each of those measures as well as more detailed





information on the potential future measures for considerations and lists of other measures that were discussed at various points during our stakeholder process. That's all of the information that we are going to present here today. And the information in these appendix slides will be discussed in more detail during the task force meetings. You can go back to the prior slide. I don't think we're going to go into these. From here, I'd just like to toss this back to the co-chairs for any potential Q&A and next steps for the meeting.

Aaron Miri

Before we get into Q&A, which I believe, Denise, if you're back, you will help facilitate. What I was going to say is there are some general updates to HITAC. If you were interested in participating, please make sure there is still time. Send a note to Mike Berry or the team and they will get you added to this. I believe the first meeting is tomorrow. As you can imagine, it's going to be a very robust discussion around this. If you look at even the most recent rollout of information blocking and the responsiveness to that from the community has been interesting and the varied responses have been very interesting. So, this would be a good way of starting to put some metrics around [inaudible] [03:02:06]. So, I appreciate this discussion. HITAC, if you've got questions, comments, items you want to bring up, ask about, dig into, please use the hand raising function.

Denise Webb

I don't see any hands so far, Aaron.

Aaron Miri

I don't either. Is there anybody on the phone? There we go. People are raising hands now. Here we go.

Denise Webb

That's Michael. Go ahead, Michael.

Michael Wittie

I was just going to quickly respond to the question in the chat box about the relationship to the real world testing program. And the basic answer there is that these are designed to be complementary. And briefly speaking, real world testing is sort of the on the ground ways to understand interoperability and functionality in the real world. Whereas EHR reporting is a national view of the picture of interoperability. And also, the other big difference is that the real world testing measures are up to certified developers to design and report on. Whereas EHR reporting is, again, a standardized set of measures that all developers that are certified to a given criterion will report on. So, hopefully, that clears that up a bit.

Aaron Miri

Thank you for that. Other hands, other questions? Okay. Good job. We appreciate it. I appreciate the detail there from Michael, Fred, and Gary. Denise, if you're in agreement, maybe we can transition here a little bit early and get going to public comment.

Denise Webb

I think that's a good idea. And I was just going to say I'm, personally, looking forward to see what comes out of the task force.

Aaron Miri

I agree. I'm so sorry. Robert just raised his hand. Sorry to cut you off.

Denise Webb

That's all right.

Aaron Miri

Robert, are you there? You just raised your hand unless that was my error.

Robert Wah





No. I raised my hand slowly because there wasn't any other comments on the other topic. I don't know where you want to have an open forum for other topics that didn't fit into the agenda.

Aaron Miri

Oh, this is outside of this. Got it.

Denise Webb

We, certainly, can do that. And I was just going to say that this task force has a very short duration. So, they will be presenting their recommendations at the September 9 meeting. And I'm looking forward to hearing those recommendations. So, I think before we go to public comment, Aaron, we should open up the floor to the HITAC.

Aaron Miri

That's a great idea.

Denise Webb

Introduce any other comments or questions that they might have. Robert, would you like to go ahead?

Robert Wah

Thanks, since I just suggested it. Like I said, there are things that are going on that I wasn't sure exactly how to fit into the current agenda. I think it does relate but I just wanted to share with the HITAC some information about some of the work that's being done at the VCI, which is a coalition of several hundred people coming together to figure out how we share what started out talking about [inaudible] [03:05:56] credentials. But we moved on to think about how do we do verifiable clinical information. And we've come down to the smart health card specification, which, essentially, is a digital envelop that has public and private key certification process to make sure it's not tampered with. And so, I just wanted to say that in the last couple of weeks, there has been some really great movement in this regard. The state of California and the state of Louisiana are the first two states to open up their immunization information systems, IIS's, to their citizens to be able to get a smart health card envelope with their vaccine information inserted into it.

And so, that's a million citizens in California that have already done this. And so, they've gotten a QR code, which is a smart health card depiction. And, again, it's secure so if you try to tamper with it or forge it, it won't verify and things like that. So, it's a great example of where you can start seeing clinical information in a patient controlled way that maintains their privacy. They control who gets to see it. And as part of that ecosystem, the Commons Project has established what we call the common trust network so that people have list of who the trusted issuers of these smart health card envelopes are. And so, you can verify that it wasn't created by some malicious source. And then, we also released common verifier app. So, if you're a restaurant or a store and you want to verify these smart health cards, you can download a free verifier app that will scan these QR codes and establish that it came from a good issuer and it has not been tampered with and it shows the clinical information inside the smart health card envelopes.

So, I just thought it sort of plays into what we were talking about in public health infrastructure as we're trying to figure out how to get a better handle on what the population's vaccination status is. But it is expandable to put other clinical information in these smart health card envelopes now that we've built this ecosystem for this.

Aaron Miri

I would add to your point, Robert, I agree. I think technology can be a definite thing. This is a reminder to everybody listening to be mindful of your state laws and be mindful of any prohibitions on vaccine tracking or similar. Case in point here in Texas, I had to be very careful being at UT Austin of what we can put out there per the governor's orders. So, just look at your local state laws and use technology as appropriate. But I think you're right on the money.

Robert Wah





I agree completely. And like I said, it was sort of initiated because of the vaccine issues but there is a lot of political and social related to that and we recognize that. But as clinicians, we all recognize the need to get ways to move our clinical information in a less friction intensive way. And I think this is one way that we can do that in a broader sense. But absolutely recognize that there are issues surrounding verification of vaccine credentials right now.

Aaron Miri

Exactly. Great comments. Are there any other topics from the HITAC members, in general? Good discussion today. Denise, are you good now for going to public comment? I think I am.

Denise Webb

Yes. We could do that.

Public Comment (03:09:40)

Mike Berry

Before we go to public comment, since we are ahead of schedule, I just want to remind everybody, once again, that we welcome public comments in written form. And you can send those at any time to ONC-HITAC@accelsolutionsllc.com or to me, Michael.Berry at HHS.gov. And we'll make sure those get included in the meeting minutes. So, with that, operator, can we open up the line for public comments?

Operator

Yes. If you would like to make a comment, please press Star 1 on your telephone keypad. A confirmation tone will indicate your line is in the cue. You may press Star 2 if you would like to remove your comment from the cue. And for participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. Our first comment is from Matt Kerschner with AHIMA. Please proceed.

Matt Kerschner

Hi. Thank you. Can you hear me?

Aaron Miri

Yes.

Matt Kerschner

Great. Good afternoon, everyone. My name is Matt Kerschner and I'm the director of regulatory affairs for the American Health Information Management Association or AHIMA. AHIMA represents health information professionals that work with health data for more than 1 billion patients a year. We appreciate the opportunity to provide comments on the work of the public health data systems task force. We are highly supportive of the work of this task force and applaud the task force on all of their work thus far to provide a data driven response to COVID-19 and future at consequence public health threats. We understand the **[audio interference]** urgent need for these recommendations **[audio interference]**, so it's necessary to narrow the **[audio interference]** any additional important topics related to this critical work beyond the scope of these recommendations. AHIMA would like to, specifically, note an area that we believe warrants additional consideration that being the linkage between workforce readiness and data equality.

Our members have reported significant challenges within their organizations and identify hiring and retaining qualified persons throughout the pandemic to maintain data quality in public health reporting. Even under normal circumstances, our members have reported struggles at their institutions relating to complex public health data reporting. Doing this work requires a high degree of specialized expertise and cross functional analysis. And there is a limited available talent pool. We urge the HITAC to consider the need for sufficient workforce education and training to make sure that data quality is being maintained and to ensure that reporting is being done accurately. AHIMA believes that this could be incorporated as a critical element in the recommended public health data workforce staffing and execution plan in Recommendation 33. Data





standards are incredibly important but the key will be ensuring data quality to make sure that the reported data is accurate, complete, timely, and meaningful.

Furthermore, we encourage ONC to work with CMS and **[audio interference]** to ensure the workforce development needs are met in advance of future high consequence **[audio interference]**. I want to thank the HITAC for the opportunity to provide this public comment and for all of your work on this important issue. Thank you.

Operator

Our next comment is from Debbie Condrey with the Sequoia Project. Please proceed.

Debbie Condrey

Thank you. Good afternoon and thank you for the opportunity to comment. My name is Debbie Condrey. I'm the chief information officer for the Sequoia Project. And as you all may know, we're a nonprofit public/private collaborative whose mission is to advance secure health IT interoperability for the public good. Prior to joining Sequoia, I worked within Virginia state government for 32 years, the past 12 years spent in leadership roles at the Virginia Department of Health. The Sequoia Project has supported the patient unified look up system for emergencies, or PULSE, since 2018 by facilitating an advisory council. They've recently expanded that work group and convened the Emergency Preparedness Information Work Group. The membership includes public health experts from around the country as well as others who are subject matter experts in emergency preparedness and response. The group's main focus is to discuss insights pertaining to a response as a country to the pandemic and make recommendations based on the collective experiences of our members.

And these members are boots on the ground experts. During our work group meetings, we've discussed data and access to data needed in order to respond to an emergency or a typical public health response. Bidirectional flow of data is key to ensuring the data is where it needs to be in order to respond appropriately to an emergency, whether that's a pandemic or weather emergency or a typical public health response in terms of syndromic surveillance. Three areas that seem key to freeing up the data so the bidirectional exchange could take place include a focus on accuracy, quality, and clarity of data, policy law and regulatory constraints within states that must be addressed. This includes the need to support state and local policy staff to identify their specific policy constraints and explore ways to better align their policies to support national data sharing goals and interoperability, appropriate sustainability funding, in addition to the initial grants available to public health.

We congratulate you and the public health task force on their work and welcome the opportunity to provide a resource to the full HITAC as you work on resolving these complex issues. Thank you so much.

Operator

And our next comment is from Shelly Spiro with Pharmacy HIT Collaborative. Please proceed.

Shelly Spiro

Good afternoon. My name is Shelly Spiro. I'm the executive director of the Pharmacy HIT Collaborative representing over 250,000 members of the Majority National Pharmacy Associations, including pharmacy education and accreditation and 11 associate members. Pharmacy HIT Collaborative submitted written comments to the ISP task force 2021 recommendations 3F. Adopting RX Norm as the single source of data and terminology would pose issues to systems and databases, especially coded to use NDC as an identifier in pharmacy transactions. Relying solely on RX Norm terminology would not only directly impact pharmacy but also a substantial segment of the healthcare industry, payers, drug manufacturers, drug distributors, and other healthcare providers.

We believe that the Pharmacy HIT Collaborative's written comment letter emphasizes the need to map NDC to RX Norm for clinical data exchange. For example, medication orders, allergies, and more. If NDC is used, it should be standardized with product specific codifications need. For example, for prescription





recalls, adverse drug events, reporting related to specific products such as dyes and fillers and more. For these specific examples, if NDC is replaced with RX Norm then, RX Norm must be linked to the product specific code. We're asking ONC to clearly identify when it is appropriate to use RX Norm coding and when to use product specific coding such as NDC. Thank you very much.

Mike Berry

Operator, are there any more comments?

Operator

There are no more comments at this time.

Final Remarks (03:17:19)

Mike Berry

Thank you very much. And we appreciate all of the comments received. And we did receive four written public comments in advance of today's meeting regarding the ISP task force recommendations. And you can find those on the HITAC calendar at HealthIT.gov. All materials can be found on HealthIT.gov. Just search for the HITAC calendar and you'll find them for each meeting. And before I turn it back to Aaron and Denise, I just want to remind everybody that we're giving our hardworking HITAC members a break. And we're not planning to meet in August. And so, our next HITAC meeting will be held on September 9. Thank you very much. And I'll turn it back to Aaron and Denise.

Aaron Miri

Denise, would you like to start?

Denise Webb

Certainly. Thank you. I want to thank all of our presenters today. And I, especially, want to thank the public health data systems task force and the ISP task force for their work on the recommendations that we voted on today. I appreciate everybody's efforts. And we look forward to hearing from the task force that was just charged today on the EHR reporting. And, again, we'll hear about that on September 9. I want to remind everybody that we're not having a meeting next month. So, everybody gets a vacation, except for the task force members. We are still conducting meetings of the USCDI task force. And the USCDI task force will also be presenting recommendations on September 9. So, I want to thank everybody and wish everybody a good rest of their summer. And I'll turn it over to you, Aaron.

Aaron Miri

Just real quick. I just want to say thank you, again, to the entire committee. Thank you to all of you that are listening in also on the frontlines. As you all know, you have seen case counts are rising in different parts of the country. So, if you do live in a part of the country that does see rising case counts, please be safe. We definitely don't want a reprise of what has happened earlier in the year. So, again, take care of yourself. Take care of your loved ones. Stay safe. Hats off, again, to the ONC and the great work and we will see you all in September. Enjoy the rest of your summer.

Adjourn (03:19:31)

