Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

June 9, 2021, 9:30 a.m. – 2:45 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
Leslie Kelly Hall	Engaging Patient Strategy	Presenter
David McCallie	Individual	Presenter
Janet Hamilton	Council of State and Territorial Epidemiologists (CSTE)	Presenter

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

Operator
All lines are now bridged.

Michael Berry
All right. Good morning, everybody and thank you for joining the June HITAC meeting. I'm Mike Berry with ONC and we are glad you're with us today. As a reminder, we welcome public comments, which can be typed in the chat feature throughout the meeting. Or it could be made verbally during the public comment period that's scheduled around 2:30 Eastern Time this afternoon. And you can also send written comments to us at ONC-HITAC@accelsolutionsllc.com. So, let's get started with our meeting. First, I want to introduce and welcome our ONC's executive leadership team to the meeting. And with us today, 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 will now call the meeting to order and begin roll call with the HITAC members and the federal representatives starting with our co-chairs. Aaron Miri.

Aaron Miri
Good morning.

Michael Berry
Denise Webb.

Denise Webb
Good morning.

Michael Berry
Michael Adcock.

Michael Adcock
Good morning.

Michael Berry
James Ellzy. Cynthia Fisher. Lisa Frey.

Lisa Frey
Here, thank you.

Michael Berry
Valerie Grey.

Valerie Grey

I'm present. Thank you.

Michael Berry
Adi Gundlapalli. Steven Hester.

Steven Hester
Here.

Michael Berry
Ram Iyer. Jim Jirjis. John Kansky.

John Kansky
I'm here.

Michael Berry
Ken Kawamoto.

Ken Kawamoto
Good morning.

Michael Berry
Steven Lane.

Steven Lane
Good morning.

Michael Berry
Leslie Lenert. Arien Malec.

Arien Malec
Good morning.

Michael Berry
Clem McDonald.

Clem McDonald
Here.

Michael Berry
Jonathan Nebeker. Brett Oliver.

Brett Oliver
Good morning.

Michael Berry

Terry O'Malley. James Pantelas.

James Pantelas
Present.

Michael Berry
Carolyn Petersen.

Carolyn Petersen
Good morning.

Michael Berry
Raj Ratwani.

Raj Ratwani
Good morning.

Michael Berry
Michelle Schreiber. Abby Sears.

Abby Sears
Good morning.

Michael Berry
Alexis Snyder.

Alexis Snyder
Good morning.

Michael Berry
Ram Sriram. Sasha TerMaat.

Sasha TerMaat
Good morning.

Michael Berry
Andrew Truscott.

Andy Truscott
Good morning.

Michael Berry
Sheryl Turney.

Sheryl Turney

Good morning.

Michael Berry
And Robert Wah.

Robert Wah
Present. Good morning, everyone.

Michael Berry
Good morning. And thank you, everyone. And now, please join me in welcoming our national coordinator, Micky Tripathi, for his opening remarks. Micky.

Welcome Remarks (00:03:08)

Micky Tripathi
Great. Good morning. Thank you, everyone. Thanks so much Mike. And thanks, everyone, for being here. I really appreciate it. And I'm just delighted to be here. I've been looking over the agenda and it's a great agenda with fantastic contributions as always from the HITAC members as well as the participants in the various task forces and workgroups. So, I just want to, as always, give great thanks to all of you for the invaluable contributions that you make on an ongoing basis. We couldn't do our jobs here at ONC without the fantastic feedback that we get from all of you. Just a few things that I wanted to just speak about and then, I'll turn it over to Aaron and Denise to get the meeting kicked off. One is I just wanted to remind everyone about the funding opportunity announcement that we have related to the Public Health Informatics and Technology Workforce Development Program that we call the PHIT program, which is an $80 million program that's a part of the American Rescue Plan for the focus on workforce development to improve the surveillance.

And ONC has one part of that, which is the program related to health informatics training, specifically, related to public health. And we will be working closely with minorities serving institutions to try to energize that pipeline. I think one of the challenges we've all had in being able to have the kind of workforce that we need going forward, as was exhibited by the challenges that we had and still have with the current pandemic, we normally need to fill the pipeline. But we know we need to look for other pipelines that have been untapped. And that's what the focus of the program is really to sort of energize those pipelines with an eye toward the minority serving institutions to be able to have robust training and education programs but also placement. So, we want to make sure that we're not only focusing on just classroom instruction as a part of the regular curriculum but also with an eye toward placement and career paths. So, we expect to release the formal announcement here very, very shortly and really look forward to your engagement on that.

But I just wanted to make sure that everyone has had awareness of that and please look out for it. And we really welcome everyone's contributions to that as you look that over and decided if you can participate. But the second thing I just wanted to announce is that we are working very hard on TEFCA, the Trusted Exchange Framework and Cooperative Agreement. And we expect that in the next couple of months, sometime over the summer, we are going to release the timeline and the milestones for TEFCA. I know that that's been a long time coming and we're working very hard with the team as well as with the Sequoia Project, the RCE, who has been a fantastic partner, and we'll have more to come on that. But I just wanted

to make sure that everyone knows that that will be coming soon. I know that that affects the way that many organizations across the country do their planning and make their investments. And we appreciate that that hampers your ability to make those investments. So, we're working very hard to get some timelines out there, get some milestones out there.

And that will help all of us then move forward. the last thing I just wanted to mention is since the applicability date of the information blocking rule on April 5, we've had lots of real uptick in questions, both questions related to information blocking as well as on the EHR certification side, the technical questions related to certification, which accompanies the information blocking aspects of that. And I just want to say keep it coming. That's fantastic input for us and fantastic engagement. We want to do everything we can to be as responsive as we can to the questions, the concerns that all of you have in industry so that we can do everything that we can to make industry successful, to make everyone successful in meeting the information blocking milestones and the requirements that are from the 21st Century Cures Act from 2016. So, the overall message on that is we welcome all of the engagement that we're getting from you. Please don't hesitate to reach out and send us more questions and comments.

We are being as responsive as we can because some of those are really tricky questions and it takes a long time to sort through what exactly is being asked and how can we address the question the way that will be clear and will be helpful. But please be assured that we welcome all of the input and all of the questions that we get and that we do everything that we can to be as responsive as we can. And, hopefully, we can be as helpful as we can because we are here to help everyone be successful with the information blocking requirements. So, thank you, again, for the opportunity to just give you a short update from ONC. And let me turn it over to Aaron and Denise for the rest of the meeting.

Remarks, Review of Agenda and Approval of May 13, 2021 Meeting Minutes (00:08:18)

Aaron Miri
Thank you, Micky, very much. And welcome, everybody, to the June HITAC. That is some super exciting information that Micky just told us. I'm excited to hear more about TEFCA and really appreciative to the ONC team upfront for the phenomenal FAQ's. Thank you, Steve, for making it an easy cut and paste for folks searching the FAQ's. I'm sure there will be more FAQ's coming out but I want to echo that. And so, thank you to all of the HITAC members also for your help and your questions and as we work through things moving this forward. So, before we get into today's agenda, I did have a quick announcement upfront. Our Annual Report Workgroup has kicked off. You'll hear more about it later today from Carolyn and I. But upfront, I wanted to solicit the HITAC and say if you're interested in serving on the report workgroup, we have had some members transition off at the beginning of the year. So, since we just kicked off a new session, we'd love to entertain any applications for that.

Remember, the Annual Report Workgroup must be made up of HITAC members and then, try to get representative of a good swath of the various constituencies represented on that. So, if you are interested, please shoot me a note or shoot Carolyn a note or Mike and we're happy to look at that. And see what we can do. So, with that, let me transition over to Denise.

Denise Webb
Well, good morning, everyone. And Micky, thank you for all of those updates. Those were important to hear, especially the status on information blocking and certification and the questions you're getting. And I, too,

am glad that we're going to get some more FAQ's out there. I know my colleagues will really appreciate that. So, we have a great meeting planned here. We are going to get to hear about all of the work that three of our task forces have been doing. And we've all been quite busy as well as our additional volunteers outside of the committee. And we really appreciate that. And so, today, we are going to hear from the USCDI task force. And Steven and Leslie are going to be presenting recommendations on the expansion process. So, we will be taking a vote on that today. And we are sprinkling more breaks throughout the morning and afternoon today to make it a little easier on everybody to step away from their desk. After we take a break, we're going to hear from the interoperability standards priorities task force.

And they also have recommendations for us to consider and vote on. So, Arien and David will be presenting on those recommendations. Then, another break. And Steve Posnack is going to talk to us about the health interoperability outcomes 2030 that we heard about in our previous meetings. And I know many of us contributed our thoughts to that but we're looking for more from the rest of the committee that didn't get the opportunity to provide any input to Steve. Then, we're going to have another break and then, we will have our last task force report from Carolyn and Janet on the public health data systems task force. No vote there. So, three task force presentations today and two votes. And then, we'll conclude with public comment. And that's what our day looks like today. So, let's buckle up and get ready to go. And I'm going to have Aaron call for an approval of the minutes.

Aaron Miri
Yeah. So, let's do it. Let's have a call for approval of the minutes from the last meeting. Do I have a motion?

Unknown
So moved.

Unknown
Second.

Aaron Miri
All right. All those in favor say aye.

Group
Aye.

Aaron Miri
All those opposed say nay. All right. Then, we are approved. Those minutes are approved. So, with that, Denise, I believe we are ready to transition to the USCDI task force with Steven and Leslie.

Denise Webb
Indeed we are. Let's take it away.

Aaron Miri
Steven, you may be muted, my friend.

United States Core Data for Interoperability (USCDI) Task Force Recommendations on Expansion Process – HITAC Vote (00:12:40)

Steven Lane

Not anymore. Thank you.

Leslie Kelly Hall

Good morning.

Steven Lane

Yes, thank you all for the opportunity to come back before you today to make another presentation regarding the second phase of the work of the USCDI 2021 task force. We are happy to go ahead and bring you another tranche of recommendations. Let's go onto the next slide. We're going to, again, review just who is involved in this work, what have been the charges for our task force, provide some background, including a brief discussion of the recommendations we made to you a couple of months ago and then, we'll go through the Phase 2 recommendations, go through a bit about how we're going to be approaching Phase 3 between now and September and then, look for a vote on the recommendations. Those recommendations have been distributed to everyone. I hope people have had a chance to look at them. And, of course, many of you have been involved in their generation. So, going onto the next slide, we had, again, a quite diverse group of folks representing both HITAC members and other subject matter experts that have been working on this with us together with nearly weekly meetings ever since the task force kicked off.

On to the next slide, you can see the charges for our task force. You will recall that back in April, we presented the work of our Task 1, including really looking at the draft USCDI Version 2 that had been published by the ONC and making recommendations about that. This second group of recommendations we're bringing to you a bit early. And the reason is because we really wanted to have a chance to inform the published guidelines that are going to be coming out along with Version 2 of USCDI when it is published at the end of next month. And then, we will be back again in September with the final recommendations, which have to do with the future versions of USCDI. So, this group is really about the ONDEC Submission System, the evaluation and prioritization processes and criteria that are used to look at newly submitted data classes and data elements. On the next slide, Slide 5, which should look familiar to most of you, it describes the annual cycle of USCDI advancement that we are in the process of exercising right now.

You'll recall that the first version of USCDI was published after extensive input from HITAC and a couple of rounds of the dedicated task force that was led by Christina Caraballo and Terry O'Malley. And now, we are in the first annual cycle of review, which started with an open call for submissions then, public comment as we were all involved in from HITAC as well. Now, ONC has been reviewing all of that and preparing the final version of USCDI for publication. And then, the cycle will start all over again. So, on the next slide is, again, the draft USCDI Version 2 that was presented to you on which our task force made some comments. And I'm going to let Leslie go from the next slide here, Slide 7, to just review to remind you what our first set of comments were and then, to start us in on the new recommendations.

Leslie Kelly Hall

Good morning, everyone. And I apologize for not having video. I'm hoping you can hear me okay. I had technical challenges this morning. If you go to the next slide please, just a high level review of the

recommendations that you heard at our last session that we wanted to add selected data classes and elements to include social determinants of health, sexual orientation, and gender identity, care team members, encounter information. We also asked to clarify definitions in scope of some data elements to include assessment and plan of treatment, diagnostic imaging, and diagnostic studies, to remove laboratory pathology and diagnostic imaging narrative data elements, and to help coordinate with HL7 to update implementation guides. That's a very high level and I encourage any of you to look at further details. Next slide please. So, our first set of recommendations surround the ONDEC submission process. And go to the next slide please.

I'm chuckling a little to myself because we came up with a wonderful way to describe the ONDEC process. And that is if you USCDI is a process with which we incubate and we, eventually, launch or create new data elements that ONDEC process is the nest where everything is gathered and really the beginning. So, understanding the ONDEC process as being very important, this group spent a lot of time reviewing the process and coming up with some recommendations. The ONDEC process includes some wonderful submission form prep sheets. And it's inviting and encouraging to people who are very familiar with the process. We had a lot of discussion about how to make sure that we were inviting all stakeholders and making sure that it was understandable and concrete. So, we were building off the good work that's already been done. Next slide please. So, you can see that the forms themselves are very clear but we wanted to make sure that we had very specific recommendations on each areas of the ONDEC process.

You'll see that in this particular data element class, it asks if there are similar or related data elements in USCDI. And there is a great opportunity to say unknown. So, just being able to identify what is known or unknown to the person submitting is a very important concept that you'll see throughout the recommendations. Next slide please. So, one concept that we are encouraging, and this is, actually, a concept that's been implemented throughout government, is the use of plain language. And plain language is think of it as kitchen table discussions. It's a way to make sure that the language is inviting and understood by all. It's quite well known and quite well used in government. Our next recommendation in the next slide includes being able to add the unknown field, as I mentioned. Specifically, has the data element been electronically exchanged with external organizations or individuals, including patients? That's very much often not known to all of the stakeholders who would be answering this. So, we wanted to make sure that it is consistent throughout to add this field.

Next slide please. Our Recommendation 3 is to provide options for submitters to request assistance via chat, email, or an interview with the ONC for the completion of a submission. This was really important to the group as we felt that with our latest challenges with COVID, our stakeholders expanded dramatically in health information technology. And having people invited to participate in the USCDI process and to submit something in the nest the first time might not be well understood. So, having options to get help increases that accessibility for all. Next slide please. We also felt that developing a primer or additions to the ONC HIT playbook to encourage and support engagement of the USCDI process by stakeholders that do not traditionally participate, for instance, patients and their care partners. Those of you who are not familiar with the HIT playbook, it's excellent. It provides a lot of good resources. And we felt this would be a complementary addition. Next slide please.

We also wanted to consider removing registration requirements. Today, the registration requirements carry through all the way to the standards advisory process and that it can be intimidating. So, we'd like the ONC

to consider removing those registration requirements continuing to keep identification requirements for questions like email and name but not to require much more in depth registration requirements. Next slide please. We also wanted to make sure that we're promoting diverse public engagement through this process. So, in making it familiar to each of us, sharing the social media @ buttons on the main page and data class or data elements, a comment button so that we can add our own previous submissions, so we can begin to see what critical mass supports a particular data element or recommendation or invite additional use cases. And by the addition of a like and dislike button, user registration would be required to post these but it would offer people to say plus one to a particular concept or idea. Next slide please.

We also felt that it would be important for a stakeholder to identify that particular group that they self-identify with. Are they a patient, a care partner, a patient advocate, to submit for a demographic section? This would help us to see perhaps who is participating but also, in future iterations, what groups might leave a process sooner. And that would suggest that we might need to insert more help in the future. Next slide please. We also felt it important to offer educational material such as a glossary of terms, which can be quite intimidating to understand all of our wonderful acronyms. This is an opportunity, again, to invite, to increase accessibility to all of those who participate. Next slide please. We also want the submitter to more easily see if the same or similar items have already been submitted. Again, this gives us opportunity to build critical mass of support but also to make sure that we're not creating duplicates but complementary use cases. This could be accomplished via all submissions at level view or improve search function, including smart, auto filled data element names. Next slide please.

We want to allow for the submission of user stories in lieu of strict use cases. This way, for instance, a patient representative or advocate or others can describe the benefit of a proposed data class or element, the harms related to the lack of interoperability of the suggested data class or element, and also the benefits. This is really important because we can lose narrative and we can use the rationale behind a particular use case by being very strict. And it's sort of a see the forest through the trees option that we need to make sure that we give the ability to tell stories and narrative. Next slide please. We'd also like to explicitly state there is a challenge section in the ONDEC process. And it's very important to know the challenges but it does not relate to a submitted data class element for prioritization mostly just for information and understanding. And that concludes our recommendations for the ONDEC submission process. Steven, did we want to take questions on each section or to continue?

<u>Steven Lane</u>
I think we do have time to take questions at the section level. And I think it's going to make sense. If I can just offer a little bit of overview here, I really want to, again, point out that we intentionally constructed our task force with a broad representation, including patient representatives, patient advocates who really took the opportunity to contribute. And I think especially in this first set of recommendations about the submission process, we really made some good suggestions to build on the work of earlier task forces, which was also designed to create an inclusive and inviting process. But I think now that we've seen it in action, there were some opportunities to make that a little bit more so, to leverage new technologies, familiar social media tools, etc. So, I think that's where a lot of this came from. A number of the things that we recommended were really based on deep dive discussions with the ONC team that developed the ONDEC system helping to understand their intentions and looking for opportunities to make it just a little bit better.

So, we're very interested in any comments from task force members about these recommendations.

Denise Webb
Steven, Clem has his hand up.

Clem McDonald
I just wanted to clarify the very initial statement you made, Denise, which was true that we've taken out radiology and the pathology classes. I think people may not appreciate that we didn't take out the content for radiology and pathology, just the extra classes of pure narrative were redundant and confusing. I thought maybe Steven could –
[Crosstalk]

Leslie Kelly Hall
Thanks for that clarification, Clem.

Clem McDonald
We have enough content in the standard, which is a new thing and a very good thing. They are in the content.

Denise Webb
Thanks, Clem.

Steven Lane
Any other hands up, Denise?

Denise Webb?
Oh, yes. Andy just put his hand up. Andy, you're on.

Andy Truscott
I was thinking about what to say and then, I put my hand up. Just a quick question. As we're going through this and I really do hope and encourage the HITAC members to vote and say yes, we should be carrying on with this work. I think this is very, very important work and it's the bastion of the next five to ten years of health IT in this country. I would like us to also consider looking further into how we can support context passing as part of the plethora of work we're working on right now. And that's been attempted in the past. And I think we have an opportunity now to, actually, think about that further. Steve, I'd be kind of interested on your views.

Steven Lane
No. I think that's great, Andy. And I think the key is that we will soon be embarking on the work of our Phase 3, which is really making recommendations about what should be included in Version 3 and that will be coming after this.

Andy Truscott
Thanks. And just so the minutes reflect my accent correctly, it's context passing, not context parsing.

Steven Lane

Actually, thank you for that, Andy. I wrote it down wrong.

Leslie Kelly Hall
I thought it was parsing.

Andy Truscott
You have to pass it to then, parse it later.

Steven Lane
All right. Let's go on.

Denise Webb
Andy, **[inaudible] [00:29:23]**. So, I put passing in my notes. Okay. Any other questions or comments from the committee? Okay, good. You're good to go.

Steven Lane
Thanks. Let's go ahead to our Task 2B. And in this case, we were asked to look, specifically, at the evaluation criteria and process that we're used to assign levels to submitted data classes and elements. And we breezed over it a little bit at the beginning but I'll just remind you that in the ONDEC process, items are submitted. There is that lengthy questionnaire in the ONDEC that is used to collect the specific information about each submission. And then, there are a set of criteria that are used to assign it to a level based on its degree of maturity. And we'll be talking a lot about how we think about that maturity. But these recommendations have to do with the process of evaluating items and determining whether they should be put at the comment level, Level 1, or Level 2. And to remind you, Level 2 are those most mature items that are potential and selectable for the next version or a future version of USCDI. Whereas those items that are put at the comment level or Level 1 are really still in the next, as Leslie described it, still in need of care, feeding, engagement with the community, Connectathon, advancement of standards, etc.

So, this process of leveling is really important because it determines which of the many submitted items are really available for prioritization and advancement. So, let's go on and we'll go through the recommendations one by one. This is a reminder of the existing criteria that were published by ONC, shared with HITAC, and were used for leveling in the last cycle. And I'm not going to read through this line by line. But you can see that the criteria, specifically, relates to the maturity of standards, the use across the community of those standards, how much the data is, actually, being exchanged, and what proportion of stakeholders are impacted. And I'll call your attention to this lower right hand corner where the criteria in the first round said that being in Level 2 would be data, class, or element needed to pertain the majority of the patients, providers, or events requiring its use. And our task force, as we looked at this, found this to be ambiguous.

Does that mean that it pertains to the majority of patients, providers, or events that occur across the healthcare landscape? Or does it mean that even in a rare type of an event or something that affects a smaller number of patients or providers, if that data is required the majority of the times that its use is required then, that qualifies. So, this really led to an entire discussion of minority use cases. And I think you'll see this coming up in our recommendations in a moment. But the key here is that the ONC has initially identified and defined criteria that really focus the USCDI on use cases that pertain to the majority of

patients, provider, and events. And I think given the makeup of our group and the discussions we've had, we really thought it was important to find ways to support minority use cases that could be very important to a smaller group of patients or providers. So, you'll see a number of recommendations about this. So, on the next slide, we'll go into how we approached this.

So, the next recommendation was that the ONC should indeed support minority use cases and that we shouldn't limit USCDI only to those situations that affect the majority of patients, etc. But the first thing we should do when considering minority use case is look to see where they can fit into existing, compatible, mature data elements and classes. So, for example, transplant is not a majority use case. Most of us don't have to have a transplant. But when we do, it's incredibly important that certain data be available. And there is certain data that is generated by the transplant process. But some of these, for example, are specific report types that, understandably, were not included, not called out in the list of note types that were included in USCDI Version 1 but could, potentially, fit into the existing note types that we have. So, this was, again, looking for an example of how we can support minority use cases by leveraging the majority work that we've done or the work that we've done for the benefit of the majority by simply providing guidance to say where does it fit into the process. Next slide.

We went on to talk about how to look at the leveling of items and looking at the impact of the use case that's being considered and suggested that when determining the level for an item that the ONC should consider the impact on care and other national priority use cases. And we should not limit our focus to those that apply to the majority of patients, providers, or situations. But the point being that data elements of particularly high impact that pertain to a narrower stakeholder group should be available to be advanced based on that high level of impact. And we'll talk later about national priority use cases. But there really is a desire on the part of the task force for providing flexibility to ONC so that, for example, when a pandemic occurs or issues related to equity are identified as a high priority that those priorities can be taken into account as leveling and advancement decisions are made. When I talk about advancement, I mean moving from one level to the next, which, again, is something that ONC does based on the data available. Next slide.

Now, we're going to talk about the idea of periodic review. I did mention that ONC has this annual cycle of submission so the new data elements can be considered. And while it's not been explicitly stated, ONC has made clear that part of that annual cycle is also to re-look at items that were previously received and assigned a level to make sure that that level was accurate. Once an annual ONDEC and leveling has been published, there really have not been many situations where an item was moved between one level and another based on feedback. But there is complex and rich behind the scenes process that ONC is carrying out to speak with stakeholder, with submitters to collect additional data to make sure that the level is accurate. But, of course, more data will come in over the course of the year. So, this recommendation is to support the idea of periodic review that all items that have been submitted to ONDEC should be reviewed regularly.

And our task force felt that semi-annual would be ideal if, in fact, we have resources available to do that, to validate the current level and priority based on the latest information that's out in the ecosystem about the maturity, the need for the data, any comments that have come in through the public comment process, as well as the current leveling criteria because, as we've said, we're recommending that the leveling criteria would change year to year based on the input of the HITAC. And those new criteria should be used to re-

evaluate the level, again, going from, ideally, an annual process of review to a semi-annual. Next slide. More about this. We felt that the periodic review should identify opportunities for advancement between levels. So, something might be published as a Level 1 and then, based on feedback or other work that goes on in the community, be advanced to Level 2, even in a mid-year process so that it might then, move more quickly into the next draft of USCDI.

We also felt that the results of these reviews should be made public. They should be documented and posted on the website. So, when you go to the USCDI website and you drill down and you look at an individual data class or element, you can't really see exactly why it was put at the level that it was. Some people say why is that at the comment level. I thought that that was more mature. And ONC has a reason. It just wasn't published. So, I think the idea is that the date of the review and the results of the review should be published and made public so people can see that. And I think that would also help to focus their commentary as it comes in. We're also going to talk about this notion of high priority data classes and elements and the desirability of ONC identifying because there are so many data classes and elements that are being submitted, that are being leveled to identify those that there really is a sense that this is important either because of its impact or because of its impact on a number of folks or the impact that it has on care that is received.

But identifying these high priority data classes and elements in every level to provide guidance to industry about the need for development of that data class. Again, this is that notion of nurturing things in the nest so that they can continue to evolve and, eventually, take flight. And then, there was a recommendation that ONC would continue to use the USCDI task force as a sounding board for questions or items that don't fall neatly into a particular category. I think the ONC has really done a wonderful job applying their criteria. But a lot of that is a bit of a black box. And we have a task force. We have HITAC that can provide subject matter expertise and a broader perspective than what might simply come from the submitters or ONC's knowledge of what's going on at HL7. So, really encouraging ONC to leverage the task force in that way in the future. Next slide. Our next recommendation has to do with creating a dashboard view of the USCDI so that folks can go in and easily see how many submissions are in each level, when they were last reviewed, the details of that review, as I mentioned, identifying those prioritized items within each level.

And then, also trying to look at the number of submissions by stakeholder categories. Which ones have been submitted by public health, by providers, by patients and their advocates, etc.? Next slide. For submissions, we felt that it was important to include the level assigned for each individual criterion. As we've showed you, there is a table and there are multiple criteria. And we thought it was important for the public and submitters to know why, at that granular level, the item was leveled as it had been as well as for the submission overall. And right now, we look at prioritization only as it applies to items in Level 2. But the idea of identifying priority items in lower levels, again, so that the industry can continue to support those. And we felt that this granular transparency would really help submitters and commenters, as I said earlier, to provide more specific feedback to the ONC. Next slide. All right. So, that was our Task 2B, all about the leveling process.

So, I think we can pause again and see if anybody has any questions or comments about those.

Denise Webb
No. We have no hands up presently. Is there anyone on the phone that's not able to put up their hand?

Steven Lane

All right. That's great.

Denise Webb

Well, beautiful job, Steven. They're all good with what you had to say.

Steven Lane

Well, we will carry on. So, Task 2C that was assigned to our task force, after the leveling is done, there has been this prioritization process, which, as I said, historically, has really just been used within Level 2. That is to say of all of those items that were felt to be of sufficient maturity, which of those should be prioritized for advancement into the next version of USCDI. And here, again, as I mentioned earlier, we really felt that prioritization was important at every stage along the way. If we continue with this nest metaphor, the idea of which of the items really need particular care and feeding and identifying those items when they're less mature so that they can advance more quickly, we felt, was worthwhile. So, you'll see that throughout the prioritization recommendations. Let's go to the next slide. So, here we felt that these were the initial prioritization criteria that ONC used to prioritize within Level 2 when it developed the draft Version 2. So, again, in order to be considered for draft Version 2, something had to be in Level 2, obviously.

It had to address a significant gap in what was included in USCDI Version 1. It was meant to be supported by existing ONC certification. And when these were published, by the way, these criteria, it was not made clear whether you needed to **[inaudible] [00:44:40]** all of them or some of them or whether there was a ranking between them. They were just published. These were the criteria that were being used. What is felt that for advancement to USCDI, an item need to require only modest technical standing as well as modest aggregate lift for vendor development and implementation keeping in mind that until a draft was developed in the context of the pandemic that it was really a concerted effort made not to ask too much of industry when we were busy dealing with this major other challenge. So, these were the criteria that we were asked to comment on. Next slide. So, our first recommendation was really to try to define two different categories that would be assessed as individual dimensions. One being the technical maturity, the degree of exchange within the industry and the other being more the priority.

How important is an item? And, of course, this whole process is about defining the priority but we really wanted to make an effort to separate that out and do that independently. And we felt that, particularly, at this time for this next cycle that the priorities should include addressing health and healthcare inequities and disparities. We should be looking at responding to the needs of underserved stakeholders. And those might be those underserved by the healthcare system or those that are what we refer to as data underserved. Those who really are hungry for data in order to accomplish their goals. And then, of course, in the context of the pandemic, looking at items that address public health as well as other priority use cases identified by ONC. So, the idea here is that in any given annual cycle and perhaps across multiple annual cycles, there are specific priorities. Not to pick winners per se but really to say that there are things that are particularly important to the industry.

So, while we all hope to see USCDI advance at pace year over year closing the gap towards all electronic health information that in any given annual cycle, there are going to be specific priorities. Clearly, these are consistent with priorities that have been identified by the administration. And we really felt that these should

be called out as prioritization items in the next cycle of USCDI. So, again, the goal here is to kind of look at technical maturity in one light and then, look at the prioritization process in another. And as I said earlier, the priority items could be identified at any level, not just at Level 2. Next slide. All right. We recommended that items within each level that are identified as high priority but that have insufficient technical maturity for advancement to the next level should be clearly identified. This is a little repetitive. I've said this in my commentary. But, again, the idea of identifying these priority items in every level so that the standards community, the implementation community, and other stakeholders can really see that these are important and can focus their work on them. Next slide.

We do feel that advancement to a final published version of USCDI should continue to require a minimum degree of technical maturity and readiness. And in particular, we had a lot of input from developers. And I think we agree that published implementation guides are really important if items are going to be able to support scalable national deployment. That there are some items in USCDI, some that were inherited from the common clinical data set that really don't have clear technical specifications, don't have clear implementation guides. There were items that were included in draft USCDI Version 2 where the implementation guides were well along the way but were not fully published. And you'll recall from our Task 1 recommendations that we said this should be included if the final implementation guide is published and we had meetings with HL7 to discuss how that could be accomplished in short order. But we really did feel that having those guides in place was important for inclusion in a final version of USCDI.

And this was not stated as a criterion by ONC but we felt that it was worth calling out. And this was phrased, specifically, as a should, not as shall because there are clearly going to be situations where this won't be possible. Next slide. We felt that it was important to indicate which Level 2 classes and elements are of high priority but of insufficient maturity to be included. And, again, simply to signal to the industry, to HL7 in particular and others to push these forward. And I'll admit that this one is a little redundant. You've heard this before but in slightly different words and we're really trying to drive home the importance here. Next slide. Now, the key here is that there are these items and they were, actually, included in the draft Version 2 that didn't quite have full maturity for advancement. They didn't have that finalization of the implementation guide.

And we felt that, in addition to identifying these and assuring that they got the focus that they deserve from the industry that sometimes, it was appropriate as ONC did this time around to include those in a draft published USCDI because there isn't a timeframe between the publication of a draft and the publication of a final version during which work can be done. Implementation guides can be finalized. Connectathons can be held, etc. So, we felt that that was appropriate and can be encouraged in the future, this idea of having almost ready items put into the draft. But, again, they really do need to be ready if they are going to be advanced all the way to a final published version. But it was really felt that this would be done only if we feel that the necessary maturity level is imminent and something that would be published in draft would move forward to the final version only if certain milestones are achieved during the time that it's in draft. Next slide.

Our Recommendation 21 was just to look for clarification. The applicability of USCDI extends well beyond ONC certification and other federal programs. And inclusion in USCDI does not depend upon it being required by certification. ONC did say to us that they saw that criterion as an or, not as an absolutely requirement but we felt that that needed to be clarified. Clearly, there is a close relationship between USCDI,

published versions, the SVAP process, and subsequent requirement for certification. But we had a lot of discussion within our task force about certification and the fact that there may be items that should advance to USCDI but may not be necessary for certification. Similarly, the whole certification paradigm to date has really focused on certifying EHR's that can be used across a broad range of uses but mostly in the ambulatory and inpatient medical care space. But other types of EHR's have been left outside of certification like long term care, etc. And the thought was that USCDI really needs to serve multiple stakeholder groups beyond those that are covered by the current ONC certification or CMS or other programs. Next slide.

We felt that it was important to continue to identify and prioritize for inclusion data elements that are routinely captured or automatically generated within health IT systems. And a tip of a hat here to Clem McDonald, one of our HITAC members who continually focuses on looking for value, looking for things that are easy to exchange, identifying those as part of USCDI really so as to support the growth of USCDI over time. The other point that Clem continues to make and I'll just reiterate it here is the importance of looking at provider burden and trying not to add a lot of elements that create more work for people to collect them and really looking for these opportunities to leverage data that's generated automatically. And I think this is our last recommendation. Go one more slide forward. Yes, indeed that is. So, that was the Task 2 speed looking at the prioritization of elements, again, extending that prioritization beyond Level 2 to also identify items at the lower levels and trying to clarify really what is going to be required for advancement into a final published version.

We're happy to entertain questions on those.

Aaron Miri
I don't see any hands raised.

Steven Lane
I do see in the public chat that Dr. Karras asked the question about how will public health submissions be identified. Here, again, you'll recall we had a recommendation to identify the stakeholder group or groups that are being represented when a submission is being made. And clearly, public health would be one of those whether it was local, state, or CDC, or other groups that re involved there. Any other questions?

Aaron Miri
Anybody on the phone that can't raise their hand?

Denise Webb
It looks like we don't have any other hands up. So, Steven, if you and Leslie are ready for us to conduct a vote –

Steven Lane
Yeah. I think we are ready. I really want to, again, thank the task force. People really dug deep. In some sense, these recommendations could be seen as not making dramatic changes in the process. But I really do think that they highlight some very specific items, make specific suggestions to ONC for development of the ONDEC, for how submissions are looked at and leveled and prioritized and really taken as a whole to provide iterative improvement in a process that has really worked quite well so far to date. And, again, our goal in bringing these to you now rather than waiting until September was really to have the opportunity

to inform the final leveling and prioritization schema that the ONC is going to publish along with the USCDI Version 2 that will inform the Version 3 submission and evaluation cycle.

Denise Webb

Well, thank you, Steven and Leslie, for presenting our task force's recommendations. And if there are no other comments or questions, let's go ahead and proceed with a vote. Do I have a motion to approve the USCDI recommendations for Task 2A through 2C to the commission of the national coordinator, Dr. Tripathi?

Arien Malec

So moved.

Andy Truscott

Second.

Denise Webb

And who made the motion?

Arien Malec

That was Arien.

Denise Webb

Oh, Arien, thank you. And is there a second?

Andy Truscott

And I'll second.

Denise Webb

And that sounded like Andy for the second. All right. All of those in favor say aye.

Group

Aye.

Denise Webb

Anybody who opposes say no. Any abstentions? Well, it looks like the recommendations are approved to go forward to Dr. Tripathi.

Steven Lane

That's wonderful. Thank you so much. So, we do want to now talk a little bit more about our plans for Task 3 for the task force. We have another few months to complete our Task 3. And that is to really focus on recommendations around the Version 3 prioritization, etc. So, on the next slide, we'll let Leslie sort of talk you through how we're going to be approaching this. And we're really interested in getting the committee's input on these items, these ideas, as well as others that you may have for our Task 3 work

Leslie Kelly Hall

Thanks, Steven. And thank you all for your support and vote. This group has spent a lot of time and done a lot of work and thank you for all of your tremendous leadership, Steven, and teaching me along the way. I really appreciate it. We are looking now with the Version 3 submission cycle more at the big picture asking for a lot of input and education to make sure as we make our recommendations, we're considering things that will promote development work, things that will signal the industry, things that we can understand at a broader level that would impact how we would make very specific recommendations. We find that there are prioritization needs to consider the extent of the applicability, the presence of clearly defined use cases and work flows, and clear value propositions of the data class element. And we know that to do these things, we need to understand more deeply trends and recommendations that will impact our work, specifically, SDOH and the ISP TF recommendations.

How will that impact the equity inclusion trends that are being asked for each of us to respond responsibility to? And then, public health issues in our task force recommendations. So, we're asking for input and inviting participants and subject matter experts to give us additional information. It's really important to note our task force discussions have really embraced many of these areas of study. In addition, we've also talked about the need for understanding and cross pollination of work that's going on. Basically, the spirit of the Office of the National Coordinator is to coordinate and understand. So, as we see new recommendations and policy that might impact data needs in the future, we want to make sure we fully understand them. And so, we're going to be taking some time to learn a good deal and to hear from subject matter experts so that we, in fact, are helping to inform the industry about how one area relates to another. I think the deep dive we did in the ONDEC process and the prioritization process, we really aligned the cadence of inclusion into USCDI.

How does something begin in the nest and end up taking flight? We want to make sure that we are informed in each of these areas and more so that we can encourage this kind of development adhering to the cadence recommendations, as well as the recommendations with regard to priority and maturity. So, that's my high level view. Steven, did you have anything to add?

Steven Lane
Yes. I'll just say these four items at the bottom are areas that we're planning to dedicate entire meetings to. We're going to be starting next week by having Arien and David McCallie come and talk about items that have been identified by the ISP task force because there were a number of points that they made in their last presentation to HITAC where they touched on what needed to be in USCDI and, of course, the work of ISP in identifying standards that are evolving and maturing that will clearly impact those items that are going to be ready to advance along the ONDEC process towards USCDI. We're also planning to have a dedicated meeting focused on public health data, specifically, where there are data classes and elements that serve public health use cases that should be prioritized for advancement in USCDI. And here, we're looking at bringing Carolyn and Janet along to assure that there is alignment with the work of the public health data systems task force so that anything that's coming out of that work that should impact USCDI is identified.

We're also going to be inviting the team from CDC that did a lot of work last year identifying items for inclusion. So, I think Adi is going to be joining us along with **[inaudible] [01:03:34]** Garrett whom we've heard from here at HITAC to talk about the identified priorities from the public health community and then, also we're going to be inviting Steve Eichner from the public health interoperability workgroup. And Dr. Karas, if you want to join us as a member of the public for that meeting that would be wonderful. And then,

we're also very interested in looking at items related to equity and inclusion. Of course, there was an executive order to all of the departments. So, the folks within HHS have done a lot of work digging into this and how they can change their processes. But the natural question arises of are there data needs related to equity and inclusion that we should be considering for advancement to USCDI. And, of course, social determinants of health and the fine work of the Gravity Project, the HL7 accelerator that is going forward.

And we've determined that our meeting with Gravity and others to discuss social determinants is going to wait until after the publication of USCDI Version 2 so that we can be informed by that work and use that as a platform to discuss how Version 3 should be structured. So, this is where we started. We're really interested in the HITAC's input on this approach and any other areas besides context passing that people feel that we need to assure that we consider.

Aaron Miri
I really appreciate your comments on health equity and classes related to that. So, I think they're excellent points.

Denise Webb
I'm not seeing any hands up yet.

Aaron Miri
Okay.

Denise Webb
That must mean everybody is happy with our approach, Steven.

Steven Lane
All right. We try to be thoughtful before we bring things to you. So, we're glad that we've brought it through adequately. And, again, I really want to thank all of the HITAC members who have been serving on the task force as well as other subject matter experts and members of the public that come and listen and sometimes provide comments in the chat. It's been a really collaborative process. And I'm very happy for its advancement and looking forward to this next round and bringing another set of recommendations to the HITAC in September. So, these are the only meetings that we've, actually, got calendared. We're working on a July meeting with Gravity and some others. But we're going to relax a little bit from our furious weekly meeting cycle as we go into the summer and we tackle Phase 3.

Leslie Kelly Hall
I'd also like to acknowledge Al's great support and work and Mike and the rest of the ONC team. We challenged them in all hours of the day and night with asking for help and direction and they're always very, very helpful. So, thank you so much.

Aaron Miri
Wonderful. And Steven and Leslie, good job.

Denise Webb

I want to echo my thanks as well. I have to say that we had some very, very rich discussions. And I learned a lot. I did a lot of listening. The work was just really robust and excellent. So, we are on to Phase 3.

Aaron Miri

On to Phase 3. All right. So, with that, Denise, if you're in agreement, I think we can go to break with a return at 10:50 a.m. So, a 10 minute break. So, at 10:50 a.m., we will return to give you a chance to get some water and stretch your legs.

Clem McDonald

This is Clem. Could I just compliment the chairs of the USCDI committee? They really managed it marvelously and worked really hard and need a big round of applause.

Aaron Miri

I totally agree.

Denise Webb

Yes, kudos.

Aaron Miri

Rock star stuff. All right. At 10:50, we'll see you.

Operator

All lines are now bridged.

Michael Berry

Thank you very much and welcome back, everybody, from our short break. And we are going to resume with our agenda. And I will turn it over to Aaron and Denise.

Aaron Miri

All right. Welcome back. Can everyone hear me?

Michael Berry

Yes.

Aaron Miri

Perfect, fantastic. I had a little bit of phone problems here. So, welcome back to the break. Hopefully, everybody got some water and stretched your legs. And so, now we are, actually, going to transition over to our next task force led by Arien Malec and David McCallie for interoperability standards and priorities. And at the end of this one, we will be going for another vote. So, I look forward to it. Arien and David, all yours. You may be on mute.

Interoperability Standards Priorities (ISP) Task Force Recommendations – HITAC Vote (01:21:18)

Arien Malec

Thank you. So, we're just pleased to give you this beautiful view of my studio here and its lovely background. I don't have the books arranged in color order and I apologize. So, we're going to go through the ISP task force recommendations, me and my esteemed co-chair, David McCallie, whom we pulled out of retirement to serve on this task force. So, we have some pretty exciting recommendations for you. I'm going to do the play by play. David is going to interrupt and correct me for all of the things that I get wrong and provide some additional color for the recommendations. So, if we can go on to the next slide. We're going to cover the charges, membership, background and then, really get into the recommendations. And we also have some special material for future considerations for a future ISP task force. Can we go onto the next slide? These were our charges. So, this process is called for in the 21st Century Cures Act as part of the required recommendations for ONC and for the advisory committee.

The way that we've manifested the standards priority requirements is to call for new items to be added into the ISA. So, think about this as if we just heard from the master of presentation on USCDI by Steven Lane and Leslie Kelly Hall. Those are the data classes that we do interoperability around and the ISP is about the standards that we use for content, terminology, and transport. Next slide. This was our task force, a mix of members of the advisory committee and community members who were actively engaged and provided us a substantial amount of support for the work that we did. Next slide. We went through, initially, a process to prioritize the work of the task force. We came in with a set of work that the first incarnation of the ISP task force had worked on. But in the intervening time between ISP Task Force 1 and ISP Task Force 2, we had a number of events across the country. And so, we went through a reprioritization process based on learnings from COVID and from the experience that we've all gone through.

We prioritized a set of activities, including health equity, EHR data use for learning health systems, and burden reduction and clinical administrative data and standards of harmonization. As one would expect, we had a set of recommendations relative to public health. Most of those we passed on to the public health data systems group that's now actively engaged in thinking about standards prioritization relative to public health. So, that was the right group to take on those activities. We also heard testimony on and provided recommendations for the public health situation we were in. David, is there anything else you wanted to talk about in terms of the prioritization process that we used?

David McCallie
No. I think you covered it. I will mention that we had numerous expert groups come and talk to us based on what came out of our prioritization method and that's what led to the specific recommendations that you're going to see.

Arien Malec
Fantastic. Let's go on to the next slide. So, we have, in the recommendations transmittal, a set of both high level recommendations and very detailed recommendations. We're going to honor the advisory committee by going through all of the detailed recommendations, all of the nuts and bolts. But if you just want a high level pass, I'd encourage you to read the executive summary that covers the process that we used, the priorities that we ended on, and the high level recommendations. Let's get into the detailed recommendations. And by the way, we are teeing this up for a vote by the HITAC. So, this Power Point is a representation of the recommendations that are in the transmittal but the transmittal is the dispositive document that we're going to do a vote on at the end of this discussion for consideration to pass on to the national coordinator. So, let me just back up. We took the three plus one priority areas that we contemplated

and heard testimony on and we pulled out a set of foundational recommendations and then, detailed recommendations.

So, you're going to see a set of foundational recommendations on foundational standards, data modeling, and vocabulary and then, a set of detailed recommendations relative to health equity, learning health system, and pragmatic clinical trials and burden reduction as well with situational awareness. So, just to orient you in space, this front matter that we're talking about, the foundational items that we believe are generically applicable across a broad range of use cases. So, in particular, we saw the following four FHIR standards coming up over and over again across multiple cases. So, for example, FHIR standards to address workflow hooks that include FHIR CDS Hooks and FHIR subscription. So, CDS Hooks is used in the EPA work that's been prioritized through HL7. It's applicable for any form of efficient support or guided workflow that is triggered off a set of conditions. It's the foundational standard for electronic case reporting now. You see our now standards.

It's a broadly applicable workflow hook that triggers additional information that may need to be captured into EHR. And it's configurable. We've got recommendations in the actual transmittal that note that all of these standards really should be under the control of physicians. We don't want to just trigger arbitrary workflows in the EHR. FHIR subscription is a companion workflow trigger that can trigger a broader range or a different range of workflows. And, again, this enables a set of trigger based workflows to be included into the EHR to collect additional information. Some of that information can be collected via FHIR questionnaire. This is used in the Gravity standards for collection of social determinants of health. But it's also applicable to pragmatic clinical trials, workflows, and any other workflow, for example, **[inaudible] [01:29:22]** entry in a public health context. We need to collect additional information that's not in the core EHR.

And then, last but not least, we've got FHIR consent that's associated with a broad range of additional authorizations, consents, and directives. And, again, this comes up in the social determinants of health space but clearly has applicability to cases associated with information exchange, cases associated with pragmatic clinical trials, and potentially cases associated with public health and data sharing. We note that these standards are at a broad range of maturity with CDS Hooks with some triggers being at the highest range of maturity. We make recommendations to ONC to take on activity to further mature the standards. David, any other commentary here?

David McCallie
Just to reiterate that last point. In abstract, these standards are extremely broad. So, for real world use, they need to be constrained with appropriate implementation guidance. And that implies experience testing them and industry partners who are willing to experiment and refine them to get the implementation to match the use cases. So, there is a lot of work ahead, I think, for the newer of these but we believe there is sufficient robustness in the base to justify pushing that forward.

Arien Malec
Excellent. Let's go on to the next slide. Common data models. So, we came across at least two places, particularly in the pragmatic research and in the need for administrative data sharing and burden reduction, the need to map USCDI and HL7 FHIR to a common data model. So, just as a refresher, USCDI really covers data classes and data elements. And then, there is some additional modeling that's done in a clinical

research context. There is an implied model for administrative data. And we believe there is some additional work that needs to be done here relative to thinking about modeling. So, we recommend that ONC map USCDI to HL7 FHIR and other older foundational standards **[inaudible] [01:32:01]** and CBA to build a clear and rapid road map to expand USCDI as you just heard in the USCDI task force. We contemplate that as USCDI includes additional elements that those elements will be available in bulk FHIR. And we would like to see a transition to World.

So, again, this really came up in our testimony on research where the research community is doing data extracts out of EHR's via database export capabilities. It would be ideal if the bulk FHIR extract method could be used to support the research work. And to do that, we'd want to see the bulk FHIR and the implied FHIR model that's sort of a graph based model map to the clinical research model. And then, finally, we recommend that ONC work with industry stakeholders and we list a number of them, as well as federal stakeholders, to map USCDI to broadly disseminated research data models as well as to HL7, FHIR, and other concrete interoperable representations. So, what we mean by that is it would be ideal if we had a good cross map between USCDI, the representation of that data and those classes in HL7 and FHIR and how those represent to clinical research models. As a spoiler alert, we contemplate that we should converge, at least for pragmatic clinical trials, on a single model.

And so, ideally, that mapping would be to a pragmatic clinical research model that's been cross mapped to FHIR. And what we get out of all of that pretty obviously is a tie between USCDI that defines interoperability requirements, the tie back to the naturally represented data that's collected in the EHR, as well as, when appropriate, additional information that's being collected, as we previously noted via FHIR questionnaires that are then bulk exportable and able to be used in a clinical research setting for pragmatic clinical trials. And I think when we get into the research world, we'll note that as we come through our experience in COVID, I think we've seen the benefits of a rapid learning cycle. This is one of the benefits that was anticipated for EHR deployment. And we've seen that, particularly, in the UK, we've been able to rapidly prototype and test out various therapies and then, put them into practice at a learning rate that we previously have not seen in clinical medicine.

And we believe these foundational standards are a key part of how we get there. David, any other commentary?

David McCallie

No. I think you covered it pretty well. And some of these points will get reiterated on the more detailed recommendations coming up. I will just say that the bulk FHIR clarity is a pretty important concept to highlight for ONC that we gathered there with some ambiguity about which certification and which USCDI work would apply to bulk FHIR. And we recommend, obviously, getting that as clear as possible before it becomes a required capability.

Arien Malec

Let's go on to the next slide. Terminology. And Clem notes a typo on the slide, which, hopefully, we'll cross check to make sure we don't have the typo in the transmittal as well. So, I'll cover that when we get there. 1.) Is for terminology that ONC work with federal stakeholders to establish policy with **[inaudible] [01:36:15]** towards terminology standards that are developed in accordance with OMB Circular A119, which I'm sure just put everybody to sleep. But that's the master guidance on voluntary consensus standards. And the

thought process here is the US federal government, when it promotes standards, should have a preference for standards that are developed through a voluntary consensus process. And OMB Circular A119 is the document that describes the wants and care abouts for a voluntary consensus standard. Again, metacommentary here. In previous incarnations of the HITAC through the HIT standards committee and policy committee, as well as through this current incarnation in the HIT advisory committee, we've, generally, preferred and seen the evolution of the health IT sector towards openly available standards.

As a case and point, the terminology standards prior to 2009, we had a mix of licensing models. We've worked on national licensure for things like SNOMED CT. We've transitioned things like LOINC to freely available and open standards. And then, we've worked with HL7 through the adoption of FHIR to be able to have FHIR licensed on an open content standard. As we've done that, we've worked as a nation with the standards developers to make sure that there is a business model for sustainment and continued evolution of those standard but a licensing model that allows those standards to be freely and publicly used. And that model drives substantial amounts of innovation. I think we've seen the fruits of that overall policy. So, we prefer licenses that allow open use by providers, researchers, developers, patients, and other stakeholders. And we list in the actual formal recommendation a number of means that can be used to get at that overall licensing. We prefer standards that are available to address multiple needs.

So, for example, clinical care, research, public health, and administrative needs and our international or cross mapped international standards to allow for multi-region pooled research. So, for example, if we see data in the UK and data in the US, it would be ideal to pool that data relative to clinical research outcomes. We recommend that ONC work with key federal stakeholders to transition the nation towards terminology to meet that policy through a number of means. And this is where we have the typo in limited to but not limited to in the but limited to wording here. And then, we also recommend that ONC's direct levers to need to standardize. And then, we have a whole set of recommendations associated with specific terminology. The previous incarnation of the ISP task force talks about the lab and results ordering capability by directional ordering and resulting for laboratory and imaging data. As part of those recommendations that previous incarnation recommended working on policy to normalize its source.

This was a sore spot for the research community that often needs to do a substantial amount of work to renormalize proprietary, for example, lab codes. And so, we're making recommendations relative to lab terminology that ONC work with its federal partners to make sure that we source normalize, normalize as close to source as possible, terminology. And in particular, that we get away from the use of proprietary lab terminology. I'm going to go on to the next slide and then, we can cover the entire terminology section. So, procedural coding, we recommend that ONC work directly and in coordination with CMS to transition procedural coding to make sure that it accords to the policy framework on terminology standards development that we previously articulated. We recommend in the transition to ICD-11 that ONC work with CMS and NLM and other stakeholders to make sure to encourage SNOMED CT and ICD-11 harmonization. It would be a bad thing if we broadly adopted ICD-11 and discovered that ICD-11 and SNOMED CT were not mutually convertible.

And then, we have a split medication terminology where, by and large, we standardized on RX Norm as our master medication terminology. But FDA uses NDC's in many areas and the NDC codes slip into many of our interoperability specifications for pharmacy exchange for prescribing and the like. We recommend that ONC work with FDA, CMS, and others to continue to harmonize to RX Norm as the standard source

terminology set and that we get away from the use of NDC's. In many cases, for people who are aware of the art here, we used, for example, representative NDC codes that aren't really what you mean but they're just the placeholder that allow you to get up to the right coding system. And it would be better if we just had a single standard coding system. So, there is a lot here in these terminology recommendations. David, what did I leave out? What context can we provide better for the advisory committee here?

David McCallie
There are a lot of words there, Arien. I think you've covered it all.

Arien Malec
I'm trying to bring the energy, particularly, through thorny topics like vocabulary standards. So, I hope you're entertained as we go through all of these recommendations. Let's go on to the next page. So, again, just to orient you in space, we've covered the broad and general recommendations associated with standards development and standards prioritization that we believe as a task force brings the nation forward across a range of use cases and uses. And now, we are diving into health equity research and burden reduction and situational awareness in particular. So, on health equity, we endorse the USCDI recommendation on social determinants of health using the HL7 Gravity Project nomenclature and value set standards. We recommend that ONC track in the ISA social determinants of health content and also capture the associated standards such as FHIR questionnaires and FHIR consent that are associated with the capturing of social determinants of health inside EHR's.

Again, just an explanatory meta comment there, the Gravity Project is a mix of data classes that are USCDI as well as enabling standards, including FHIR questionnaires and FHIR consent that enable, with appropriate patient consent, the capture of additional social determinants data. And so, in order to move towards a more granular capture of health equity data, we need the full standards picture there and recommend that ONC work to promote the use and adoption of the enabling standards. We recommend that ONC establish policy to ensure the deployment of associated implementation guidance and EHR certification requirements to make sure that the social determinants and demographic and address information that is captured in the EHR, actually, flows through for multiple purposes, including public health.

So, again, as a gloss here, some of the reason that we discovered that results data is not being captured in, for example, immunization workflows or, in particular, lab order and resulting workflows and getting to public health for contact tracing and for broad scale COVID impact assessments and dashboarding was not that the demographic information and address information was not captured. There is a double negative there. So, the EHR's and clinicians absolutely are collecting appropriate information as part of their routine collection of data for clinical care as part of the chart of record. In many cases that information is not flowing to the commercial labs but then, are required to flow data onto public health. And that's because that information is being dropped in the interface engine somewhere because it's not required as part of the proprietary standards that are being used in between provider organizations and labs.

So, that's a concrete example of this general case of let's make sure that we deploy the implementation guidance that ensures that information flows through source capture in the EHR in accordance with the USCDI into the places where it's been downstream used for evaluating health equity. It does no good if we have health equity standards and get appropriate capture in the EHR but then, we don't have the

interoperability specifications to flow that information on. And, again, I think we saw some real world examples of that as we've gone through our experience with COVID-19. And had we promoted the adoption and use of ordering and resulting standards earlier, we would have seen data flowing faster through to public health and would have avoided some of the issues that we got into in contact tracing and not being able to contact patients who tested positive. We recommend that ONC continue to work to harmonize the patient address models and standards to provide better key location interoperability.

So, we've heard previously as an advisory committee from the work in conjunction with the USPF on getting a health standard for address information. Address information collected in EHR's helps to geolocate, for example, disease outbreaks or disproportionate disease burden. We also noted in some of our work and heard in the public health data systems work that geolocation of work can also be an important way of identifying disease outbreaks or disproportionate burden. And we make recommendations at the end about location and type of work occupation. But, again, if we get that geolocation done correctly, if we get the address information collected correctly upfront, if we put that address information through our interoperability specifications, we then have the data in order to look at geolocation and looking for hot spots for disease burden and hot spots for public health burden. On to the next slide.

David McCallie

Arien, one comment if we could go back one slide just to repeat what Arien said but just to drive home the point. In 4C, it's a policy problem, for the most part. The standards exist but they aren't being used. And if that doesn't get fixed, it's not a standards issue. It's probably a lever issue. What policies could ensure that the data, actually, flows? And then, on 4B, again, just to reiterate what Arien said but to say it twice, the deployment of the Gravity standards may occur or will occur in phases where the clinical nomenclature or the SDOH nomenclature could be widely deployed before necessarily some of the API's that exchange those data elements are fully tested sufficient to endorse them for part of certification. So, staging some of that expansion of the capture and sharing of social determinant data is probably going to be necessary. It won't happen all at once.

Arien Malec

Thank you, David, for that. And I want to triple underline these points about, in many cases, we do not have a standards problem. We have a standards deployment problem. And when we look at some of the issues that we have on social determinants of health and health equity, the major issue that we have here is a standards deployment problem. And, again, we're triple underlining this point that ONC should be looking at the policy levers to ensure that we have the standards deployment that goes along with the data capture that we have in EHR's. All right. Let's go on to the next slide where we talk about research. So, as I mentioned previously, one of the experiences that we've had in our COVID times, in a horrible set of dark clouds, there are always silver linings. And I think one of the things that we learned out of this experience is that we can conduct real world, pragmatic research very rapidly and inform clinical practice in real time. And that the dream of broadly deployed EHR's materializing in a learning health system is not a pipe dream or a fantasy.

It's something we can, actually, get to. But to get there, we need the ability to turn the deployed EHR base that we have in the US into a learning health system machine. And I would note that the US is fantastic at sponsored clinical research. We were able to get vaccine development done in record time. We did a really nice job at retrospective research. We heard from the research community really good and elegant stories

about retrospective research. But it was really the UK that did the lion's share of the prospective, pragmatic research. And, again, just to situate us, what we're talking about is not the sponsored clinical research that's sponsored by a drug manufacturer, a drug company sponsor through an investigational new drug process. We're talking about pragmatic trials. We're talking about comparative effectiveness trials. We're talking about does this therapy work? What dosing regimen works the best for already approved therapy where we want to inform the community of practice? And, again, I think we saw really good use cases, both positive and negative, in our experience through the pandemic.

For example, use of steroids, use of anticoagulation therapy, and use of already approved agents that were, in some cases, ruled out as appropriate therapy. So, foundationally, there were a number of research models that are currently being used for this purpose. And what we found was that many of the health systems that are doing some of this research do duplicative mapping depending on which organization they're working with to do the research. In this area, it would be good to get down to a single research model for these purposes. There is already work being done between, for example, **[inaudible] [01:53:49]** to get to a harmonized single model. We're not looking for a meta model or cross maps between models. We are really looking to get to a single research model for these purposes. And these purposes are pragmatic clinical trials that are done against already approved agents to improve or to implement the learning health system.

There are federal policy levers here. For example, the DA does a fantastic amount of research. DOD does research through the military health system. The Indian Health System conducts research. Obviously, NIH and NCI have obvious areas where they conduct both sponsored research and research towards the learning health system. And clearly, FDA, CMS as part of the work that they're doing for all payer claims sets as well as some of the work that they're doing around value based care is a key stakeholder for getting to a common research model. And then, we recommend that ONC create sections in ISA relative to both the models and for standards and implementation guidance associated with conducting pragmatic clinical research. So, again, we've already talked about consent. We clearly need good consent models for conducting pragmatic research trials. We need prospective randomization, enrollment and de-enrollment. So, one of the things that the UK did better than us in the recovery trial work is they had a centralized randomization for some of the trials that they registered in the recovery trial work.

And it would be useful if we had a set of plug ins into EHR's to allow randomization to occur. And, again, we believe that could be done through a combination of questionnaires and CDS Hooks and subscription to the open drive randomization workflows. Separation of research and clinical data. So, EHR's often may need some blinding support to be able to separate out research data. We have, in many cases, the need to document in a true, I shouldn't say true, in a sponsored clinical research world for preapproved medications, biologics, and devices. We have the need to collect documentation in the EHR about exposure or potential exposure in the case of blinding to research compounds. And in many cases, the terminologies we use, for example, RX Norm, only have terminology for approved and registered drugs. We need to make sure that we have terminology support for not yet approved drugs that are going through, for example, an IND process.

And then, we recommend that ONC work with stakeholders to assess other EHR opportunities relative to research. And, again, this is all by way of turning the EHR landscape that we have into a learning health system powerhouse. As I said, I think we've learned in our COVID times that we, actually, can implement

a learning health system and iterate through knowledge and learning much faster. David, any commentary relative to this recommendation?

David McCallie

Yeah. Just a little bit of elaboration on the notion of a single common foundational research model. We are not, obviously, implying that every researcher must use the same data model. But that data that flows out of EHR's that are under ONC's purview should flow into a foundational model from which researchers could easily extract what they need and supplement it with the specific additional data that's necessary to drive their research project. So, it's a foundational model, not final model. It's a core model, not a required use of some ONC created research model. Researchers will use the models that they need. But getting the data out of the EHR's has been one of the problems they've faced.

Arien Malec

And as a commentary on that as well, I think we're careful to say in our recommendations that we're not asking or calling for high position burden activities that subordinate clinical care to research needs. Instead, what we're looking for is the maximal use of data collected for clinical care to be used additionally for research needs. Let's go on to the next slide. And here, we talk about harmonization of clinical administrative data for burden reduction. We, generally, re-endorse the ICAD task force recommendations in this area and relative to our task and priority for the ISP. We recommend that ONC add sections to the ISA to track administrative standards, particularly, those related to the harmonization of clinical and administrative data and track the evidence that are being done through DaVinci, Fast FHIR, X12, and CPDP, HL7, FHIR Accelerator Project. We've got a lot of innovation in this area of administrative burden reduction.

The net of that innovation is driving administrative needs as early in the process as possible driven off of clinical data capture in order that the administrative back end processes do not pose a burden both to physicians and to patients. And I think anybody who experiences some of the unpleasant aspects of the US healthcare system will tell you that clinicians in the US are amazing. And we provide really, really excellent care with kind and caring care practitioners. When we get to the administrative side, when we get to paying for care, when we get to transparency of pricing, we get into the unpleasant side of the US healthcare system. And our recommendations here are relative to making sure that we smooth out some of those rough edges to make the administrative side of the US healthcare system as smooth and pleasant as possible both for patients and for clinicians. And then, to that end, we recommend that we harmonize the implied administrative data model to FHIR and to USCDI.

Again, the intent here is not to subordinate administrative activities to clinical charting and clinical care. It's to make sure that the data that we capture in clinical care is maximally useful for administrative needs. And I think, sometimes, this is some of the testimony that we got from the research community, which I think will be of no surprise to anybody, sometimes we subordinate clinical care to administrative requirements. If we do this the right way, we can flip that paradigm and have clinical care drive downstream administrative requirements. David, anything else here?

David McCallie

Nothing to add.

Arien Malec

And then, our extra recommendation on the next slide is related to situational awareness where we heard from the SANER Project some of the tremendous work that's going on there. And so, we have two recommendations for ONC. One is to lift situational awareness interoperability priorities in the ISA and catalog and track and go through the maturity process for the associated standards and implementation guidance towards broader adoption. So, again, just to orient people for what this is, this is in an emergency, do we have Emergency Department readiness? Do we have personnel? Do we have supplies? Is there tracking of PPE, tracking of ventilator, tracking of any scarce supplies and making sure that we've got awareness at the level of the heath system and not just to the level of a single institution for what overall constraints exist? Do we have appropriate ICU bed space, etc.? And we discovered over and over again, in emergencies that it's a scramble every time.

So, this time, it was a pandemic. Other times, it's a hurricane or here in the Bay Area, it's an earthquake. And we want to make sure that we pre-compute as much of this as possible without creating bespoke requirements every time. And to that end, one of the things that we heard in this process is that there is disparate policy levers that are used, different agencies of HHS. CDC does one thing and the assistant secretary for **[inaudible] [02:03:44]** does another. And so, we want to see policy coordination to make sure that there are the right mechanisms to create appropriate incentives and requirements for preparation for emergencies and pandemics for situational awareness. And those are our recommendations. We do have some special follow ons for the next ISP. So, maybe we can cover those now and then, go to the advisory committee input. So, we did placeholders a couple of things for future incarnations of the task force.

Care plans, chronic disease management, data sharing between federal and commercial entities, particularly the use cases associated with that data sharing, portal data aggregation across multiple portals, occupation and location of work, particularly relative to public health, and data exchange formats for price transparency. Right now, it's a little bit of the wild, wild west for the price transparency work and it would be useful if we harmonized on a common standard. So, I think with that, it is, with the chairs' permission, time to go to questions.

Aaron Miri

Good job, David and Arien. I appreciate all of that. All right. HITAC, if you have questions, please raise your hand. I see Clem with your hand raised right now. Go for it, sir.

Clem McDonald

Well, I put some comments in the text. And there are a couple of them. I guess you noticed the fix but did not put it in. But the other ones, I really worry a lot about the way, I think, it's 2C and there is a later one are talking about a common data model. I know that we talked a lot about it on the committee and I sent in the last comment too late. But I really worry that it will encourage the creation of yet another by the way it's talking. And I'd like to highlight the fact that there are five or maybe six common data models. And of them, at least three already adhere to standard codes in CDI. So, I don't know what it means to harmonize to USCDI when they already use it in their fields. That's No. 1. And that's FHIR, PCORNET, and OMOP already do that. A couple of them that might be candidate refuse that. So, I don't think they should get into the mix. We won't get anywhere if we get all of them in the mix. And two of them are already kind of working together voluntarily. And I think what they really need is funding to be able to convert their models to whatever they decide is the right end state rather than trying to stimulate a unified model.

We've been there already once and it didn't work out great. That's one point. I guess that's all. Oh, the last one, when you were talking about getting close to the data as possible for lab data, there is a standard called Livid. It's a FHIR standard now, I think, that provides a structure for laboratories to specify what their internal codes translate to as values as either codes for the name of the test like LOINC or for codes for the value of the test like SNOMED and/or if it's numeric, which most of them are then, the use of UCUM codes as specific units. That should be highlighted to make it happen faster.

Arien Malec

Thanks, Clem. We definitely got the UCUM comment and I think Clem has been really helpful in pointing out that, in past incarnations when we've talked about research models, we've created meta models and bridge models and those kinds of things. And so, there are HIE's in the recommendation to note that what we're calling for is exactly what Clem alluded to in the work that's being done between the OMOP and the PCORNET model to harmonize to a single common model that's aligned within USCDI. With a point on harmonization, the best harmonization is one where it's already done and where there is not much more to do. And so, that feels like that would be a good thing to encourage and develop. And likewise, we do call for ONC to fund the work and support the work that's already being done. And so, if you want to read between the lines of we probably should be working with the pragmatic actors who were working in the lines that Clem is talking about. I think you can read between those lines and I think those would be useful things for ONC to do.

David McCallie

Let me add to that. I think, Clem, the spirit of what you're suggesting and what we are trying to capture in the slides is the same. In particular, for example, the work being done with OMOP and HL7 around ensuring that the sort of object oriented view of a FHIR data stream can be layered properly into a relational model so that you make sure that you understand what's in what field in the HL7 messages and if there is a need to map or translate, you understand what those mappings are. That's the work that's already underway but should be recognized, catalogued, and encouraged perhaps with funding so that it smooths the path to those who wish to do bulk FHIR extract and trigger clinical research from all of this EHR data that the country paid for.

Clem McDonald

The funding is a little bit down that. So, for example, and I've talked to the PCORNET people. I think they would like to convert or be more aligned with OMOP but they've got 60 some sources. They can't tell the sources to change overnight. They've been working with them for four or five years. So, they need funding to be able to convert the inflows into what the final model is. I think that's pretty important. I don't know whether we could propose that, too, now that you've already got it written.

Arien Malec

Thank you, Clem. I think that's exactly in line with what we're recommending. I think sometimes when we make recommendations, there is a balance between making very specific recommendations in a certain area and making policy oriented recommendations. So, we try to make policy oriented recommendations. But I think that's exactly the kind of move that accords with the policy that we're outlining in our recommendation.

Clem McDonald

You guys did a good job so I shouldn't be kind of nipping around the edges.

Arien Malec

Thank you, Clem.

Aaron Miri

All right. Next up on the docket is Robert Wah.

Robert Wah

Thank you, Mr. Chairman. And I appreciate the task force and the leaders going through the minutia of all of this. And we appreciate the recommendations that are being put forward. I guess what I want to bring up, again, is what I talked about at the last meeting. The issue of procedural standards and classifications. There is a reference in here about trying to harmonize with international standards. Again, I'll reiterate the fact that there is quite a spectrum out there about international standards in this area. Some countries don't code procedures at all. Other countries, Scandinavia, UK, Australia, Germany, Canada, France, and Japan have developed their own code sets. So, harmonizing across all of those I think would be a significant challenge. But, specifically, I guess I'm concerned about when I recommended that experts in procedural terminology be solicited for the deliberations of the task force, I think the comment was we did hear from the AMA on this.

Looking into that, the AMA did testify, I think, for the ICAD, specifically, about administrative simplification because the AMA has a large remit. So, one of the areas they were concerned about is administrative simplification and what can be done to help the clinical workflow decrease the burden on physician offices in providing care for our patients. But they did not testify or solicit for their expertise in the area of procedural terminology. So, I think there is more to be done here and I'm concerned that some of the recommendations are less fully informed because of the fact that the task force did not hear from procedural and workflow experts because, as we think about modifying some of these terminologies or use of them, it's going to have a significant impact on the workflow of our physician offices. And so, I bring that up. I may make a symbolic vote against Recommendation 3 simply because I don't feel that it was fully informed by some of these procedural experts. But I just want to say that I think we need to tread carefully in this area so that we don't upset the workflow in a way that's detrimental to physician offices providing care.

Arien Malec

Thank you. Just a couple of comments there. In addition to the ICAD task force we got directly from the AMA, the AMA did provide a letter of public comment into the task force that's a matter of public record. I think in hearing some of the concerns that you raised in the last advisory committee and also responding to that particular letter, I think we moved our recommendations to the policy framework. And just to remind you, the policy framework calls for standards development using voluntary consensus standards open terminologies that are freely available for implementers and terminologies that are ideally harmonized and mapped. That doesn't mean, and maybe you're reading into that, a call to use SNOMED CT rather than CPT. That's not the intent at all. The intent is to work with, for example, AMA as a stakeholder as the steward for CPT and transition CPT to a standards development process that accords with the policy and already engages in some of the harmonization and cross mapping international standards that you know.

And, clearly, if there are other countries that are using proprietary or national code sets then, cross mapping international standards is sort of besides the point. But again, if we want to think about the ideal research community would be one where there was cross mapping and procedural codes between, for example, the UK and the US so that we could identify common research needs that would be a useful outcome. So, I think we moved our recommendations to really focus on the policy aspects and stay away from specific recommendations, except in areas where there was obvious burden that was called out. So, again, thanks for your comments. And I do believe that the recommendations that we put in place are policy oriented and are in line with recommendations that this advisory committee and previous incarnations of advisory committees have made to the ONC.

Aaron Miri

I do think it's a good point though, Arien and Robert. I just want to make sure that we do note that if there is additional concern there, there is opportunity to clarify and keep working through this on that specific item. We do intend to take a vote here. So, I just want to make sure, Robert, that your question was properly or was fully addressed or you were able to articulate it in a way that you feel is stated for the record. Is there anything else you want to add to that or is what Arien just responded with good?

Robert Wah

No. Like I said, I don't want to impede the process. And like I said, I think all of us appreciate the hard work of this task force and having been done. And I don't want to hold up the set of recommendations but, again, I felt obligated to voice my concerns in this area. And I feel I have. And I think there is perhaps a little bit of a disagreement about how best to move forward with it. I think my read is that these recommendations will, in fact pass by the committee. But it's important, I think, as we think about implementing the recommendations that we take into consideration the need for incorporating the impact, like I said, on clinical workflow and how the offices are going to, actually, respond. So, again, like I said, in some ways, it's symbolic. But I do want to make sure I do put on the record that there are concerns about this.

Aaron Miri

Sure. Good points. Dr. Wah, good points. And we definitely want to make sure we take those into account. So, thank you for that. Next in cue, I see Clem with your hand raised again. Go ahead, sir.

Clem McDonald

Well, I have some of the same concerns that Bob has. And the NCVHS has made proposals in the same direction with the same end goals but without the specificity. And I put in the text, the URL, I think these are really tough issues and especially hard when we have to kind of unify with the international because outside of certain areas, it's very, very various. So, is it possible to vote on one item and not all of them and whether we could soften that a little bit for this round?

Aaron Miri

Yeah. I appreciate that. We were, actually, clarifying that, Clem. It is a quorum vote so it is an all or nothing component. So, we did just clarify that because were just talking about it on the side to make sure we understood what protocol and procedure is. So, it is an all or nothing. Of course, you can state whatever you would like for the record and go from there.

Clem McDonald

Can one have a minority report?

Aaron Miri

As in the movie? I'm kidding. No.

Clem McDonald

I just was serious.

[Crosstalk]
Robert Wah

They're in a concept called revision.

Arien Malec

I think we tried to address both your concerns and Bob's concerns. And just to be really clear, we are not calling for any change to procedural terminology. All we're doing is outlining a general policy framework and then, specifically, calling for work with procedural coding to make sure that it accords to the general policy framework. I think people are overreading or over interpreting in the task force recommendations something more specific than is intended.

Denise Webb

Arien, this is Denise. I do have a comment then. If it appears that members are overreading into what's written, is there some revision, Robert, in the wording that would clarify the intent that Arien just explained? Because as you know from having been a previous co-chair that we do like to try to vote on all of the recommendations as a package. And I know in the past, we've had to agree as a committee to make some slight modifications and then, vote with the modifications. So, is there something that would –

Robert Wah

So, thank you for that. And I do appreciate the effort that we're trying to do here. I think two things. One is there is always the possibility, and if I need me to I'll make a motion, you can what we call do division. So, division of the question would be to sort of separate out each issue and then, you could have a vote on each recommendation. Somebody could make a motion to say I want to divide the question into individual subheadings of each recommendation because the way the recommendations are, there is a number recommendation and there is a subheading with a letter. So, you could get very granular about that. And I'm not necessarily recommending that. I would say parliamentary, there is a way to get to talking about each individual recommendation or even down to the subletter recommendation. So, again, procedurally, there is a way and I'm not saying that's the way we should do it. Second, I guess, is I've never been a big fan of wordsmithing as a committee of 20 or more.

And it's even harder when we're doing it virtually. So, I'm not trying to suggest that I would like to wordsmith this document in this forum. But it may be necessary to table the finalization of one or two parts of this and then, take it offline and get some better venues to hammer out the correct language.

Denise Webb

Would you like to make a motion to take Recommendation 3 and vote on the remaining? Is that what you're suggesting, Robert? Or are you formally going to make a motion?

Robert Wah

Yeah. So, I realize the impact of this means continuation of the task force, which they were hoping to see the end of the tunnel here. So, sure. I'll do that. I will recommend that we table Recommendation 3 pending further work with the task force to make sure that it is clear because I think there is some misinterpretation maybe on my part even of the words that are provided but also to consider further investigation with the experts in the area of procedural coding.

Aaron Miri

Okay. Do we have a second for that?

Clem McDonald

I'll second that.

Aaron Miri

Okay. So, procedurally then, just to make sure and, Mike Berry, I'm going to lean on you here just to make sure we do this right, we would be voting as a HITAC on everything except for Item 3, is that correct?

Denise Webb

Well, first we vote on the tabling of Recommendation 3 and then, vote on –

Michael Berry

Yes. Let's start there and then, just separate out Recommendation 3 and table it for further discussion.

Aaron Miri

Got it. That's what I was asking for. So, the first vote is for the HITAC to vote to separate Recommendation 3 for further work. And then, the second thing is a vote from the HITAC on the remainder on the balance of recommendations. Perfect. I just wanted to make sure procedurally. Thank you. So, we have a motion and a second. HITAC members, we are voting on separating Recommendation 3, the totality of recommendations. So, that's the first vote. All of those in favor say aye.

Group

Aye.

Aaron Miri

All of those opposed say nay.

Arien Malec

Nay.

Aaron Miri

I believe without counting them that the ayes have it. So, Recommendation 3 is separated. So, now, HITAC's second vote is on the remainder of all of the other recommendations. We'll be voting on the body of that, the totality of that. First, we have to have a motion to do it. So, do I have a motion to approve everything except for No. 3?

Steven Lane
So moved, Steven Lane.

Jim Jirjis
Second, Jim Jirjis.

Aaron Miri
Thank you. All right. So, HITAC, voting again on everything except for Recommendation No. 3. All of those in favor say aye.

Group
Aye.

Aaron Miri
All of those opposed say nay. Okay. So, I believe that that is passed. I believe that procedurally was done right. Am I correct?

Michael Berry
I just want to confirm the no vote for the record on the first vote.

Aaron Miri
On the first vote, who was that that said no on HITAC?

Arien Malec
That was me, Arien.

Aaron Miri
Perfect. Thank you. That's what we needed. All right. You've got to love process. Well, David and Arien, thank you very much for your leadership. This is very, very complex information to get through and work through and to teach us and to put into common English. So, thank you for that. And I know it's many, many, many hours of it. And so, great, great work to the two of you. Denise, anything you wanted to add to that?

Clem McDonald
Yeah. I'd like to say the same thing. They did a great job. And they wrote beautifully. And I heard that Arien did maybe more but I don't want to get into that.

Denise Webb
Before I say anything, I do see that –

Arien Malec
Just procedurally maybe to Mike Berry, is the recommendation out of this that we're going to do a do again for Section 3 and repromoted recommendations to the HITAC for our next meeting? I don't want to lose the work that we put into this that I think are a body of recommendations where maybe we can clean up on a

specific concern. And maybe it's two specific concerns in procedural terminology. So, I want to make sure that we have the opportunity to take this work back to the full committee.

Michael Berry

Right. Well, we reconvene your task force and work this out. And then, the next HITAC meeting is July 14. So, we could bring it up then for another vote so that we could settle everyone's concerns.

Arien Malec

Fantastic.

Aaron Miri

Perfect. Dr. Lane, I see you joined us back and you have your hand raised and I don't want to miss –

Steven Lane

Yeah. I wanted to understand procedurally, we separated Recommendation 3 but we have not voted on Recommendation 3. We heard concerns but we don't know what the majority of the HITAC thinks about Recommendation 3. So, I just don't know if Recommendation 3 deserves its own vote.

Arien Malec

I would move to take Recommendation 3 back to the task force for consideration and then, repropose recommendations to the full task force.

Aaron Miri

Right.

Steven Lane

I'm happy to second that motion.

Aaron Miri

Okay. Perfect. Clem, were you trying to say something?

Clem McDonald

Yeah. Well, Recommendation 3 has really a whole lot of parts. And they are involved probably subject to but we don't have time to get into all of that. Some of the parts I don't think have any disagreement.

Aaron Miri

Got it.

Denise Webb

So, Aaron, I'd like to just note that I know in the past, we have had votes on recommendations and had to take others back and bring them forward. And, usually, that process goes fairly quickly because the focus is on the one that's been voted on.

Denise Webb

(Audio interference) they're not going to have to go through the whole extensive presentation of those that were already agreed upon, although we will vote on the whole package.

Aaron Miri
So, we voted as a HITAC to separate Recommendation 3. We voted to approve everything but Recommendation 3. So, the last piece of this then is exactly, Arien, what you and others were asking for, which is to take the motion back to the task force to go work on and wordsmith, work through, those sorts of things. And I think that's the last piece. Is that correct, Mike?

Michael Berry
Right. So, you'll have to call a vote on the motion given.

Aaron Miri
Okay. All right. HITAC, one more vote. So, on the vote now to take the Recommendation 3 back to the task force to work on, I believe I heard a motion from Arien. Are you motioning that?

Arien Malec
I am motioning. So moved.

Aaron Miri
Do we have a second?

Steven Lane
And I already seconded it, Steven.

Aaron Miri
You already seconded it. All right. All of those in favor of the HITAC say aye please.

Group
Aye.

Aaron Miri
All of those opposed say nay. Okay. I think we followed the process. Good stuff. That's the joy of this one is we get to work through these things and have a collective vote. I think it's important for folks to voice their thoughts and opinions. And that's how we get great work and great recommendations out of it. So, thank you. And thank you, Robert and Clem and others, for bringing that up. I think it's important that we're all heard and all voices are heard equally. Very good stuff. Denise, anything you want to add real quick?

Denise Webb
Well, I just want to say thank you, Arien and David. I know that's complex material to present and great job.

Aaron Miri
Yeah. Totally agree. So, with that, we do have a few extra minutes. So, we're, actually, going to break for a little bit longer to give you a chance to grab a bite and then, we will return to an enthralling conversation

with Steve Posnack. So, 12:30 please be back. And it should be fun times. So, we'll see you in about 30 minutes or 28 minutes. Thank you.

Operator
All lines are now bridged.

Michael Berry
Great. Thank you very much. And welcome back, everybody, to the June HITAC meeting. We're glad you're back with us today after our short lunch break. And now, I'd like to turn it over to Aaron and Denise to kick us off for this afternoon.

Aaron Miri
Absolutely. So, now we have the beatbox version of this afternoon. No, I'm just kidding. We are looking forward to Mr. Posnack giving us an update on things, especially where we stand with the health interoperability outcomes for 2030. So, I hope everybody got some lunch and get ready for a good afternoon. Denise, anything you want to say?

Denise Webb
No. I'm anxious to hear these presentations.

Aaron Miri
He's going to beatbox, I promise. Mr. Posnack, all yours, sir.

Health Interoperability Outcomes 2030 (03:00:48)

Steve Posnack
Thanks very much. I was joking with Mike that if I needed to fill more time that I would have to do some poetry reading or interpretive dance for everyone. But it's a pleasure to be with you. Good afternoon for folks on the east coast or good day for everybody else. I could say greetings from cicada central. Besides the typical heat and humidity in DC, you should be glad that we're virtual this time around for this meeting. So, earlier today, we had a good bit of dialogue around present day. You can consider this next part being your chance to go back to the future if you caught my tweet from earlier. But if we look back at the 2010 to 2020 period, we made a ton of progress. But there is still work to be done. There is still unfinished business. There are still outcomes that we haven't yet achieved. And so, we at ONC are looking to identify and pull together a prioritized set of outcomes for 2030 with interoperability in mind and with interoperability as that key ingredient.

And so, I'd like to be clear that as we have this discussion, the interoperability outcomes that we talk about are for the industry as a whole. They're not just things that ONC would do individually. And while ONC can play a role and will play a role, as well as our federal partners, consistent with our federal health strategic plan, which aims for 2025, we're looking at these 2030 interoperability outcomes from an it takes a village perspective and approach, especially since there are different segments of the healthcare ecosystem that may have a lead role at different times over the course of years. So, just keeping that overall surround in mind. And similarly, because this is healthcare, there is likely going to need to be a mix of changes in policy, in technology, in workflow, technology design, payment in order to reach any particular outcome that we

put forward. And so, what proportions they take, what sequence they may need to go in that doesn't really matter if we're not well aligned, if we're not coordinated if you will on the outcome that we want to achieve.

So, with a crisp outcome in mind and a vision for the future in focus, it helps all stakeholders more clearly identify what they think they can contribute and how they think they can help and where there may be gaps still that remain. And so, part of this process and the dialogue that we hope to have with all of you is to get some of those inputs and feedback as we go through our process with the ecosystem as a whole. So, that's a bit of upfront context. And as we move into the discussion and the feedback session, I just wanted to emphasize two things. One is that we would like to avoid specifying an answer or solution within the outcome. Something like CMS should do XYZ different. That would kind of cut to the chase or short circuit the point of having an outcome statement for which we could have a number of different ways to find ways to achieve that outcome.

And then, second is don't forget to treat 2030 as an upper bound and that these outcomes can and should be viewed as things that we want to accomplish or achieve within and before 2030. So, there is an opportunity for us to certainly get things done before that date. But 2030, obviously, from a round number and an end of the decade perspective serves as a way to put that book end between what we're trying to accomplish. So, as a heads up to our meeting facilitators today, if we could pull up a document for today, I wanted to thank all of the HITAC members that responded to our encouraged homework assignment in advance of the meeting. The team here, in particular Matt Swain and Peter Karas, who helped to organize our outcome statements into seven high level categories and we're not saying these are the right categories. But we're just saying that these are categories that make sense based on what people have put together.

So, in that respect, in addition to the specific outcome statements themselves, it would be great to get the HITAC's feedback on categories. So, if any of these seven resonate with everybody and you're like yeah, we should keep that kind of category as the overall framing about how to organize the presentation of these outcomes for the future, as we talk about outcomes, they can take many different forms. But a couple of easy tips that I'd like you to consider and think about as we have this dialogue is that there are things that we as an industry should be doing differently by 2030. And that may mean stop doing something if we want to take it from a slightly negative bend to it that because of interoperability, we can do something better and we should phase out something that we're currently doing right now. And then, equally, to look at things that are new that we have not yet accomplished but we know really needs to be done and that we don't want to lose sight of over the years to come.

And then, lastly that the outcomes that aren't necessarily an all or nothing kind of proposition for the work that we're doing. So, I think some of you had submitted ones that were percentage oriented or could look at more qualitative statements around a majority, those would be okay, too. And so, if that's the type of outcome that resonates best with industry and we can seek to achieve that as opposed to reaching 100%, which is often difficult in certain situations depending on what the outcome is that would be okay to specify, too. So, don't feel too constrained to having them be all or nothing accomplishments from an outcome statement perspective. So, with that, a bit of my prepared upfront remarks before I start to sing backup for our illustrious chairs. And with that, I'm going to turn it over to Denise and Aaron to MC as they usually do. And the team and I will take notes and listen intently. But I am also here to chime in as needed and give

you any other direction or input as the conversation evolves. So, I know none of you are wallflowers. And I know you know how to use that hand raising feature.

Now is your chance to chime in and just have an active dialogue. It's one of those free flowing opportunities that we would love to have as part of the HITAC meeting today. So, I will turn the mic over to Aaron and Denise.

Aaron Miri
Sure. All right. So, HITAC members, as Steve asked, would you please raise your hand or if you're not on the Adobe Connect, if you would please voice cue so we can get you into the cue here to speak about some of these suggestions. Again, we want to have feedback looking at categories, looking at content, other things you've thought of recently based on today's discussion and all of that good stuff and get a robust dialogue going on. So, HITAC members, would you please raise your hand with any questions or comments or if you want Steve to read poetry, you can also raise your hand for that, too.

Denise Webb
So, I don't see any hands so I'll volunteer to start. As I was reading through this, I was thinking about what might be missing. And I was thinking about a number of stories that I've heard about trying to get all of the health records together to deal with maybe a very difficult disease that they don't even clearly know what it is or maybe they know what it is but their provider has never seen it before and really has not a lot of experience with the particular state of health and the particular disease. And so, it made me think about that movement around patients like me and how it would be really great sometime by 2030, if not earlier, if the providers had a seamless way to tap into patient data so that they can find patients like theirs that they're struggling with to figure out what's going on with their patient and that maybe somebody else on the other side of the United States or even overseas has seen it before. Or maybe a lot of others have seen it and they just haven't seen it.

You see patients having to go out and do that often times, they go to great expense and do it on their own. And I don't know how to quantify that in specific words but I thought about that as I was reading these that that would be a really great thing to achieve through interoperability.

Aaron Miri
So, in depth, real time, robust research. Similarities across the globe. That's an amazing comment. I also noticed here that I can only see a portion of the document so I'll ask to scroll the document down a little bit so we can see the other sections. There we go. So, again, HITAC members, read this, look at it, give us feedback.

Denise Webb
And Aaron, I was speaking more kind of on that whole clinical decision support spectrum when trying to decide what treatments will work for your patient or what's been tried that maybe doesn't work. I've heard those stories but it worked with me and I got cured.

Aaron Miri
No, it's a great point. I do see Mr. Kansky with his hand up. John?

John Kansky

So, I have a simple, clear version of this comment and a slightly more nuanced and confusing version of the comment. So, let me make an attempt. I think the seven categories that emerged feel right. There may be some others. But I went looking for improvements in care delivery. And it's there in Category 6. Maybe we could scroll down to there. And it's lumped with care coordination. And I went reading through that category. And I sent in three of these and none of them had to do with care delivery. So, I'm guilty of my own comment here. But we've got public health top of mind and you've got consumer empowerment top of mind. And we've got other things top of mind. I don't think anywhere in Category 6 does it say that healthcare will be cheaper or of higher quality because of interoperability. So, that's the simple version of my comment. It seems like we should believe, based on the business that we're in, that nine years from now because of interoperability, healthcare will be higher quality, safer, and less expensive.

The more nuanced version of that, which is something that many of us have probably been in discussions with others over the years is, basically, prove it, Kansky. That is to say that, of course, we believe that interoperability will lead to safer, higher quality, or less expensive healthcare. But it's incredibly confounded by 65 million other variables to make that linkage directly. And thankfully, I didn't hear Steve Posnack ask us to prove it yet.

Steve Posnack

Thanks, John. I think you touched on, as you were formulating the categories here, there are others that, like you mentioned, you could create a category around costs. You could create a category around care delivery, connectivity. Convenience is another one. If you want to look at outcomes, there are things easier to do. Are they more convenient for providers, for patients, caregivers, and the like? You could also look at the community dynamic as a whole. And similarly, this morning in preparation for the discussion as well, other participants, health professionals in the healthcare ecosystem, I'm not sure that we have anything in nursing that got represented here but is there something for that community of the healthcare workforce that should be an outcome for 2030 as well? So, I know Terry submitted some things related to the home and community based services. There are certainly aspects related to social determinants of health, which I know came up earlier in both conversations that we had.

So, there are definite points of interest that I think have been top of mind. But if there are others that members of the HITAC have had sitting there on their radar or as a point of order for the constituencies that they represent or the daily work that they do, now would be a good time to air those out again and make sure that we have them well captured in terms of what those groups would look to 2030 and say interoperability made this happen.

Aaron Miri

Those are great comments. I see, Michelle, you're in the cue next.

Michelle Schreiber

Yeah. Thanks. This is a nice and long list but a couple of things. 1.) Going back to the previous comments, I'd like us to see that interoperability has really driven value. And I agree that that's high quality, high safety, better experience, lower cost. But we really can sum it up in that we've driven value because I think interoperability is the way to do that. I'd also like to kind of say that interoperability has supported care everywhere. In other words, where we're moving in the self-care is beyond boundaries of going to the

hospital or nursing facility or wherever. But we can provide care everywhere. And the interoperability is really what it's going to take to support that. And, finally, under equity, I would just vote to expand that a little bit. It's not just people with disabilities. It's that all patients, all consumers will experience health equity no matter what or where they live.

Aaron Miri
Great point, Michelle. Steve, anything you want to say to that?

Steve Posnack
No. It makes a ton of sense. I appreciate the additional feedback, Michelle. And I think that's where, to John's earlier point, how are we going to know that we accomplish these. And so, I think we want to drive toward value and know that interoperability has had those impacts on value. It's just a matter of figuring out then what are going to be those indicators that we look at throughout this time period? And it could be that some of those measurements change. But one of the other points that I probably should have built into my opening remarks is and we framed that a little bit in the blog post that we published, having the outcome statements have a sense of what the succinct measurement or intuitively how we would try to measure that outcome is going to be the devil in the details aspect of some of this work. So, there could be some qualitative outcome statements that may make it difficult for us to, specifically or routinely, measure.

But, ideally, we would find ways, either proxies or other types of overall healthcare ecosystem changes that we could say if these costs went down or there were more people participating in alternative payment models, those things will happen because interoperability is better in these areas.

Michelle Schreiber
Hey, Steven. That's why all quality measures should be digital by 2030.

Aaron Miri
I like that. No non-discrete data. No more PDF's. I like that. All right. Next up in the cue, we've got Ken.

Ken Kawamoto
Thank you. Can you hear me now?

Aaron Miri
Yes, sir.

Ken Kawamoto
Perfect. So, I love these lists. Just a few thoughts to add. One is the difference between process and outcome. And I think we have a lot of process in here. But along those lines of we really want outcomes, I just suggest we maybe consolidate into the outcomes enabled by these processes. Another one is whether it's measurable because improve, decrease, it's a little bit fuzzy. So, I suggested things like instead of people receiving half of the care that's recommended, let's make it 80%. Instead of preventable medical errors being a top three cause of death in the country, let's try to get it into only top six. Those kinds of things or give at least half of these EHR's excellent usability rather than poor usability. Those kinds of metrics, I think, could make it measurable. I think that also it might be worth consolidating because I think

one of the things we found through a lot of our activities is when we create 30 things, we don't really do any of them.

So, I think to the extent that we can consolidate things, I think it makes it more accountable because when there are 30 measures, maybe it ends up in a report anywhere but nobody is focusing on it. And along those lines, maybe the quadruple aims framework could be used around that. So, a lot of these, I think, go into that of patients have better outcomes, patients have a better experience. There's an improved clinical experience and less frustration and costs are lower. And I'd love to have something like we will no longer lead the world in per capita healthcare expenditures by 2030. No. 2 would be great for that one.

Aaron Miri
Great points, Ken. I like the scientific approach. Steve, anything to say?

Steve Posnack
Yeah. Absolutely. And I think Ken hit on an important point for how we go about formulating this in the future. And one other point that I'll just emphasize that I mentioned before, this will be a prioritized set of outcomes. We're not going to cast a wide net and then, wind up with 150 outcomes for industry as a whole to do because it would be hard to focus everybody. So, ultimately, we'll have to make some tough choices about how to prioritize and how to pick the outcomes that we think resonate and even in and of themselves will move some collateral outcomes along with them. And they'll be the focal point for an energy of work, I guess I would say, around interoperability and how that can help. So, yeah. Using the quadruple aim framework is a great suggestion. Thanks, Ken. We'll take a look at how we can fit that in. And also, to note, in addition to the HITAC input here and feedback, we also have, as a public service announcement, our web page up on HealthIT.gov for everyone else to submit their outcome statements.

If you're just mowing the lawn, as we jokingly say, or brushing your teeth, you're like oh, we could do this with interoperability, go ahead to the website and pop that in. And so, keep it short, keep it simple, keep it focused and we'll look at all of these as a way. And I think we do expect a lot of reconciliation and consolidation do, in this case, do a lot of lumping as opposed to splitting and conceptually try to find things that give that overall north star, full direction and then, have opportunities for the industry as a whole to plug in. I think this will help lay out different ways for the various stakeholders in the healthcare ecosystem to play their part. And it's not just going to be, as I mentioned before, all one size fits all from a federal perspective, all dependent on the standards to own an organization. It's going to be that whole it takes a village concept.

Aaron Miri
Good points.

Denise Webb
Before Clem jumps in because he's next on the list, I just want to say I think that's such an important point you made, Ken, about measurable performance metrics. And it's great to say all of those things that we can do by 2030 but how do we know. We need some quantifiable measures. So, I think that's a really good piece of feedback in the final product.

Aaron Miri

Good point. And perhaps even split into adult and pediatric recommendations. We could really look at it with a finer lens. Clem, you're next.

Clem McDonald

Yeah. There has never been a technology that doesn't have a dark side as well as a bright side. And I'm overstating it because I love all of this stuff. But one of the problems is now, with interoperability, we can be increasingly overloaded with information. So, I think we've got to find a way to present the key stuff. Actually, to boil it down and show what's important on the way. That may not be an interoperability thing per se. But then, you get a lot of leverage. If you get all of this information and you know what to look for, boom, if it shows up on the right part of the screen, it's important. But you don't have to drag through all of it. And those who are in practice, I know I have gotten charts that were 2 feet tall back in the paper days. And you can flip fast. You just didn't look at it all. You kind of picked out a few things to look at. But the system could do that for us, I think. But it would need a whole area of research probably. Just a thought.

Aaron Miri

Good points. Steve, do you want to respond to that?

Steve Posnack

I'm assuming Clem sees himself as more of the Jedi than the Sith. So, yeah. Those are all really important. And I think, again, as we look toward the outcomes and how they get framed, the way in which we approach just the wording in those outcome statements, at the end of the day, to give people a sense of momentum and a sense of accomplishment and that it will feel different when we've accomplished these outcomes. And that's a lot of what we're trying to get at as well is that we know there are pain points. We know that there are workflows. We know that there are gaps in standards and data representation as was covered earlier today. And those are all things that we know we need to continue to work on. How we go about that, who collaborates, how we coordinate, what policy changes may need to be in place. So, having that outcome that we want to achieve and then, either working backwards or working forward from today to accomplish that is something that we're trying to lay out and frame for industry as a whole.

Aaron Miri

Good points. All right. Abby, you're next.

Abby Sears

Thanks. We didn't have time to send in our comments on this, Steve. And I'll make sure that we do that in the next couple of days so that you get those. They'll predominantly be focused in the areas of equity, as you can imagine, and the sharing of data and making sure that we have equitable access to all of the patients' data across a continuum of care that they received from social services to mental health services to acute care needs. And most of it will be around that. I loved what was said about disability patients. I would argue that that could be a broader term than just the disabled patients but all patients that are at risk. So, thanks for the work that you're doing on this and we'll make sure we get our comments in for you.

Steve Posnack

Great. Thanks so much. And we did get some late submissions. And so, this document is the most recent version in case there is a little bit of discrepancy between what originally got sent out in time for materials to make sure that you all had materials but also to keep this fresh for folks. So, we'll make sure the most

recent version is made available to everybody as well. And as we've talked about equity and the department's work overall and our response to numerous executive orders and designing with equity in mind to say the phrase slightly differently, interoperability with equity in mind is an important part of the work that we do in making sure that we achieve or seek to achieve certain outcomes that we aren't creating digital divides and other types of dynamics that would affect different segments of the population.

Aaron Miri

Good points. Michelle, you're next.

Michelle Schreiber

Thanks. I think Ken captured this to some degree under 3A with half of the EHR's would be **(audio interference)** excellent usability. I guess I'd like to see us focus even more strongly on the workforce burden reduction that we've had with EHR's. So, in other words, that EHR's are no longer the single highest source of complaint from providers or something to reflect the fact that we have, actually, made life easier for people and reduce burden.

Aaron Miri

I like that. Other HITAC members that want to weigh in, comment, opine, suggest, read poetry, anything? I do want to say, Steve, I applaud ONC and you guys doing this. This is a good idea. And this is exactly the right way to get it out there in the industry and get folks aligned. So, kudos to you guys. Clem, you're next.

Clem McDonald

Well, I'm going to bring not a worrisome side but I think we should remember that the human organism is still not perfectible. And we're not going to make everybody healthy all of the time. There was a guy commenting **[inaudible] [03:27:35]** who did all of this genetic stuff and he was asked what he thought about this one famous guy who is so intent on living forever that he did all kinds of weird stuff. And his response was he doesn't know biology. That is, biology is going to win in a lot of these things. So, we need to be a little careful about some expectations.

Aaron Miri

Okay. You're right. I feel like I'm pretty health, Clem.

[Crosstalk]

Aaron Miri

That's good. I like the poetry. That's good. Dr. Lenert, you're next, sir.

Les Lenert

So, systemness is what I think interoperability is about. I like the quote that says we have a sector in the healthcare, not a system so that the notion of systemness is there. So, I came up with one exemplar of that and I thought no one died from loss of follow up of known medical information. Trying to make it as practical as possible is that every day, it's only one type of medical error. And I think Ken raised the issue of reducing medical errors. But really, interoperability, to me, is about making it concrete as to what this means is that if one doctor has a test result and the patient never gets it, people die from that every day and that should never happen again.

Aaron Miri

Yeah. Got it. I like that. Steve, do you want to comment to that?

Steve Posnack

I think that was a really important and humbling point about the importance of our work in healthcare, especially as Les mentioned. And so, there are, certainly, a number of areas where I know many of you in HITAC have a passion for safety and the way in which technology can play a role. There is automation as we look at connectivity is another area. And in connecting that, again, you could do two sides of the coin in terms of convenience and reducing burden. Look at them together as a way to say we've made things better for people. We've made things easier for us to accomplish or to engage in our care. And those are the types of outcomes that we're driving towards every day. But getting them down on paper, having a goal that we're all shooting for, people being able to attach their work to a particular interoperability outcome, which is something that we're looking to see if that's going to be possible based on how they're framed for different groups and individuals, organizations to say yeah, we believe in this and here is some work that we're doing to contribute toward that outcome.

Aaron Miri

Yeah. Good point. Dr. Jirjis, you're next.

Jim Jirjis

Thank you. I just wanted to add a little bit to what Clem was saying earlier about people not understanding biology. One way to think of it is we're trying to measure whether we were successful with patient outcomes is I know we all have probably heard the adage that you can divide healthcare up into the well preventative, the pre-ill, at risk, those with chronic disease, those with an acute event, those in recovery from an acute event, all the way to end of life care and death. And what most healthcare efforts do is try to slow down the progression from left to right. So, measuring outcomes, in the end, we all die but around any one of those, there might be meaningful metrics around preventing the number of people who have complications from the chronic disease, for example. And so, that may add a construct that may or may not be useful if we try to measure better health outcomes.

Aaron Miri

Steve?

Steve Posnack

I think that's a really important observation. I don't like to reflect on my own mortality all of the time, certainly, as each birthday passes. But the other dynamic though to Jim's point that I think is really important is how we approach thing we can't do well right now. And we know there are certain impediments if the technology is clunky and everyone likes to blame the technology or there is a company policy that makes it difficult to do something different or new or innovative or open up the market for other competitive services. That, again, is the blending. Trying to focus everyone on a single outcome helps us sharpen where those pain points are. And if we have experiences today where you're like this is not an ideal workflow, patient experience, caregiving experience, thinking toward what the best version of that would look like is a way for us to help construct some of those outcomes that we're looking to achieve with interoperability.

Aaron Miri

Makes sense. Clem, you're up again. What have you got?

Clem McDonald

Well, one of the challenges is that people don't know what to do when something happens. For example, if they don't get to the hospital soon enough or whatever. The chest pain business, the stroke business. And we could do something better with some new technology and interoperability to help know what to do. And we could maybe get better outcomes as well. I don't know how to flush that all out. But we should assume there will be a lot of new technology. And we should assume that video cameras can give diagnostic information just watching people somehow. There will be some new stuff. Anyway, I think giving guidance and what to do when they have a worry would be helpful and it could be done through interoperability.

Aaron Miri

Good comments. All right. Other feedback, HITAC members? Now is your chance. Folks on the phone if there are folks on the phone. I don't see anybody else. Steve, do you feel like you got the feedback you needed? Is there something else you'd like for us to comment on or assist with?

Steve Posnack

Yeah. Certainly, if there are others and, again, we wanted to have this open discussion with HITAC as our distinguished federal advisory committee members and make sure that you all had some time to give us some direct feedback and have an open dialogue about areas of interest that are intersecting with the work that you do in the field and the work that ONC does in government. As you have other ideas, and this is, certainly, open to HITAC but also to everybody tuning in, you're welcome to go to the HealthIT.gov page, submit additional outcome statements. Certainly, we will incorporate all of the ones that have come through our turn of the crank here with you all at HITAC. But if there are others in your organization or others with whom you work with that would make sense to have them think through some things and submit them to ONC as well, we want to get as many submissions as possible so that we can have a real rich body of work to look at, patterns, trends, and figure out what would be the best framing.

I think there are going to be a lot of similarly themed outcome statements at the end of the day just simply based on the work that we were able to do with all of your submissions. And then, we'll look to, again, take that next step for this fall to lay them out because we do have roughly eight years to look forward to depending on how you want to count the end of the decade. Those are running the bases on that math. But as we look to accomplish some of the things that all of you have just brought up, there are a number of steps that need to occur either in parallel or in a step like fashion and how we can go about that, how we can optimize that where ONC's role is to help coordinate, all of those things are what we're going to be trying to derive out of the outcome statements that we get. So, we really appreciate the dialogue. Any other hands raised aside from Clem? I'm just kidding, Clem.

Aaron Miri

So, John just raised his hand. So, Mr. Kansky, if you want to go real quick, go forward, sir.

John Kansky

Steven, I think you're just getting at it but what's the end game? Is this inspirational, aspirational, or to inform some action? If you could kind of dial that in.

Steve Posnack

Yeah. The other joking response is perspirational. So, this is what we want people to work towards. And these are outcomes that folks can rally behind and get involved in and channel their work toward. And, hopefully, they'll align with the direction that folks across the industry already feel like we need to go in. But it memorializes it and puts it down on paper and identifies as the Office of the National Coordinator for Health IT and those acutely focused on interoperability and our success. These help frame what we're looking to achieve into the future. And from a work product perspective, we don't want this to be a super long document and really get to the point and straight to the facts of here are the outcomes. Here are the ones that we think are really important. Here are the ones that we think are going to bring along a whole lot of other outcomes as well.

As I mentioned, there is going to be some number of them in that prioritized set. And that's not to say that others aren't important, the ones that get "left off". It's just that the ones that, ultimately, we're able to select and identify as the top priority ones, we feel, would have the broadest impact on industry as a whole and help bring other things along. Hopefully, that answers your question, John.

John Kansky

Yes. Thank you. That helps.

Aaron Miri

Okay. One more time for any other hands, any other comments. All right. That's a great discussion, great dialogue. That's good. And you didn't have to read your poetry, Steve. I want to hear it at some point but that's good.

Steve Posnack

It's just real time reading from the Code of Federal Regulations is probably the best I could offer at this point. And like a book on tape with annotations for why certain provisions are in our rules. So, I really appreciate everyone's input, dialogue. Keep it coming. Certainly, we can accept inputs from you through your HITAC membership perspective. But equally, HealthIT.gov is open for business. July 30 is when the comment period closes or the submission period closes for this initiative. And please spread the word, as I mentioned, because we're looking to get as many as possible to take a look at and help shape the ultimate work product.

Aaron Miri

Awesome. Thank you, Steve. We really appreciate that. Okay. Denise, I think we're ready to roll on to the next one.

Denise Webb

Right. So, I know there was a break on the schedule but since we are in a virtual meeting, people are welcome to get up and take a break. But our next presenters are ready to speak on the public health data systems task force work to date. And that's Carolyn and Janet. And they're ready to go. So, I know many of you would probably appreciate some give back of your time at the end of this. So, if it's okay with everybody, we're going to proceed to Janet and Carolyn.

Aaron Miri

Go for it.

Public Health Data Systems (PHDS) Task Force Update (03:40:52)

Carolyn Petersen

In the camera, objects are closer than they appear. So, thank you for the opportunity to update the HITAC on where our public health data systems task force is at so far. As you will recall, we talked about putting this together back in April. We had a day long hearing last month in lieu of our regular HITAC meeting where we heard a lot of excellent feedback and got a lot to think about in terms of how to proceed with recommendations. And we have had some meetings to start down this process. So, could I ask ONC to bring up the slide with our roster of our task force members? And this is who we have in our task force. Several people from HITAC as well as a number of individuals from public health areas and others as well. Could we go back to the regular slide deck please? Let's go forward. So, we'll start by reviewing our charge reading this, of course, for everyone on the phone as well as those who are on Adobe.

"This task force will inform HHS's response to President Biden's executive order on ensuring a data driven response to COVID-19 and future high consequence public health threats. The public health data systems task force shall first, identify and prioritize policy and technical gaps associated with the effectiveness, interoperability, and connectivity of information systems relevant to public health. This would include a focus on surveillance systems, infrastructure improvements, health equity, clinical engagement, research and innovation, and educating and empowering individuals. And second, it will identify characteristics of an optimal future state for information systems relevant to public health and their use." Next slide please. Subsequent to developing that charge, we determined that we probably were not going to be able to accomplish all of that work and bring forth to HITAC a full scope of recommendations at your July 14 meeting where we need to vote on that.

So, we've updated our task force charge scope. And that is explained here. We will focus on bidirectional data exchange between public health data systems and clinical data sources. And this will include a focus on challenges, gaps, and ideal state for data sharing between public health systems and clinical data sources like EHR's, lab systems, vaccine management systems, operational and other relevant data sources. Topics that were previously in scope that now will be recommended for future HITAC discussions include research and innovation, social services data, and in depth analyses of specific public health data systems. And recommendations and discussions around health equity and public and patient engagement will be addressed at the topic level instead of representing unique topics of meetings and categories for recommendations. So, we're kind of bringing those themes through everything we do and looking for potential implications, gaps, and challenges and, of course, ways to try to address those as well. Next slide please.

And with that, I will pass the mic to Janet who will start leading us through the direct recommendations we have to date and then, we will have some discussion.

Janet Hamilton

Thank you so much. Let me just make sure folks can hear me okay.

Aaron Miri

Yes, we can.

Janet Hamilton

Okay, great. So, I just wanted to start as we look at these draft recommendations that these are "under construction". So, we recognize that the charge has been monumental. We are very appreciative of the focus on public health and the need to improve the work and the way that public health is able to do its business but also recognize that given the time that we had, we're about part way through in terms of where we are, in terms of the meetings that we have had scheduled as well as really refining these. So, as you will see, these marked as draft. I think we all expect that there will be more refinement in the actual language of the recommendations as they are written as well as additional recommendations based on the upcoming discussions. So, we just want to start out with really putting that on the table and look forward to comments from HITAC both at the refinement level but also at higher levels in terms of any questions that you might have or opportunities for us to do additional exploration. Next slide please.

The first thing I wanted to start out with that has come out really strongly from the group and I think will really be important as we look at the recommendations and how to put those forward to the HITAC is this overarching, guiding principle that we have often talked about the needs of healthcare and the needs of public health and that we really need to talk about this in a new normal where public health is, actually, part of healthcare and that we don't view these things as opposite sides of the spectrum but that they are fully integrated and that this new normal will be something that we'll be asking the HITAC to be thinking about as well. This is an ecosystem and they are completely intertwined in every way. And how we do our business in public health is so tied to the ecosystem. And how we really move into this space of a new normal so that we don't end up in a have and have not kind of environment. And we would really be interested in any feedback on this guiding principle as well. Next slide please.

So, first under the topic of syndromic surveillance, I think we will have additional recommendations but this is one where we did get some further consensus from the group. And this is really about further exploring non-traditional data sources and other surrogate markers that could be leveraged to identify both early clusters of disease incidents as well as to monitor events as they unfold. So, there certainly has been exploration of non-traditional data sources by CDC as this space of syndromic surveillance has evolved. But I think we also recognize that there is a lot more to be done here. In this exploration, the task force also had specific comments. But it's not just about what data sources to include but to really look at the availability of the data sources, the accompanying demographic data that may or may not be present in those data sources, as well as the timeliness of these data sources for thinking about how they can be incorporated in the future.

In addition, there was specific discussion about the area of ambulatory care and, in particular, urgent care data and the need for additional levers to expand collection of these two specific data sources. I think, in particular, urgent care data has been recognized as being important. But we don't necessarily have the levers in place for full engagement of urgent care data and full incorporation of that. In terms of non-traditional data sources for exploration, there were a couple that were surfaced as potential priority areas. And those include point of care testing data, large employer absenteeism data. There certainly has been exploration in the space of school absenteeism but this was really thinking about large employer absenteeism and the use of prescriptions and, specifically, prescription data, in particular, from large chains

and pharmacies. So, not so much the over the counter drug retail sales but prescriptions. So, prescriptions for things like Tamiflu, etc. Next slide please.

In the topic of electronic laboratory reporting, again, we do anticipate additional recommendations to be coming forward. But this draft recommendation is that ONC, CMS, and CDC should explore providing additional incentives for laboratories to utilize standard ELR notifications and corresponding certifications for lab resulting and ordering processes to address full end to end data flows between the order, the laboratory that's performing the test, and public health. I think this is a space where there is recognition that there is a lot of electronic laboratory reporting that is currently being done. But some of the gaps that we see on the data side when the data is received by public health recognizes that there are pieces in the process that still need to be addressed. So, I think this is really trying to take a step in this direction where we're not just looking at the outbound message, which is where ELR has primarily focused but really looking at the entire process from when the order is generated within the provider office or provider location.

Additional considerations include how to support public health agencies to receive a minimum at least standardized ELR notification. I think there is recognition that there is variability on the side of public health for sometimes what they can receive and that that onboarding process by providers can be intensive and sometimes burdensome and that we do need to look at a process where we can at least get a minimum going. And then, certainly, we recognize that state laws do play a role in governing public health reporting. But at least the minimum pieces should be easier and more standardized. The task force should account for and consider different regulatory authorities and incentive structures with specific recommendations on what levers should be used within both ONC and CMS. We should consider how the data should be routed and reported when we are looking at those incentives. So, for good laboratory data, for example, maybe we need more incentives on the provider ordering side to improve some of these data flows.

To consider how to incentivize public health reporting beyond eligible hospitals, which has been impacted by meaningful use. So, I think we can all appreciate that we've had a great focus on eligible hospitals in the past but how we can also use incentives to support ambulatory providers, urgent care, the large national laboratories, and other settings. And finally, that we should also look at incentives that are not only just on, again, the reporting or the outbound message and that the message can or cannot occur but that there are additional incentives around specific data elements and the completeness and timeliness of that information. I think, for example, the completeness of certain types of data elements like patient contact information, critical demographic data like race and ethnicity, and not just that a report is able to be sent but able to be sent within a timeframe that meets the needs of public health. Next slide please.

There has been quite a bit of discussion amongst the group around funding. Very early on, we had a number of members within the task force really recognize that, sadly, a lot of where we are today is that we have just not adequately funded our public health infrastructure and our public health data infrastructure. I think there is a lot of recognition around the incredible investments that have been made, particularly in the private healthcare infrastructure. And we have not seen similar investments on the side of public health. And that has made it harder for that healthcare public health interaction to occur. So, specifically, draft recommendations around additional appropriations from congress to CDC to support robust, annual sustained funding for the development and maintenance of public health data systems that are capable of supporting routine activities as well as large scale response.

There was also a bit of discussion around once there are funds within CDC as an agency that sometimes, the way that the funds are allocated to the agency or certain types of cooperative agreement structures with state and local health departments do not necessarily support a fully enterprise and interoperable approaches across disease domains and so, this recommendation that CDC should develop plans for cross cutting program funding of technology investments that support interoperability across public health platforms. And finally, that CDC should allocate funding for capability development that serves multiple public health agency goals separate from, again, just disease specific funding. So, for example, contact tracing is a function that occurs for multiple diseases. It occurs for COVID-19. It also occurs for SPI's, measles, many other vaccine preventable diseases. And we need to be building this as a function, not necessarily as a disease specific activity.

And there should be minimum functional standards for public health that are not just about interoperability and standards adoptions but, ideally, address infrastructure expectations that would really improve scalability to meet response needs. Next slide please. Additionally, on these funding recommendations, again, just recognition by multiple task force members and a lot of consensus that public health funding has been largely inadequate to meet the needs and effectively exchange data with a private healthcare infrastructure. And there is also a recognition that funding models need to be equitable across the states and that we do have situations now where we see haves and have nots. And we really want an approach that is a rising tide lifts all boats and to investigate also how current funding streams may, actually, impede data sharing. So, sometimes, we, actually, see that because a funding stream is so categorical in nature that it does not necessarily support the full level of data sharing that we would like to see, and so a recommendation for CDC to investigate that. Next slide please.

Another space where we've had quite a bit of discussion and we recognize that our recommendations are due on July 14 is that CDC and ONC should consider creation of an ongoing public health task force or workgroup with adequate authority to address topics outside of the scope of our task force. As Carolyn mentioned, we have already limited our charge based on the time that we have available. And we don't think that we will be able to fully represent the needs across preparedness for future high consequence public health emergencies. And so, really being thoughtful about how we can address this in a more ongoing fashion and/or that there could be specific activities that other workgroups are formed to address. I think one area in particular that we've already identified that's going to be very challenging is some of the resource management pieces, which I think we can all appreciate has been critical in the COVID-19 response but likely something we just will not have the ability to address in a robust way.

We do also recognize as a task force that we should consider leveraging existing working groups as a starting point and also that we need to have alignment with other ongoing efforts in formation of such a group. And finally, also that state and local public health agencies should be consulted and involved more in standards development processes, in particular, potentially, even designating specific public health representatives. Next slide please. So, here are some other draft recommendations. These are a little bit weedier in terms of a little bit more focused on tactical pieces for specific surveillance use cases. So, ONC should support the development of implementation guides, clarifying and specifying standard data sets and value sets for reporting public health data and accompanying testing and certification for both senders and receivers. ONC and CDC should work with providers and standards communities to ensure use of standards and implementation guidance that include demographic and contact information elements that are required for public health reporting, specifically, race, ethnicity, and contact information.

Along the lines of we've had some specific discussions on electronic case reporting, so ONC should require ECR and ECR Now within the certification program and CMS should explore making ECR implementation a condition of participation for hospitals. Further inclusion should also be considered for non-hospital-based providers as necessary. The CDC should support public health jurisdictions to implement fully ECR for all reportable conditions. There has been a huge focus, of course, on COVID-19. But there are around 100 different reportable conditions depending on the jurisdiction to receive data into their surveillance systems and improve the efficiency of reporting as well as to relieve providers and public health from the burden of parallel or manual reporting. CDC, ASPR, and HHS should work with state and local partners to align reporting requirements at the federal and state level to avoid duplicative requires or failures to meet surveillance goals at the state and local level as well as to align redundant requests across federal agencies. And I think that we can all appreciate that during the COVID-19 response, there were many data requests. And we did see duplication of those as well as sometimes federal requests that didn't necessarily support the data flow of data flowing to state and local public health agencies where, of course, direct action is taken on much of that information. Next slide please. Additional feedback in terms of gaps in standards adoptions that standards should be developed to meet state and local health department needs with engagement and alignment between provider and vendor communities. Sometimes, this process has been done where we haven't had that full level of engagement. And I think we all recognize that it is the continuum that's important. And any development that is done without full engagement of all parties is likely going to be lacking. That we consider, again, the entire ecosystem of public health data when thinking through how to best implement and incentivize standards to consider how to incentivize adoptions of standards by technology vendors also outside of EHR's and that there are specific EHR's in different settings.

So, for example, in nursing homes and others where we haven't necessarily focused incentivizing certain types of data needs as well as reporting needs. The technology vendors also should not dictate what capabilities are and are not but rather should build to the needs to support public health reporting such as ELR, syndromic, ECR and exchange with immunization information systems. These capabilities should really be built in and met as part of the product development process. Next slide please. I'm not seeing the next slide come up on my screen yet. So, again, another draft recommendation here on technology and infrastructure factors. CDC and ONC should explore the development of centralized reporting pathways and gateways to avoid duplicative reporting workflows for providers. CDC and ONC should also agree on a standardized set of public health reports and processes so that HIE's and other stakeholders to could build to those standards.

CDC and ONC should also evaluate any federal policy barriers that prevent HIE's from participating in public health reporting and should analyze and publish guidance aimed at, actually, educating states as well about any state laws or state level privacy barriers that could prevent HIE's from also participating in robust public health reporting. Next slide please. And these are grouped in an other category. So, in these other draft recommendations that have surfaced that we should have a minimum set of data elements to be defined to complete patient matching across public health and clinical systems to include demographic information and that we would need the complete collection and submission of this information and that should be incentivized. I think there is, certainly, recognition that we need to do a large amount of patient matching within public health. There is recognition, I think that things like national provider numbers or national healthcare numbers for individuals, I should say, would be ideal.

But in the absence of those, how do we ensure at least a minimum amount of information is included along the reporting pathway so that adequate matching can occur? More public health subject matter experts should be engaged in the TEFCA development process and also that the task force will consider and recommend ways to improve the collection and reporting of complete race, ethnicity, LGBTQI, and disability information in order to robustly address health equities. This health equity discussion, as Carolyn mentioned, has been baked in throughout. And we also look forward to continuing to have some more specific discussions on these pieces to really address these structural issues. Next slide please. And this is looking forward in terms of future topics and our meeting schedule. So, I will just display that for you here in case you have questions about other pieces. And let me stop here and see what else Carolyn might have to add through some of these slides or things that maybe I did not bring out as robustly.

Carolyn Petersen
Thanks, Janet. I think that was a wonderful run through of all of the discussions we've had so far and what we have thus far identified as issues that will be coming up in the recommendations we ring to the HITAC next month. Thinking about that overarching charge, certainly, one thing that's on my mind as the patient consumer kind of perspective on the HITAC is that this is a really different paradigm than we have lived in America. Historically, it's been public health and the clinical environment. And they're not together. They're a separate thing. When we talk about bidirectional data flow and public health being able to make things available to the clinical environment and the clinical environment having data that may be of help to public health in doing its work that creates different access in a different way for Americans to be engaged with governmental function. And one thing that we are also trying to get at in these discussions is some of the sociotechnical issues.

If we're able to collect more granular data, for example, theoretically, that would help us do a more granular job of advising governors about activities like lock downs or implementing other kinds of guidelines, maybe social distancing and other things that can be helpful in a more granular way. So, instead of doing this at a state level, we might be able to do it just at a city level. That's a benefit to Americans, of course, in that it creates less disruption in daily life and perhaps can preserve some of the economic concerns that are very important to people. But it also is based in degree on some more surveillance than perhaps we are accustomed to having in our daily lives or are aware of existing in our daily lives. And so, how all of this work is communicated to the public and how we express the transparency, how we help the public understand that this work is trustworthy and the actors are trustworthy and are working in ways that benefit, not just the population health but the individual health is going to be very important.

And that is something also that we hope to bring out or at least to point to in the recommendations in terms of future work and who should be involved in that and what role the health IT community and the HITAC has in that.

Aaron Miri
Okay. Well done. Very well done.

Denise Webb
I appreciate those thoughtful comments, Carolyn, and your presentation today from both of you. And I think it would be nice to see what others are thinking now that they've heard your presentation, particularly, since

these are draft recommendations. And I think their feedback is very important at this juncture. And Robert is first in line. He's got his hand up so let me turn it over to Robert.

Robert Wah

I had to come off mute. I didn't realize you guys were calling me that fast. Great presentation and very important issue that we're talking about here. And thank you for all of your thoughts and work on this. And it's great to be able to intervene before this is a final recommendation. So, anyway, what I wanted to key in on was your early slide talking about non-traditional data sources. And also, consider expanding the thoughts about public health. There has been a lot of discussion in the public health community and I'm, certainly, not privy to all of the latest and greatest in this area. But the idea that beyond the acute infectious diseases that we talk about classically in public health is should we be talking about non-communicable diseases. And I think we all know non-communicable diseases like hypertension and diabetes probably kill more people than infectious diseases do in this country.

But they're also, as we see with COVID, major contributors to the morbidity and mortality of an infectious disease. And so, as we think about really re-imagining public health and our health IT approach to it, I would suggest we think about non-communicable diseases as well. And all that is to lead up to as just a case study or a possible type of new data source, I'm the chair of a clinical advisory group with a company that has 10,000 of these weight and blood pressure machines that sit in pharmacies and grocery stores across the country. It's already up and running and our thinking on the clinical group is this is an information source that could be used to help inform public health activities. We're getting something like 3 million measurements a month in 2019. It will probably be 1 million measurements a week once we get the new operation up and running. That's a lot of blood pressure and weight measurements that are coming out of these things.

And the other thing I'll point out is it's our observation that these machines are right where people are. They're not in doctors' offices. They're where people are every day, drug stores and grocery stores. And some stores in very rural areas are using them as sort of a health focus for an underserved community where there is just nothing else. And so, I would just use that as an example of unusual data sources that haven't been explored before. It could be very powerful in the use of technology to further public health. Like I said, it's an expansion of the concept of public health, non-communicable diseases but also a different kind of data source because, like I said, 1 million measurements a week. Plus, the other thing is we have a captive audience. While they're sitting there for six minutes, they're looking at a little iPad sized screen. And we can put, "Are you interested in more information about diabetes? Would you like to take a quiz about hypertension and things like that?"

So, there is just a lot of activity in this kind of area that I think could be very useful in advancing public health issues.

Aaron Miri

Good deal.

Janet Hamilton

I'll just say, if you don't mind, those are just excellent comments. And I think it also goes to the other recommendation we had about what is the right ongoing way to formulate some groups so that we can

address these issues and the funding piece. We've talked a lot in public health about the need to be able to absorb this volume of data for millions of COVID-19 cases. If we look at real time data or near real time data for chronic diseases and all of these other kinds of measurements that go along with some of that, that's an economy of scale that we're just not currently functioning at. And I wholeheartedly agree with your suggestions. And I think I cut someone off. I'm sorry.

Denise Webb

Oh, no, I apologize. That was me, Denise. Robert, what you said really resonates with me because when I was in the Wisconsin Division of Public Health as a state health IT coordinator, I remember the discussion around syndromic surveillance data and the certification requirement and meaningful use and the focus on getting data from Emergency Rooms and urgent care. And there were many public health programs that said we would find great value in having that same type of data from ambulatory clinics and why people have a visit at an ambulatory clinic to study falls. People don't necessarily go to the Emergency Room. They go to their ambulatory clinic for those chronic type problems or back pain. So, they're not able to have the same benefit that the infectious disease programs have by not having that same data set. And so, I used to talk to stakeholders outside of public health, especially providers and say why having the ambulatory ADT and syndromic surveillance data could help inform other aspects of public health, not just infectious disease. So, I just wanted to comment on that. I agree with your statements and I support them.

Aaron Miri

Okay. Good points.

Denise Webb

Next **[inaudible] [04:19:33]** with Steven Lane.

Steven Lane

Thank you. I just wanted to comment, not so much on the content of the recommendations but on their organization. I noticed that syndromic surveillance and ELR have been called out independently. And ECR, which is, obviously, another very important method of data exchange and one which I happened to have been personally involved in a lot over the last year and a half got sort of buried in a slide with some other things. And I would just suggest that as we craft these and put together final recommendations to come back to HITAC that we sort of organize it in a consistent way so that's very clear.

Janet Hamilton

Point well taken, wholeheartedly agree. I will own that and just some really compressed time right now and absolutely could not agree more.

Denise Webb

Clem, you're next in the cue.

Clem McDonald

Thank you. So, I've got three points. One is I think there is not enough money in the universe to solve the public health problems with the way it's organized. Fragmentation is death. You've got these little, bitty systems for 25 or 100 different diseases. It doesn't make any sense. I know it comes because of the funding streams and so you've got to work upstream. But the same with having 100, 200, 300 different public health

organizations in the country. You're never going to get the scale you need to make a good system that could be just built out to a lot of places. Maybe you could get the five really big public health departments that had a lot of technical knowledge to concoct one or design one and get it funded. And everybody could use it. I know the states have different laws. It causes problems. But still, we can't have people doing a boutique in each state, in each place, and every place and get the job done. So, that's one thought. The second one is I'd like to cool the thinking about the ECR.

And this is really Les Lenert's thought that having to concoct these questions, those also differ all over the place. We heard there were 20 different ones from 20 different places. So, it makes it really hard for people to work with and there is hardly any feedback from the clinical side about what would be easier to capture. So, if you just get it pouring out of the computer, that's the very best way. So, I hope Les will kind of emphasize that some more. I guess I really only had two points so we'll stop there.

Denise Webb
Thank you.

Carolyn Petersen
Certainly, everyone on the task force recognizes the challenge of funding of public health, its impact, and the way that it has limited what we could do up to this point. I agree that a lot could be done to reduce fragmentation and to make things smoother and facilitate opportunities. But I will also be upfront that we're going to remain pretty generic in terms of recommendations around funding because our charge and where we can exert our best influence is in that health IT and public health interaction, engagement point. We aren't in a position to significantly influence public health funding. So, we will support increases but we will not try to be **(audio interference)**.

Clem McDonald
Well, I'd like to push it because there is likely to be a big tidal wave of funding. And this could be a chance to change the way it's concocted to make everybody do it themselves differently. They won't make them do it differently but that's what happens so often to get a bigger market so that industry could build the system out the way an informed group of public health departments could guide them and all of the little ones could go along because you practically can't do it any other way. And do it on a large scale. Do it once, not 500 times. Then, you can afford it. With a big wave of funding, you could afford it.

Denise Webb
All right. Les, you're up next.

Les Lenert
Yes, thanks. I just wanted to follow up on Clem's point that while 57 states and jurisdictions and numerous municipalities might have specific protocols for notifiable conditions, maybe if we stopped talking about case reporting and started focusing on automating case investigation by queries of EHR as the desirable future state that what we want to be able to do is support public health doing automated query of a case that they've been notified about, potentially, through ELR and getting as much data as they can as fast as they can and then, updates of that as the case evolves over time. And it would be great if we could do that one time push but it might make more sense to have a single standardized pull operation and then, public health can work in different jurisdictions to complete the parts that are unique to each state.

So, I think that, again, my suggestion, and I think Clem was picking up on this, is that we stop thinking about case reporting, which is the push operation to have to anticipate each state's needs and we think about facilitating case investigation with a standardized pull operation using maybe FHIR or CCD but probably FHIR to allow people to automate case investigation, which is really what our goal is. Case notification reporting to investigate but then, getting the additional data that only EHR and then, can be expanded on.

Janet Hamilton
This is Janet and I appreciate these comments. I think the process for a report to come to public heath where there is enough information for public health to begin to do some action still needs to happen. And it's not just lab results that are needed for that. And I think this is a marrying of how do we get the information into public health so that we can start our case investigations and our actions. And I think in today's world, those processes don't function in a way to meet public health needs.

Les Lenert
I'd agree with that. And, again, the more automated we can make case investigation the better. And clearly, it needs to have the right triggers and then, it needs to have the ability to follow up on getting the data that are really critical. Some of which for evolving infections may not be anticipatable. I think part of the problem with COVID-19 is we didn't really know what to report. And so, those standards need to be evolving, which, again, sort of says what's the threshold probability that you want to begin a case investigation and then, to more that forward. But I agree with you completely that it is more than just having a positive lab result because some lab results like serology might be a lifetime of infection. Others may indicate an acute infection definitively.

Denise Webb
Steven?

Steven Lane
Yeah. I just wanted to load onto what Les was saying. First, I don't think we need to move away from our focus on electronic case reporting but really expand that so it's seen as a continuum from reporting to investigation and really to case management. One of the lovely things that was included in the ECR framework was the reportability response. The idea that information could come back from public health to treating providers. And I think as we look towards what you were discussing, Les, the ability to support case investigation with FHIR based queries and minimum necessary data to really think of that as a dialogue and an ongoing discussion between the public health subject matter experts and the treating providers. It's not simply report and investigate but it's report, investigate and then, manage collaboratively between public health and clinicians.

Aaron Miri
Okay.

Denise Webb
John Kansky is in the cue next.

John Kansky

Full disclosure, I'm a member of the task force. Hopefully, not too simplistic of a comment amplifying a little bit on what Robert said a while ago. There is nothing in our scope that says public health is about communicable disease. And a lot of that is very top of mind and we're talking about case reporting and case investigations appropriately. I'm wondering if in our recommendations we need to somehow speak directly to the other needs of chronic disease using an example diabetes. There is plenty of need for information gathering, information exchange, information analysis to manage the chronic public health condition around the diabetes and other public health things. So, again, hopefully, that's not too simplistic but it doesn't appear to come through in our recommendations yet and maybe we need to figure out how to make sure that comes through. Thank you.

Janet Hamilton
This is Janet. And I'll just say I appreciate any identification of further areas of exploration and gaps. And just to reiterate, we haven't even had all of our meetings yet. So, it's wonderful to be having this conversation with you all here so we can ensure that we're pushing different pieces and parts for that additional exploration. Thank you.

Carolyn Petersen
And can I say also if additional thoughts occur to the HITAC members, please feel free to send those to Janet and I or to forward those to Mike Berry who can get those to us. We do value your input and we realize it's really compressed timeframe with not a lot of opportunity for HITAC members to look at this and think about it and try to frame it all out in your head in terms of where the recommendations should sit and what you're comfortable with. So, please know we do see it as an ongoing process.

Denise Webb
Clem, you're in the cue again.

Clem McDonald
Sorry. I'm too talkative. I want to talk about a complicated issues. We talk about two-way streets but, effectively, public health says give us this stuff, here it is and no questions asked. Shouldn't there be some dialogue about that? Some stuff is easier to gather than others. To work together but it tends to feel like here it is, you do it. And then, of course, it's different in every jurisdiction, which makes it hard for certain kinds of organizations. So, that's what I worry about ECR. And here it is on your screen, you can't see the next patient until you answer these 30 questions. So, it's got to be some balance in the two-way and a lot of discussion on both sides, I think, would be a lot better. And if we could pull from medical records then, it's no cost. You could do it all of the time. And the other question is for some diseases, it's quite clear why you need this data. COVID was the blaring example. But in Indiana, we set up a system to report out of lab systems.

And we increased the number of gonorrhea reports fivefold. So, it went from half a million to two and a half million. But realistically, is that crucial to know the numbers? Maybe it is but those patients, presumably, were being treated because someone ordered the test and they came back. So, some of them aren't the same scale of urgency or importance as other kinds of reporting I'm assuming. I may be wrong.

Janet Hamilton

Thanks, Clem. I was just going to say I think the public health response is a critical piece. And not every case always has an immediate public health response depending on the disease and condition. So, I wholeheartedly hear that. I will just say the current model of the ECR and the initial case report is not about taking any additional clinicians' time. It is functioning completely in the background. The public health puts triggers in place. And so, I wholeheartedly agree. I don't think any bit of public health wants to take clinician time away from seeing patients. Computers can take the data that's in the EHR and we just need it to be in places where the computers know to move it to public health.

Clem McDonald
I have to say I liked all of your recommendations by the way.

Denise Webb
Les?

Les Lenert
I just wanted us to think about expanding the TEFCA recommendations because that's in a specific area where ONC can contribute and focusing on how TEFCA should address public health integration. Not just to have experts to do that but to, specifically, speak about how TEFCA can integrate public health authorities into a national health information exchange system and what laws and policies need to be in place to allow health information exchanges to be able to contribute fully to pandemic or other public health emergency response. It's one of the biggest issues, I think, we saw in the COVID-19 is that HIE's were ready to respond but their responses were shackled by either state law, lack of willingness of people to exchange data with the HIE's to further that. And John Kansky spoke a bit about this. But I just think our lever is really TEFCA.

Denise Webb
Jim Jirjis.

Jim Jirjis
Thank you. I just want to support that comment. And from our perch, I think Clem mentioned we heard that there were 20 different entities. So, here my biggest concern about all of this is not that we can't map out how it ought to work from a standards and interoperability but that there won't be incentives for each state to agree to, actually, a national model. We have LOINC codes. Today, we still don't get LOINC codes when people report out COVID-19 results. So, what we've found is we've had to hire people to, actually, run round for each admission and figure out the patient was tested in another hospital or clinic what its status was because we don't have interoperability. Don't you wish we had a TEFCA like solution? And each of the labs could come up with their own mnemonics and we had to hire people to, actually, map all of those terms to a value set and set up monitoring systems when the next lab system came online that no one told us about.

And that's even before you get to the 20 different interfaces, contracts, implementation methodologies for getting the reports to the states. So, here if there is some way to have hooks that incentivize, not just public health but lab and others. And I completely agree that leveraging the TEFCA methodology, I hope, is part of the plan.

Denise Webb
The cue is clear.

Aaron Miri

All right.

Denise Webb

Do Janet and Carolyn have any final remarks that you all want to make before we get ready to go to public comment?

Carolyn Petersen

I will thank the HITAC members for all of your comments and expanding upon some of the points that we presented and offering us some additional feedback and things to consider. We look forward to going through the transcript and identifying these things and looking for ways to incorporate them in the recommendations. Given that we have limited opportunities to go through iterations with the HITAC, to be honest, some of these recommendations probably will be fairly broad. We will not be able to be particularly prescriptive about a lot of things like exactly how to build out the process with TEFCA or some other things designing, for example, some of the engagements that are being referenced in the chat. That will be a level we will not reach in our timeframe. But, certainly, we can look at how to incorporate these things in recommendations about future activities. And we look forward to incorporating your feedback in that way. Thank you.

Aaron Miri

All right. Excellent job, Carolyn and Janet. Well done. Good leadership.

Denise Webb

So, are we able to go to public comment early?

Public Comment (04:38:45)

Michael Berry

Yes, we can. Operator, can we open up the line to 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 line from the cue. And for participants using speaker equipment, it may be necessary to pick up the handset before pressing the star keys. Our first comment is from Nancy Spector with American Medical Association. Please proceed.

Nancy Spector

Hi. Thank you. My name is Nancy Spector. I work for the American Medical Association. Thank you for allowing my public comment. I wanted to speak with regard to the ISP task force report earlier and note that the AMA supports the action that was taken by HITAC to send Recommendation 3 back to the task force for further consideration. We also want to say that we agree with the HITAC that procedure coding experts would benefit the ISP task force's review of their recommendation. And we are happy to work with the task force in providing procedure coding terminology experts to help them with better understanding the industry needs. And we will reach out to ONC and the ISP task force co-chairs to assist with scheduling that.

Denise Webb

Thank you.

Michael Berry

Operator, do we have any other comments?

Operator

There are no more comments at this time.

Michael Berry

Okay. While we wait to see if any additional comments come in, I just have a few brief announcements. And the first one is just to remind HITAC members that Aaron and Carolyn are inviting people from the HITAC, HITAC members only, to join the Annual Report Workgroup. We need one or two members. And I'm sure several of you are excellent writers and editors. So, we could really use your help. Also, the next HITAC meeting is going to be held on July 14. And all of our materials from today and every HITAC meeting and task force can be found on HealthIT.gov. You just need to search the HITAC calendar to find those materials. And finally, since we are a little head of schedule for our public comment period, the public is welcome at any time, actually, to send written comments to us at ONC-HITAC@accelsolutionsllc.com. And they will be incorporated into the appropriate meeting minutes. With that, I will turn it back to Aaron and Denise. Thank you.

Aaron Miri

Perfect. Denise, do you want to go first?

Final Remarks (04:41:33)

Denise Webb

Well, let me just sum up our day. We heard from three of our task forces and we successfully completed the recommendations from the USCDI and got those approved to go forward to Dr. Tripathi. And then, for our ISP task force, they're going to do a little bit more work around Recommendation 3 and come back to us in July. And then, I think we got some excellent input to assist Carolyn and Janet with the public health data systems task force recommendations and getting to a place of final recommendations for us in July. I want to thank everybody for their participation today. We had a lot of good dialogue and great engagement. Thank you.

Aaron Miri

And I would echo the same thing that Denise said. So, first of all, I want to thank the HITAC really for the good discussion today and even the healthy debate. I think that's very important, as we heard in public comment, well appreciated by the industry. That's the point of the HITAC. That's the point of our opinions, our expertise, our differences of opinion and coming together and reconciling that and getting an excellent product out the door that really represents this multi-stakeholder group very, very well and effectively. So, thank you for that. And 2.) I would say it is important for all of us to know that as we have been, in the past couple of months, going through a lot of changes related to ADT rules recently with CMS and part of that information blocking and adjusting in an industry that a lot of change is occurring. And so, the provider community is adjusting to that and working with folks. Providers are working through that. Hospital CIO's

are working through that. Vendors are working through that. Some vendors simply say I have until 2022 to do anything with the patient portal.

It's those kinds of things we have to keep in the back of our mind as we come up with these recommendations what will it, actually, translate to boots on the ground. So, thank you for that. Thank you for all of your efforts on the front lines and stay safe. We'll see you in July. So, with that, we're adjourned.

Adjourn (04:43:54)